Biological Attack Response and Recovery:

End-to-End Medical Countermeasure Distribution and Dispensing Processes
### Abstract

This analysis examines current medical countermeasure (MCM) response capabilities when faced with a large scale biological attack and identifies gaps in the MCM distribution and dispensing process. The study recommends cost-effective ways to alter the MCM process and supporting activities to achieve greater efficiency and flexibility and to enable recovery. The analysis used National Planning Scenario 2 in which aerosolized anthrax is released in three cities initially and two cities two weeks later as a baseline. The study of over 100 process gaps coupled with end to end system analysis revealed that population compliance is one of the most important factors in reaching recovery, an area that is often ignored in response analysis. Twelve overarching deficiency themes were developed and over twenty five possible corrective or preventive actions were identified and assessed against impact on lives saved and expected cost to implement. Nine priority recommendations that have the greatest impact on recovery within resource constraints emerged from this analysis.

### Subject Terms

WARRP, Medical Countermeasures, Biological Attack, National Planning Scenario 2, Aerosolized Anthrax
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Executive Summary

After the 2001 U.S. anthrax letter attacks, Congress reacted by appropriating billions of dollars to address the biological threat. However, 11 years later, there is still no consensus as to how bioterrorism should be thought of or treated. Is it a public health problem or national security threat? It is a national or local issue? Who is ultimately in charge of and accountable for response? Although officials continue to search for an analog, it is difficult to find one that requires the same type of response as bioterrorism. It should be treated as a unique problem, one that is not quite a public health threat, yet not quite akin to other WMD attacks.

Even in the face of this ambiguity, many efforts have been made to increase U.S. preparedness and response capabilities for a biological attack. The purpose of this analysis was to examine current response and recovery capabilities and to identify the gaps in the medical countermeasure (MCM) distribution and dispensing process. Ultimately, this study was designed to recommend cost-effective ways to alter the process to achieve greater efficiency and flexibility and to enable recovery. Since anthrax in its inhalational form is often considered the most probable biological threat and is the most studied, it is the case study agent for this analysis. As directed by WARRP, this analysis used National Planning Scenario 2 as the case study, in which aerosolized anthrax is released in three cities initially and two cities two weeks later.

This study identified four elements required for recovery from a biological attack. (1) Detection and Characterization involves quickly determining the presence of a biological agent of concern, determining its characteristics and identifying the geographic distribution of the dissemination. (2) MCM Distribution and Dispensing includes distributing the medication to the affected jurisdiction and dispensing the appropriate countermeasure to the entire affected population. (3) Population Management and Risk Communication involve the delivery of clear, consistent and constant communication and instruction to the affected population to encourage compliance. (4) Remediation consists of a set of activities required to return the affected area to normal activities.

By conducting this study from a Systems Engineering perspective, starting from the end of the distribution and dispensing process and analysing the interdependencies and sensitivities, analysis revealed that population compliance is one of the most important factors in reaching recovery. As the recommended regimen is a 60-day course of antibiotics from the date of last exposure, it will be important for the affected public to seek medications, initiate prophylaxis, and continue on the full course of treatment. Population compliance is an area that is often ignored in response analysis.

In addition, gap analysis of the MCM distribution and dispensing process as it relates to recovery revealed several themes to be addressed:

- There is no answer to “who’s in charge” of a biological attack response
- High-consequence decision making for a biological attack has not been exercised in real time, and the inability or delay in making these high-level decisions may stall or stop response
- State and local government plans are developed independently without clear or consistent directives, and there is no overarching coordination for response plan execution
- A local public health approach does not appreciate the urgency of a biological attack or the intent of a thinking adversary
- Little formal recovery planning has been performed for actions after the initial post-48 hour response
- Clear and consistent risk communications from a trusted source will ultimately affect public confidence and ensure compliance
• No serious consideration has been given to alternate scenarios (e.g., multi-drug resistant (MDR) strains, reload)
• There is no integrated, comprehensive national plan or effort to leverage the private sector to assist in distribution and dispensing
• There may be an inadequate amount of product available nationwide in both the Strategic National Stockpile (SNS) and the private sector supply chain to respond to large-scale biological attacks
• An inadequate workforce for both planning and response is a major issue because of the decrease in Departments of Health staffing and the heavy reliance on volunteers
• Funding cuts across public health departments within all levels of government will cripple the ability to plan for or respond to an attack
• There are no clear goals and objectives for response to a biological attack, including for MCM distribution and dispensing

Nine priority recommendations that have the greatest impact on recovery within resource constraints emerged from this analysis. The criteria for the recommendations include defining and improving the outcomes of the end-to-end distribution and dispensing process (i.e., addressing the themes identified above), providing the greatest return on investment, and being relatively easy and cost-effective to implement. These recommendations are:

1. Put the Federal Government in charge of bioterrorism response and identify a single federal agency to serve as the lead
   The Federal Government should take responsibility for coordinating and directing a national response to bioterrorism, including MCM distribution, dispensing and follow-on care. The Federal Government should develop standardized processes, procedures and messaging. This would help close the gaps related to the current model where states and locals are in charge, which results in a disjointed and uncoordinated system for response.

2. Improve the effectiveness of strategic risk communications
   The federal agency in charge should review and refine strategic communications to ensure they are correct, consistent and constant, and that they are distributed to appropriate communication channels pre-event. This is a low-cost/high-impact method for increasing population compliance, and for addressing psychological and sociological reactions of the public, thereby reducing morbidity.

3. Provide pre-event communication to decision makers and to the public
   Sensitize decision makers on the unique complexities involved in making time-sensitive, life-and-death decisions during a biological attack with limited, imperfect or incomplete information. Communicate with the public pre-event so that they understand the characteristics of bioterrorism attacks and know their roles in preparing for an event and during response.

4. Use the Federal Government lead agency as the one point of contact for private sector partnerships and leverage the relationships nationally
   Increasing the regional and national use of retail drug stores and commercial partners would provide advantages such as decreasing costs, leveraging existing skilled workers, providing options and access points to the public and increasing the availability of antibiotics. Use private sector logistics partners for distribution, pharmacies or big box retailers for dispensing and other pre-defined organizations as closed points of dispensing (PODs).

5. Expand “push” dispensing models for initial antibiotic dispensing
   Deploy push dispensing models – including the National Postal Model – to additional cities and regions to supplement public PODs, especially when public transportation is
compromised or shelter in place is ordered. This will also enable the response to reach home-bound populations or those that will not report to a public POD.

6. **Plan to vaccinate during the initial response phase with concurrent antibiotic dispensing**

   Utilize the public POD model to dispense vaccines and antibiotics to the affected population during the initial response period. Vaccinations will need to be administered during the first week for the best effect and highest return on investment.

7. **Provide commercial home MedKit access to first responders and to the population**

   Provide MedKits to first responders and their families, which would reduce the time to respond and dispense and would incent responders to report to duty by ensuring they and their families have antibiotics for immediate use. Also, develop commercial MedKits for purchase by the general population pre-event so that they may begin prophylaxis immediately when an event occurs. This could increase compliance by providing an alternative to public PODs.

8. **Develop a plan for providing completion prophylaxis, or antibiotics for days 11-60**

   Develop a standardized national plan, including roles and responsibilities, for obtaining, distributing and dispensing completion prophylaxis to the affected population.

9. **Develop a plan to address multi-drug resistant strain vulnerabilities**

   Develop a standardized, national, pre-determined response plan for combating an MDR strain of anthrax.
**Introduction**

The hypothetical challenges posed by bioterrorism only became reality after the 2001 U.S. anthrax letter attacks. Following these attacks, Congress appropriated billions of dollars for research and development, prevention, preparedness and studying the bioterrorism problem. No one is confident or complacent concerning the progress achieved to date. Most bioterrorism experts assess that the U.S. is better prepared today than it was ten years ago, but no one believes we are adequately prepared. Despite extraordinary efforts and expenditures, confusion remains as to the basic nature of the biological threat. Officials have searched for analogs with which to compare bioterrorism, and we are still divided on the question: Is it a public health problem or national security threat? For some, the answer is both and for others it is one or the other.

Biological attacks are most often characterized in terms associated with natural pandemics and disease outbreaks and are judged to be best handled as a public health problem. Both pandemics and biological attacks can result in secondary social and economic consequences that transcend local, state and national borders. However, while often cited as an effective terrorist, Mother Nature is not a thinking adversary, which is the main factor in distinguishing biological attack from public health threats. Deliberate releases of diseases can cause explosive point-source outbreaks that can result in tens or even hundreds of thousands of people being infected with high-dose exposures that may not afford responders with the response time related to a normal incubation period or clinical manifestation of natural disease infections. Biological attacks are like pandemics in that they affect the health of a large population of people and can be mitigated with medical countermeasures, but they are unlike pandemics in the accelerated time pressure and sensitivity for response. Biological attacks require an effective, coordinated response that is measured in hours and days – not weeks or months. Public health officials will not have the relative luxury of conducting surveillance, performing epidemiologic investigations, collecting and analyzing data, or studying after action reports to determine the scope and seriousness of the disease. A biological attack stands in stark contrast to public health emergencies where the “tyranny of time” will not allow for this same type of approach.

Biological attacks should be treated as a national security threat. It is the intent to harm that equates biological attacks with other weapons of mass destruction (WMD) attacks, including nuclear, chemical, and radiological. These are all considered grave national security threats, deployed with harmful intent to compel the target to conform to the will of the attacker. The governing theory of biological warfare is not Koch’s Postulates, which are the biological criteria for judging whether a given bacterium is the cause of a disease, but Clausewitz’s theory of war, which states that “War is thus an act of force to compel our enemy to do our will...not merely an act of policy but a true political instrument, a continuation of political intercourse, carried on with other means.”¹ As with all intentional attacks, a national security response is required.

However, the biological threat is not directly analogous to any of the other WMD categories either. First, biological agents can be deployed covertly. They cannot be seen, felt, or recognized when the attack occurs, and the challenge of latency or incubation exists, which means the effects are delayed from the time of release to onset of illness. There may be no defined beginning or end to the attack and no immediately defined geographic barrier to the effects. This makes guaranteed detection or diagnosis and definitive characterization very difficult to achieve. Unlike nuclear attacks, infrastructure is physically spared in a biological attack. The risk associated with a contagious biological agent such as smallpox or plague permits a single localized attack to spread far from the original release. Therefore, biological attacks have certain qualities that demand that they must be treated differently from other WMD events.

The tendency and inclination to manage biological attacks as a public health problem obscures the necessity to treat them as a national security threat because of their intentionality and

potential to inflict grave harm on our nation. Because of the ambiguous nature of potential biological attacks and the inability to rapidly and accurately characterize the scope and severity of the event, high-regret decisions will have to be made with limited, imperfect, or incomplete information. To avoid a potential catastrophic loss of life, decision makers must act quickly and cannot afford to spend time collecting data or waiting for information to make a perfect decision. In fact, they will have to have the courage to make a series of decisions to save countless lives that well may cost them their political life when viewed through the lens of hindsight and political judgement.

Compounding the challenges associated with biological attacks is the continuing ambiguity of who should ultimately lead the government response: should the Federal Government or state and local entities be in charge? A terrorist nuclear attack is viewed as a WMD event and would be handled as a federal-led response, whereas a bioterrorist attack is considered a public health problem and would be handled locally. Since the distinction has not been made of where responsibility for a response falls, there is currently no one in charge, and lines of command and control are muddled. Also, there is no clarity as to which federal agency or agencies have jurisdiction if, in fact, the Federal Government is ultimately in charge. Since so many agencies are involved in the response, who ultimately has the coordinating role? Who is accountable for providing resources for response? In this austere budget environment, is addressing this threat going to be a priority for this federal agency in charge? And how do we begin to recover from such an ambiguous threat?

**Anthrax as a Biological Threat**

Anthrax is considered by the intelligence, national security and public health communities to be the most likely bioterrorism threat to the nation, and it was therefore chosen as the case study for this analysis. Anthrax, or *Bacillus anthracis*, is a naturally-occurring, spore-forming bacterium. It can infect humans via three routes: cutaneous, which infects the skin; gastrointestinal, which is ingested; and inhalational, which is breathed into the lungs and ultimately infects the bloodstream. The inhalational form is the most relevant to terrorist scenarios and is the most dangerous and deadly.

There are three stages for inhalational anthrax: incubation, prodromal, and fulminant. The incubation period, where the patient presents with no symptoms, can last anywhere from 1-11 days depending on the infecting dose, though there is significant potential variability and uncertainty with this range. After the spores germinate and begin to multiply, releasing toxins, patients start presenting with non-specific, flu-like symptoms in what is known as the prodromal phase. Once a patient reaches this stage, oral antibiotics may not be entirely effective as prophylaxis. In the fulminant stage, patients often present with respiratory distress, and the historical mortality rate can be as high as 97% whether treatment is initiated or not. In the 2001 anthrax letter attacks, aggressive intensive antibiotic and supportive treatment, which is very costly, resulted in a lower mortality rate of 45% in the eleven cases of inhalational anthrax.

Though not demonstrated in the 2001 anthrax attacks, *Bacillus anthracis* can be processed and aerosolized, or disseminated through the air, in such a way that increases the chances for inhalation and also promotes a wider dispersion of the spores. Anthrax spores are very persistent and can survive decades in the environment, which raises additional implications and challenges from re-aerosolization. The phenomenon of re-aerosolization provides potential for residual spores deposited on surfaces to be re-suspended in the air and infect long after the

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primary aerosol has passed. Re-aerosolization or a new attack may be indistinguishable and will result in significant implications for response and recovery. The ultimate time to recovery may be indeterminable because of re-aerosolization risk.

The combination of ease of infectivity, mortality rate, and environmental persistence make anthrax an attractive choice for a bioterrorism weapon. Because of these characteristics and evidence that terrorist groups have shown interest in developing anthrax for use in attacks, the Federal Interagency Community has developed a planning scenario, known as National Planning Scenario 2, focused on an aerosolized anthrax attack:

This scenario describes a single aerosol anthrax attack in one city delivered by a truck using a concealed improvised spraying device in a densely populated urban city with a significant commuter workforce. It does not, however, exclude the possibility of multiple attacks in disparate cities or time-phased attacks (i.e., “reload”). For federal planning purposes, it will be assumed that the Universal Adversary (UA) will attack five separate metropolitan areas in a sequential manner. Three cities will be attacked initially, followed by two additional cities 2 weeks later...This attack results in 328,484 exposures; 13,208 untreated fatalities; and 13,342 total casualties. Although property damage will be minimal, city services will be hampered by safety concerns.

This study uses this scenario as the basis of the analysis. The five-city scenario is not widely utilized and represents a somewhat worst-case, although one that is considered a plausible case.

In the event of any scale or scope of an anthrax attack, there are four elements to recovery:

- Detection and Characterization
- MCM Distribution and Dispensing
- Population Management and Risk Communication
- Remediation

**Detection and Characterization**

This element involves quickly determining the presence of a potential biological agent of concern, determining its characteristics and identifying the geographic distribution of the dissemination. Ideally, environmental detection would permit early recognition of a release in time to initiate a response before the onset of clinical symptoms. In lieu of rapid environmental detection or in its absence, the onset of clinical symptoms would likely herald the occurrence of an attack.

In terms of characterization, it is important to quickly determine if the strain used is resistant to any antibiotics. If, for example, the strain of anthrax strain is resistant to ciprofloxacin, doxycycline or both, response actions would have to be dramatically altered. Ciprofloxacin and doxycycline are the two antibiotics recommended for anthrax prophylaxis, and they are also common antibiotics used to treat many bacterial infections.

The affected area subject to the attack will also require characterization. It will be important to determine the areas that require avoidance or remediation so that recovery steps can be taken as soon as possible. This will involve a wide-area sampling strategy and a plan for decontaminating whatever environments are affected.

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**MCM Distribution and Dispensing**

Once it has been determined that a biological attack has taken place, rapid delivery of medical countermeasures will be required to pre-empt illness in those that were exposed to the agent. The agent must first be identified to determine which countermeasures to distribute (e.g., if the agent is anthrax, doxycycline and ciprofloxacin will be distributed). The Centers for Disease Control and Prevention (CDC) Strategic National Stockpile (SNS) will then release the appropriate medications to the impacted state, which will be responsible for distributing the medications to the affected area. That jurisdiction will be responsible for dispensing medications to the entire population of the affected area, as it will not be possible to tell who was infected initially.

This process will need to be completed quickly as the medications given to prevent illness (prophylaxis) are only effective before symptoms appear, which can be anywhere from 1-11 days,\(^8\) but will most likely be around 3-4 days. After symptoms appear, prophylaxis is no longer effective and the health care system does not have the capacity to treat large numbers of infected individuals, as the treatment is resource-intensive. Therefore, rapid distribution and dispensing is essential to preventing high levels of morbidity and mortality.

**Population Management and Risk Communication**

Rapid delivery of medical countermeasures into the hands of the affected population is an essential task. However, unless the population actually complies and takes the medications as directed, all the effort to achieve rapid detection, characterization, distribution and dispensing will be for naught. Recent surveys indicate significant percentages of the populations who may receive antibiotics following a bioterrorist attack may delay taking them until they feel ill.\(^9\)

Convincing a population that they should take a medication without “hyping” the threat or risk of illness and death is a delicate balance. First, it will be important to keep the population calm, so that they will understand and respond appropriately to clear and consistent messaging. The medication should be available to the population as soon as messaging indicates the necessity and instructs them to initiate oral antibiotic treatment as soon as they receive the medication. An important adjunct to the messaging concerning taking the antibiotics is ensuring sufficient amounts are available and that there will be minimum risk of the supply being depleted. A clear process for receiving adequate medications will be essential in preventing complicating or unhelpful reactions from the population, such as rioting or looting.

Also, there should be clear direction and frequent reinforcement that the affected population must continue to take the full course of antibiotics (60 days) to fully prevent illness. Population compliance is one of the most important factors in keeping unnecessary morbidity and mortality to a minimum.

Strategic risk communication should also emphasize and incent the population to remain in the affected area as there are currently limited plans for distributing or dispensing medication outside of the affected jurisdiction to those who may travel or flee. If the population does evacuate, it may be very difficult to convince them to come back. Further, rapid re-occupation of the affected area will be a very important factor in recovery.

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Remediation

Remediation consists of a set of activities required to return the affected area to a new normal state. The first activity will be distributing and dispensing the remainder of the 60-day course of prophylaxis. The affected population should be able to easily access a complete 60-day course of antibiotics from the government. As previously identified, population compliance will also be important for remediation. Without actually taking the provided medications, population remediation will not be possible.

Vaccination is another avenue that can be used for population remediation. Vaccination shortens the requirement for antibiotics from 60 days to 30–45 days. Also, in the event of reload or risk of re-aerosolization, the population will be protected, likely requiring no further antibiotics. Finally, vaccination can effectively protect a population from the potential risk of multi-antibiotic resistant anthrax strains. Vaccination essentially takes the threat “off the table.”

Decontamination is another task that is essential for remediation. Currently, the U.S. has no experience with decontamination of a wide, outdoor area. Existing experience with biological decontamination is limited to the 2001 Amerithrax attacks, where the spores were contained within an indoor setting. However, it will be important to make the entire area ready for re-occupation as quickly as possible so that recovery can begin.

The purpose of this project was to examine current U.S. response and recovery plans using anthrax as a test case and to identify the gaps in the end-to-end process that would affect the ability to execute the four elements above. Recommendations were developed for cost-effective ways to alter the process to achieve greater efficiency and flexibility and to ultimately aid in recovery.

Description of MCM Distribution and Dispensing

Current U.S. response plans for dispensing medications to the public in the event of a biological attack center around the federal SNS supplying medications to local Points of Dispensing (PODs), which then dispense medications to the public.

In 1999, Congress mandated that the Department of Health and Human Services (HHS) and the CDC establish a National Pharmaceutical Stockpile, which would contain medications not readily available in the commercial market to address threats to the U.S. The stockpile was renamed to the Strategic National Stockpile when its designated use was expanded to include not only pharmaceuticals, but also medical materiel that could be used in an all-hazards situation. The creation of the Department of Homeland Security (DHS) originally transferred the SNS from HHS to DHS. The Pandemic All-Hazard Preparedness Act transferred control of the SNS back to HHS, and the Directorate of the SNS is organizationally aligned within the CDC.

The concept of PODs was originally developed to address the smallpox threat by creating a public health-directed mechanism to conduct the necessary medical screening and vaccinations to the public at central locations. It is a method for the population to go to public health officials to try to go out and vaccinate the entire population. PODs are the public health-preferred method for providing vaccinations to people who are not

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currently presenting symptoms, but may have been exposed to a disease-causing agent.\textsuperscript{13} Since the POD model was already in existence and biological attacks were deemed public health emergencies, the role of PODs was expanded to include dispensing antibiotics to the public during a biological attack.

The current model for response starts with the detection of an attack. Once an attack is confirmed, the governor of the state in which the attack occurred submits a request to HHS to deploy the SNS. The decision to deploy the SNS is made by the HHS Secretary. Once SNS deployment is approved by HHS, the CDC releases the assets to the state and distributes the medications to a Receipt, Store and Stage (RSS) site, where the medications are transferred from federal to state control. The state then distributes the medications to the local PODs in the affected area. Local public health officials and volunteers are responsible for dispensing the medications from the POD to the population. Initial dispensing involves handing out 20 pills to each person, which accounts for 10 days of the 60-day regimen.

Prior planning and preparation must also take place for a response to be effective. The federal, state and local governments must establish a plan for carrying out these processes. Then they must put resources against those plans in a preparation step. Also, after the response has been carried out, recovery should be the focus. Recovery involves remediating the area and returning it to normal activities. The end-to-end distribution and dispensing process as defined in this study is shown below in Figure 1, and the gaps identified in this analysis tie back to these steps.

**Figure 1. High-Level Process for MCM Distribution and Dispensing**

This high-level overview represents the government’s current course of action for the distribution and dispensing of antibiotics. However, once the medications are transferred to the RSS, the details of this process are state-, county- or city-specific. Public health departments are responsible for developing their own dispensing plans for response. The Cities Readiness Initiative (CRI) provides funding to 72 metropolitan statistical areas (MSAs) to develop their individual response plans and prove they are able to carry out a response to a biological attack.\textsuperscript{14} Each location is given flexibility to develop dispensing plans to best suit their population, and they often supplement the POD model described above with alternate modes of dispensing.

The two alternative methods of dispensing include “push” and “pull” models. Push models deliver the medication directly to the population, whereas pull models require the population to report to a centralized location to receive their medications. The most widely recognized example of the push model is the National Postal Model. This model involves volunteer postal workers delivering medications to all the residential addresses in certain zip codes as they would the mail. In 2009, President Obama stated that the U.S. should pursue the National Postal Model as a national capability.\textsuperscript{15} However, this model is currently only operational in one city, has been activated in another, and is likely to be expanded to three additional cities.\textsuperscript{16}

There are other push distribution models that state and local governments have explored. One urban jurisdiction with many high-rise apartment buildings developed plans to deploy


\textsuperscript{16} Interview with Subject Matter Expert.
volunteers to those buildings and place medications on resident doorknobs within each building.\textsuperscript{17} Other jurisdictions’ plans include using school buses to deliver medications to houses in more rural areas.\textsuperscript{18}

Alternate pull dispensing models are also integrated within several state and local government response plans. Some suburban areas have implemented drive-thru PODs that allow for people to stay in their cars and drive through the dispensing site to receive medications as they would in a fast food restaurant.\textsuperscript{19} Other jurisdictions are implementing closed PODs that allow for a business, community or any designated group to identify themselves ahead of time with a set demand and, after an event occurs, to receive the requested amount of medications from the RSS to hand out to their pre-determined population.\textsuperscript{20}

\textbf{Analysis}

WARRP’s objectives in analyzing the MCM response and recovery process were to make cost-effective recommendations to help achieve the goal of dispensing medications to 100\% of the affected population within the first 48 hours and to permit full recovery of the affected area within six months. These are aggressive performance targets, and achieving 100\% coverage of the at-risk population may not be possible in any situation. However, planning scenarios that would target any less than 100\% would likely undermine public trust in a government response. Also, any extended delay in recovery is similarly not acceptable because of the potential economic consequences that would likely result as many businesses and people would either be forced to leave the area or would voluntarily do so.

A Systems Engineering approach to analyze the distribution and dispensing process was taken. It began with a retrospective look at the process identified in Figure 1 to identify sensitivities and interdependencies. This analysis identified that a major fact in achieving the objective of saving as many lives as possible is compliance with government instructions to take antibiotics and complete the full 60-day course. As indicated by Figure 2, there is a decision tree that each person in the affected area must follow, and there is only one acceptable path which results in potential lives saved. A person must first seek the antibiotics, receive the medications, and ultimately decide to take the pills as soon as they receive them and continue on the full course of treatment.

\textsuperscript{17} Interview with Subject Matter Expert.
\textsuperscript{19} Ibid.
\textsuperscript{20} Interview with Subject Matter Expert.
However, public surveys reveal that the path shown above is not the course of action that many people would follow. In fact, the survey numbers were used in the analysis, and it was found that even if distribution and dispensing were completed within 48 hours, 39% of the population could potentially succumb to anthrax because of non-compliance (Figure 3). This sensitivity analysis shows that public compliance is likely the most important consideration in saving lives. If the public complies, medication effectiveness and POD throughput are the next two most important factors.

Figure 3. Sensitivity Analysis

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The idea of population compliance is often overlooked in response analyses; it is assumed that the public will behave rationally and according to plan. The underlying assumption is that the affected population will report to the POD in the allotted time, receive their antibiotics, and begin taking them as instructed. The surveys referenced previously demonstrate that this assumption may not be correct, and there are currently no contingency plans to account for population behavior that promote compliance. There is currently no identifiable action in the response plans after PODs are opened and, in fact, the affected population’s behavior or compliance is not considered in current plans. As Richard Danzig identified in his 2007 paper, the public is thought of as an obstacle to be overcome in a response rather than as a resource or partner to be utilized.22

Population compliance was rarely mentioned during the interviews and literature search associated with this study, but it was identified as a major theme during this analysis. In addition to population compliance, several other factors were identified that may either stop or stall the effort, preventing achievement of the goals to dispense to 100% of the population within a 48-hour timeframe.

This analysis began with constructing a value stream map for end-to-end distribution and dispensing, which served as the framework to identify and organize gaps. The framework was conceived through an extensive literature review and interviews with subject matter experts and captured in an interactive process mapping tool. Over 117 gaps were defined, mapped to process steps, and assessed for impact on the end-to-end process. Each gap was also analyzed to identify potential root causes which were rolled into the “themes” presented below. The objective of the process and gap analysis was to generate an understanding of the issues driving potential process failures and poor outcomes, not to create a comprehensive list of individual gaps. The list of gaps is delineated in Appendix II, with gaps organized by the process stage that they affect (as shown in Figure 1).

Several “themes” emerged from the value stream analysis and are listed and described below along with supporting quotes from those interviewed for this study:

1. **There is no single answer to “who’s in charge” of a biological attack response**

   Ambiguous command and control in response to an attack was a clearly identified gap in multiple stages of the process. At the most basic level, there is no clarity as to whether responding to a biological attack is ultimately a federal or local responsibility. Many people subscribe to the “all disasters are local” mantra, meaning locals would be in charge with state and federal support, while others say a WMD attack on the nation means that the President and the Federal Government will be in charge. This ambiguity results in confusion as to who will be providing primary resources, who will assume the supporting role, and who will be responsible for the response processes.

   There is also no clear answer to which federal agency is in charge of federal response processes. There is no clear delineation as to roles and responsibilities among federal agencies, specifically HHS and DHS and their subordinate agencies CDC and FEMA. Therefore, state and local governments are confused as to who they should coordinate with on which issues.

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2. High-consequence decision making for a biological attack has not been exercised in real time, and the inability or delay in making these high-level decisions may stall or stop response

Most senior executive decision makers identified as being involved in responding to a biological attack do not have experience or training making life-and-death decisions that account for the complexity of biological attacks. However, in the event of a biological attack, life-and-death decisions will have to be made quickly and most likely with limited, imperfect or incomplete information. This is at best intimidating and at worst debilitating.

As the U.S. does not currently provide opportunities for decision makers to exercise these types of decisions in real time, they may be unprepared for what awaits them during a time of real crisis.

3. State and local government plans are developed independently without clear or consistent directives, and there is no overarching coordination for response plan execution

Currently, U.S. response plans are state- or local-government specific. Home rule, or the authority of a local government to prevent state government intervention with its operations, determines what level of government is in charge of public health response. If the state does not operate under home rule, then the state is in charge of response plans with counties and cities reporting to it. If it is a home-rule state, then the counties or cities are in charge of their own response plans. This structure creates the potential for several thousand response plans in the U.S. Right now, there is no acceptable venue for sharing information or best practices among state and local governments.

Also, all federal assistance is delivered in the form of recommended guidance, which state and local officials can choose to follow or deviate from. This leaves each state and local government to build independent response plans and in many cases “re-invent the

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wheel.” Some state and local governments have collaborated across state or county lines to implement a standard response plan, but this is not required and depends upon the initiative and personalities of those officials in charge.

If a state or local government chooses to partner with a private sector entity, government officials must independently negotiate memoranda of understanding (MOUs) with each private sector partner. Industry interviews revealed private sector frustration with negotiating MOUs with each state and local entity, resulting in potentially several thousand different agreements, each with differing terms and conditions.

**Interview quotes for Theme 3:**

- “The lack of a standardized approach [among states and localities] greatly complicated the management of pharmacy activities [during H1N1].”
- “Each county and state had different reporting requirements. For future events, the process needs to be more directive than consultative. Tell them how to do it. Provide directives rather than recommendations. In the absence of clear guidance, states and counties did what they wanted to do, resulting in inefficient and ineffective processes.”
- “The CDC allows each state to make its own decisions. CDC simply provides the drugs. Some states took the lead [in H1N1 response], while others pushed responsibilities down to the counties. The lack of consistency among states was a big problem.”
- “It would help if the process was more directive instead of consultative. The federal government simply provided recommendations [during H1N1]; states and counties decided whether or not to take them.”
- “Whatever process is designed should be consistent across states. The concept of ‘home rule’ makes this exceedingly difficult, since even counties and underlying municipalities often have divergent processes for emergency response.”
- “There is little control of the [MCM] inventory once the CDC transfers the material to the states. The resources cannot be redistributed [to other states] once they are pushed out.”
- “Across the country, there are heterogeneous operational capabilities. We need to implement the same process across the entire U.S., in all jurisdictions.”
- “Need to look at responses regionally or nationally instead of as a local event only.”
- One city was “totally unaware of the progress that had been made by the CDC, and assumed that nothing had been done. Federal planners operate behind a veil. They would like if the CDC kept the field planners apprised of progress that had been made or updates.”

4. **A local public health approach does not appreciate the urgency of a biological attack or the intent of a thinking adversary**

A public health emergency and national security crisis are often approached quite differently. The public health system is a highly disaggregated system designed to deal with a wide spectrum of health issues at a local level. The day-to-day work in this system consists of providing maternal and child health assistance, conducting studies and confronting local health issues such as tuberculosis and HIV, but not exclusively infectious diseases. Preparedness tasks are often buried beneath a series of competing priorities. In the event of a public health emergency, like pandemic influenza, the event usually takes place over weeks to months and the timeline associated with these events allows them to be approached methodically. Even though these events can affect many parts of the country, they are still managed as local events.

National security crises, like biological attacks, are much more complex and urgent situations, as they represent an attack on the nation by a thinking adversary. However, biological attacks are the only type of WMD attack that is defined as a public health emergency. Any other type of WMD attack would be seen as an attack on the nation and would garner the appropriate national security response. As a biological attack would
start locally, but would quickly become a national and potentially an international problem; the onus for response should be on a national coordinating body.

During a national security crisis, such as a large-scale biological attack, time pressure may not permit extensive data collection. It must be responded to quickly and urgently, especially if the adversary is still at large and could attack again. In addition to health officials, biological attacks would require the expertise of law enforcement, defense, and intelligence officials. The outcome of such an event may result in initiation of a war or the use of nuclear weapons in retaliation.

### Interview quotes for Theme 4:

- “From the FBI perspective, a bioattack is an attack [on the nation], not a public health emergency. It would be a federal issue, and the federal government would be in charge.”
- “A biological attack would quickly be raised to an Incident of National Significance. All levels of government would be involved, as this would be an attack on the nation. It would not be confined to a local event.”
- “Many people do not see this as an attack on the nation, but see it as a public health emergency, which means we are very limited in response strategies. We will rely on public health officials for response rather than a federal defense response.”
- “Public health officials think, ‘What if I’m wrong?’ They do not like to pull the trigger [on response] without a level of certainty.”

### 5. Little formal recovery planning has been performed for actions after the initial post-48 hour response

CRI grantees are required to prove they have the capacity to dispense prophylaxis to 100% of the target population within 48 hours in order to receive HHS grant funding. Cities must demonstrate their ability to comply by conducting exercises and meeting certain requirements in order to continually qualify for CRI funding. Given the narrow performance requirements for funding, all planning and preparation that has been done focuses on the first 48-hour response. Properly executing a response in the first 48 hours is critical, but solely focusing on that time period ignores the importance of what comes next, which is the recovery phase. Because “recovery” has not been defined, grant managers do not have any performance targets for post 48-hour activities within award requirements.

Currently, there are no definitive plans for dispensing the necessary antibiotic prophylaxis for days 11-60. According to interviews, officials assumed that this portion of the response would be easier to accomplish, therefore requiring less planning. However, with no formal planning whatsoever, officials were unable to describe how additional antibiotics would be dispensed. Some speculated it would be through PODs, others through pharmacies.

Without completing the full 60-day course of antibiotics, the symptoms of anthrax may not be prevented, and people can be susceptible to developing inhalational anthrax. In planning for a crisis, it is prudent to identify and make as many decisions ahead of time as possible. If a plan for completion prophylaxis is developed ad hoc while officials are still responding to the unfolding crisis at hand, it is likely that the plan may initially succeed, but ultimately fail. Developing a plan ahead of time may relieve the burden of having to make critical decisions during the crisis, leaving the officials to simply respond and execute the plan.
Interview quotes for Theme 5:

- “The follow-on dispensing plan is wide open. Locales may use PODs, they may use pharmacies...who knows?”
- “The biggest issue with recovery is how little attention has been given to it.”
- “One huge gap is planning for days 11-60. Many groups have made great strides in planning for days 1-10. [There are no] finalized plans for days 11-60. Those days will require a lot of federal input and assistance.”
- “The issues of recovery are not really being discussed.”
- One interviewee “guess[ed] that the information and/or plans at the federal, state or local level will not be clear-cut on how to deal with the post-48 hour response.”

6. **Clear and consistent risk communications from a trusted source will ultimately affect public confidence and ensure compliance**

State and local governments are responsible for developing their own response plans. Because communication planning is conducted at the local level, there is currently no national clear, integrated communications guidance from any entity. Each state and local government must develop their own communications strategy and script their own messaging. As a result, very few stakeholders have pre-scripted communications that are ready to deploy in the event of an emergency.

The CDC is currently developing communications that can be used during an event, but state and local governments are not required to use them. This could easily create chaos if the messaging is not consistent across the U.S., especially in a multi-city attack where consistent national communications will be so critical.

To ensure population compliance, the public needs to receive communications from a trusted source, and much of the U.S. population does not always have confidence in government communications during a crisis. Trusted sources could include the media, local community groups, churches, health care providers, etc. Communications planning should consult these groups ahead of time to include them in the messaging so that the message remains consistent.

Interview quotes for Theme 6:

- “Mass prophylaxis stalls if there isn’t a cooperative citizen, and their cooperation depends primarily on the message that is communicated.”
- “Another gap is accurate and timely communications. There must be consistency and clarity of messaging. We will need clear, easily accessible, multiple-platform messaging.”
- “Good public messaging will be necessary for any response mechanism to work.”
- “Credible, well-prepared and anticipatory messaging will be key. It is important to get media on the side of the government right out of the gate. The messaging needs to be consistent in order for the public to cooperate.”
- “A huge challenge is communications to the public. Planning in this area is inadequate at best. What kind of behaviors is an event with 24/7 news likely to bring to bear? Plans do not take into account the psychological or sociological reaction of people.”

7. **No serious consideration has been given to alternate scenarios (e.g., MDR strains, reload)**

All current planning for biological attacks is done for one-city scenarios with predictably treatable strains of the biological agent. Very little, if any, attention has been paid to alternate scenarios such as multi-drug resistant strains or multi-city attacks, even
though the DHS Material Threat Determination and National Planning Scenario identify such potentialities. Both of these are real threats as the technology for creating drug-resistant strains is ubiquitous and since creating enough biological material to conduct one attack is not that different from creating enough to conduct multiple attacks.

Although interviewees and literature acknowledge these threats, there are no current plans for responding to either. There have been no exercises conducted using either of these scenarios and the U.S. will be generally unprepared to respond to anything that deviates from the one-city treatable strain scenario.

Interview quotes for Theme 7:
- “Reload is not as much of a part of the conversation as it should be. It is a real concern for bio.”
- One interviewee “has never seen a federal plan for MDR anthrax.” They suggest “that they would tweak the existing response plan as events unfold to combat MDR. There have been discussions at the HHS level to determine what the operations would be in this case, but nothing has been decided.”
- One planner “hasn’t really focused on planning for a double strike or multi-city attack. The Unified Command would move resources as best as they can to address two problems. A double strike and/or antibiotic resistance would cause a real problem.”

8. There is no integrated, comprehensive national plan or effort to leverage the private sector to assist in distribution and dispensing

As previously stated, if state and local governments choose to leverage the private sector for distribution and dispensing, they must individually negotiate MOUs with each private sector entity. The reverse is also true in that any private sector entity that chooses to assist in the response in more than one jurisdiction must negotiate individually with each jurisdiction. This results in many disjointed processes and procedures for what will quickly become a national problem.

Current government response plans require leveraging a contingency supply chain that has never been exercised or used, while parallel private sector supply chains exist that perform these functions every day. However, given that each state or jurisdiction is in charge of their own response, it is difficult for the private sector to be involved because of the fact that they operate fluidly across state and county lines where the government response plans may not allow them to do so, confining them to the state or county where the MOU was signed. The bureaucracy involved with disjointed state and local government plans may prevent greater participation from the private sector.

Interview quotes for Theme 8:
- “Katrina was the benchmark disaster for realizing that the private sector could get supplies through a lot quicker [than government] and without the red tape.”
- “The government shouldn’t create their own or new systems [for response]. The public and private sectors have to trust each other in this process.”
- One state “has been putting a lot of pressure on BARDA, SNS, HHS to establish agreements with big pharmacies on the federal level. There has been some success working on the regional level, but there has not been much progress on a national level.”
9. **There may be an inadequate amount of product available nationwide in both the SNS and the private sector supply chain to respond to large-scale biological attacks**

In planning the supply for the SNS, there is a tension between having enough antibiotics on hand to protect the U.S. and not having so many antibiotics that if an event did not happen, huge amounts of medicines would go to waste because of expiration. Comments made during interviews indicated that the SNS has sufficient antibiotics to cover three major MSAs simultaneously, but in the analysis of National Planning Scenario 2, it is likely that there is not enough product to cover the five major MSAs mentioned in the scenario. It is not clear whether the likely demand by the worried well has been considered.

The aggregate supply of doxycycline and ciprofloxacin within the private sector supply chain was evaluated as well. For these commonly-prescribed antibiotics, the private sector relies on a just-in-time supply due to the predictability of demand. Because of stable demand, these products are not stockpiled within hospitals or pharmacies. Also, many of the active ingredients for these antibiotics and the antibiotics themselves are produced overseas. Therefore, the U.S. cannot rely on the private sector “bubble” to quickly produce or supply the remainder of the medications if the SNS is depleted in a multi-city attack.

Also, diagnostics to identify pre-symptomatic, but infected people are not available, which means that a potentially large number of uninfected people will receive prophylaxis. This gap is in direct conflict with assumptions made by planners that they will know the infected from those not infected in time to direct scarce supplies to those who truly need them. This is a fallacy on two levels: first, there is not a method to distinguish the infected and non-infected and second, an already untrusting public is unlikely to believe that they should suspend treatment without unassailable proof that they are not infected. For these reasons, demand for product is likely to be much higher than currently planned.

**Interview quotes for Theme 9:**

- “There is a concern that there is not a sufficient amount of material in the SNS or in the commercial market [to respond to an attack].”
- “In the event of an anthrax emergency, there may not be enough retail supply to meet demand. Inventory is just in time. They do not maintain huge buffers in stores.”
- “In planning SNS assets, they found that a three major city scenario would have taxed the SNS, and the five city scenario would bring it to its knees.”
- “One of the biggest gaps is do we have enough quantity of product to provide to the public in the case of a large-scale attack?”

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24 For example, Hovione Pharmaceuticals, which produces a great amount of doxycycline, is headquartered in Portugal and produces much of its product in Macau. "Hovione PharmaScience Ltd., with a manufacturing site in Taipa Island, Macau, increased its doxycycline production in order to meet increased demands from US, provoked by the bioterrorists attacks with Anthrax. Together with Bayer’s Ciprofloxacin, the product manufactured by Hovione is an antibiotic specifically approved by the US FDA (Food and Drug Administration) to fight Anthrax in its three forms of infection: cutaneous, gastric or inhaled....The Hovione Macau site began its active pharmaceutical ingredients production in December 1986 and was approved by the FDA the following year. This site today has 150 professionals and manufactures the more stable Hovione products. The Macau factory is responsible for one third of Hovione total production.” "Hovione’s Factory in Macau Supplies Antibiotic against Anthrax." Hovione. 31 Oct. 2001. Web. 11 Apr. 2012. <http://www.hovione.com/h_press/press_rel/pro1_006.htm>.
10. An adequate workforce for both planning and response is a major issue because of the decrease in Departments of Health staffing and the heavy reliance on volunteers

State and local public health funding continues to decline, especially during difficult economic times. With this decrease in funding comes a severe decrease in state and local health department staff. Competing priorities also drive budget allocation decisions, and preparedness planning often falls to the bottom. Since state and local health department staff serve as the crux of POD response, staffing is likely to be a debilitating response gap. This is compounded by serial decreases in federal Public Health Emergency Preparedness grant funding that supports state and local preparedness efforts.

In addition to state and local public health department staff, the POD model also relies heavily on volunteers. As one report notes:

The POD model of countermeasure distribution is extremely personnel intensive, particularly with a 48 hour distribution requirement. If we are to assume that POD throughput is about 500 patients/POD/hour (San Francisco test data; LA County and Houston planning); and that each POD requires 220 staff (2 shifts, 110/shift) per POD (LA county, Houston planning); then more than 9,000 staff and volunteers are needed to distribute therapeutics in two days.25

The requirement for thousands of volunteer POD staff is a hurdle that most states and locals may be unable to overcome, and locals may not have adequate resources to respond to an attack of this magnitude on their own. One study found that mortality rates are directly correlated to local dispensing capacity;26 therefore, it will be crucial to either creatively find ways to ensure adequate POD staffing or to identify alternate models for dispensing. Also, there will be a continued need for high staffing levels beyond the initial response for tasks such as ongoing treatment and surveillance.

Interview quotes for Theme 10:

- “In training exercises, the maximum number of PODs set up at one time is about ten. There are not enough volunteers to stress the PODs, so we don’t know what it’s really going to feel like when an emergency hits.”
- “There is no continuity of personnel across public health in emergency planning. Public health departments are suffering from brain drain.”
- “For planning purposes, the assumption is that 60% of volunteers will show up to work PODs. Jurisdictions need to learn how to optimize PODs with non-optimal staff levels.”
- In working on the preparedness and response issues for several years, one interviewee’s main worry is “not having enough staff.”
- “Manpower is the biggest weakness of PODs. Estimated needs are huge. The majority would have to come from volunteers. In an emergency, they expect only 1/10 of volunteers to show up. They likely won’t be able to open up all of the PODs.”

11. Funding cuts across public health departments within all levels of government will cripple the ability to plan for or respond to an attack

Public health funding is being cut at all levels, and preparedness is one of the lowest priorities among state and local Departments of Health given that they are overwhelmed.

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* Cited with permission from P. Albright
with performing day-to-day tasks. In addition to staffing cuts, departments are also unable to ensure the presence of adequate local caches or to devote sufficient time and resources to solving potential distribution and dispensing problems. Federal grants for funding, including CRI grants, are not guaranteed and could be cut at any time. This lack of funding surety makes it difficult for state and local governments to put a sufficient amount of resources against the bioterrorism problem.

Funding cuts are also prevalent across the board in the Federal Government. As memories of the 2001 anthrax attacks fade, competing priorities continue to require the funds once earmarked for bioterrorism. The SNS is one example of a program that is continually facing funding cuts. Not only are they responsible for maintaining the stockpile, but they are also the federal group assigned to assist states and locals with their response plans. Without appropriate funding, or new partnerships with the private sector, these functions may also fade away.

Interview quotes for Theme 11:

- “Public Health Awareness Cooperative Agreement Funding is eroding. This will make it difficult to address preparedness gaps at any level.”
- “The impact of budget cuts has been huge on local health departments, especially in the areas of planning and response. They will probably not have an adequate workforce to carry out the response in most cities because of these cuts.”
- “State and local public health departments are on the verge of shutting down due to a lack of funding. If labs don’t have funding, they don’t have the capacity to diagnose these diseases. Public health infrastructure is key. Public health is a lynch pin in making sure these response and recovery processes occur.”

12. There are no clear goals and objectives for response to a biological attack, including for MCM distribution and dispensing

Preparedness planning to date has not considered or accounted for the outcome expected by the public. For example, the CRI grantees must provide evidence that they can dispense medications to 100% of the target population within 48 hours, but the metrics set up only measure isolated pieces of the process rather than the efficiency or flexibility of the entire process. Reasonable and practical metrics have not been established to measure the effectiveness of this process. One “goal” is achieving a 1000 person/hour throughput, which is often referred to as the gold standard. However, if a local jurisdiction can only set up and staff one or two PODs, then the 1000 person/hour standard will not come close to providing the dispensing capacity to reach the entire population of a large MSA.

Another aspect of the process that is often ignored is population compliance. Current objectives in the dispensing process often end with the population receiving their medication. However, even if the population receives their medication, but chooses not to take it, then the mortality rate will still be high. Rather, goals and metrics should center around saving the lives of 100% of the population and working in reverse to ensure that the process can support that goal.
Interview quotes for Theme 12:

- “The CRI objective is to get antibiotics to the target population within 48 hours, but it does not clarify what the target population is.”
- “The overarching problem is that the [biodefense] community has not agreed on what the goals and objectives of our biodefense efforts are.”
- “The dispensing of MCMs itself does not predict success. The responsibility of the federal government goes beyond administering the product. People at all levels think the systems to determine if the MCMs are being taken or if they are effective are coming from someplace else. No one is claiming responsibility for these metrics.”

The response process was also analyzed to determine how it would be affected by several different scenarios:

- **Base Scenario:** Single Release, 48-hour detection, antibiotics are effective
  This scenario is the one that current plans are built around. While the U.S. is most prepared for responding to a one-city attack, gaps still remain. However, by taking some steps to address some of the larger gaps, it is likely that the U.S. can respond to this scenario with only moderate loss of life.

- **Reload:** Initial release detected in 48 hours followed by second release in the same or another city, antibiotics are effective
  Reload is a scenario for which there has been minimal planning. All plans and assumptions are made around a one-city attack. A multi-city scenario will lead to a competition for national resources. These will include SNS materiel and federal resources such as incident management, technical, security, logistics, medical, laboratory, environmental, forensic, public assistance, and communications personnel and equipment. Where a natural disaster such as Katrina prompted many entities in the U.S. to send resources to the affected location, a biological reload scenario would most likely prompt hoarding behavior from other jurisdictions as they wonder if they are next. A multi-city scenario will also prompt difficult decisions as the Federal Government decides how many resources to send to the affected locations and how much to reserve for the possible next attack. This will be especially true with SNS resources such as anthrax vaccine. With the limited vaccine availability in a multi-city scenario, the government will have to make difficult vaccine allocation decisions to affected areas and consider a reserve in anticipation of another attack. As the outlook for recovery is not good for a one-city attack, the outlook is even more bleak if multiple cities are hit. However, the appearance of a more dire situation may work to increase compliance amongst the public. It may also have the opposite effect of increasing chaos and panic. Either way, with current plans, the loss of life is likely to be great.

- **MDR:** Single Release, 48-hour detection, antibiotics are not effective
  Currently, the Federal Government has no plans for combating an antibiotic-resistant strain of anthrax. Interviewees indicated that they would respond according to their plans and would alter the plans as strain information emerged. However, by the time the strain is determined, it may be too late to deploy alternate antibiotics before symptoms appear. This would mean that more people would reach the prodromal phase, requiring hospital treatment. Hospitals would quickly become overwhelmed, meaning that most people would not receive treatment and the mortality rate would be very high.
The only method for quickly combating MDR anthrax is vaccination as a part of the initial response. However, the U.S. has no current plans or policy for deploying anthrax vaccine and the supply in the SNS limited.

If MDR anthrax is used in an attack, given current plans, it is likely that most of the infected population would die.

- **MDR / Reload:** Initial release detected in 48 hours followed by second release in another city, antibiotics are not effective

  Analysis revealed that this is a scenario for which the U.S. is totally unprepared. Not only does the U.S. lack a sufficient stockpile of alternate antibiotics (e.g., rifampin, clindamycin) to counter a MDR attack in one city, but we also do not have enough vaccine to vaccinate one large MSA. The U.S. has no plan for countering MDR anthrax and currently has not exercised a reload attack. This scenario would result in a crumbling of all response efforts and many lives lost.

  It is possible that by the time the second attack occurred, the strain of anthrax would be identified as MDR. This could give a bit of an advantage in that the correct antibiotic could be sent initially to the site of the second attack instead of as follow-on treatment. However, without more product readily available in the stockpile, we would be facing a threat for which there are no antibiotics owned by the government. In other words, we would be aware of the threat we are facing with no means to combat it.

**Recommendations**

This analysis resulted in nine priority recommendations that will have the greatest impact on the overall process and that will provide the greatest return on investment. In this austere budget environment, recommendations were developed that would be cost-effective to implement. Over 25 potential recommendations were assessed based on the scope of potential impact on the desired outcomes of number of lives saved, number of sicknesses avoided and other metrics. The cost, risk and implementation difficulty of each recommendation was also assessed to help prioritize and identify the nine recommendations with the best return on time and money invested. Some potentially valuable recommendations were subordinated due to their cost and complexity. While the priority recommendations are described in detail, a full list of recommendations and the methodology for prioritization are available in Appendices I and III.

The top nine recommendations address gaps in the process steps indicated in Figure 1. Each recommendation is described below in detail, including a notation of which gaps are addressed and how it will affect metrics. These nine recommendations would address 73 of the 117 gaps.
**Recommendation 1: Put the Federal Government in Charge of the Bioterrorism Response and Identify a Single Federal Agency to Serve as the Lead**

Currently, states and local governments are in charge of the bioterrorism response within their own jurisdiction, and they rely on federal support. This stems from the mantra that “all disasters are local.” While this is true in many disaster scenarios, bioterrorism is an attack on the nation. It is inherently a national problem and requires a national coordinated effort, and one federal agency should be in charge of this coordination. This shift in authority would not be expensive to implement.

As the response process is structured now, the Federal Government provides guidance to state and local governments for how to build a response process centered on public PODs. State and local governments can choose to structure their response processes according to the provided guidance, or they may choose to create their own processes based on response structures individually tailored to their demographics. While tailored processes may create a more effective local response, it is important to have high-level goals and standards that every
jurisdiction should follow. The Federal Government should institute those goals and standards and hold state and local governments accountable for implementing them.

Federal Government coordination will address several gaps this study has identified. First, Federal coordination can aid in addressing regional disparities by providing response guidelines that every jurisdiction must follow. Regional response coordination is currently dependent on the initiative and personalities of the state and local public health departments and/or first responders of that region. While some regions are set to mount a coordinated response across state or county lines, many jurisdictions operate independently of those jurisdictions that surround them, which may create chaos during an event that has no respect for jurisdictional boundaries.

Second, private sector coordination can be handled best by partnering at the federal level. Many private sector entities were frustrated during the H1N1 experience because of the inconsistencies among state and local governments. Hundreds of MOUs had to be negotiated by each private sector entity with different state and local governments. Each had different processes and reporting requirements. This overwhelmed the private sector, which is accustomed to moving fluidly between state and county lines. The Federal Government should take the lead in negotiating one government contract with each private sector entity, which would enable them to respond nationally with one standard process.

Third, the need or expectation for leveraging federal resources can be determined prior to the event. Currently, states and locals must demonstrate that they have exhausted their resources before the Federal Government will provide support. In an event of this magnitude, any time delay may cost lives. Allowing the states and locals to exhaust their resources before requesting federal resources may cause a significant time delay. Also, as budgets are being cut, state and local public health resources are becoming more strained. The Federal Government should assess state and local capabilities prior to an event and determine which jurisdictions will require immediate federal resources. This will be especially crucial in a multi-city attack where federal resources will be in high demand.

Fourth, achieving complete coverage across an entire population will require the creation and operation of multiple dispensing channels. High-volume channels can support the majority of the population, but at-risk groups like the elderly, poor, homebound, non-English speaking, and children may require alternative dispensing channels. An MCM Response Architecture that layers multiple channels to account for variability across population segments and to provide resiliency is necessary. The MCM Response Architecture must be managed at the national level to allow effective wide-area response, the most efficient use of materials and the best use of scarce human resources like public health personnel. For example, providing dispensing alternatives managed by trusted third parties may free up public health resources to operate ancillary channels focused on their regular customers - community segments needing extra help. Reaching those community segments will help with the goal of increasing population compliance.

Lastly, since this is inherently a national event, coordinated national messaging will be critical to encouraging population compliance. Any variation in messaging across or within states will harm the credibility of the government. The Federal Government should develop pre-scripted messaging that can be consistently leveraged across state and local jurisdictions in the event of an attack.

Gaps addressed

- **Gap 1, Overall**: Heavy reliance on local public health departments for preparedness and response. These departments are experiencing huge amounts of turnover; attrition rates leads to understaffing at public health centers, lack of institutional knowledge. Preparedness is not a priority within most state and local health departments.
- **Gap 2, Overall**: Regional response plans are developed on an ad hoc basis depending upon the initiative of the state and local health departments (e.g. VA, MD and DC or NY, NYC, NJ and CT).
• **Gap 4, Overall:** “Home rule” creates a complicated structure that inhibits a coordinated national response.

• **Gap 7, Overall:** The local ability to decide to request SNS, set up a dispensing infrastructure, and allocate resources to the dispensing infrastructure may not be timely.

• **Gap 16, Overall:** No clear answer to who’s in charge at the federal, state, or local level or between levels.

• **Gap 19, Overall:** Public health-oriented thinking is neither sufficient nor appropriate when facing a resourceful adversary.

• **Gap 22, Overall:** Federal resources including incident management, technical, security, logistics, medical, laboratory, environmental, forensic, public assistance, and communications personnel and equipment may all be required in biodefense events - possibly simultaneously in several localities.

• **Gap 28, Plan for MCM Dispensing:** Lack of biodefense-defined outcomes, planning assumptions, or requirements at the national level.

• **Gap 30, Plan for MCM Dispensing:** Federal guidance comes in the form of recommendations, rather than clear directives.

• **Gap 34, Plan for MCM Dispensing:** Lack of a widely accepted national biodefense architecture.

• **Gap 39, Plan for MCM Dispensing:** State, local and county plans may differ significantly. Operational plans, rules, regulations, requirements may differ during an event. The concept of “home rule” further complicates response capabilities.

• **Gap 44, Prepare for MCM Dispensing:** Biodefense budget is fragmented and not aligned to required preparation, response and potential recovery.

• **Gap 57, Detect and Characterize Event:** There are multiple organizations involved in collecting event information (including JTTF, CDC, FBI). Process owner is ambiguous. Responsibility and accountability is also ambiguous. There is no clear coordinating body for all the collected event information.

• **Gap 71, Initial MCM Distribution:** Process for activating SNS for neighboring states/localities unclear in a regional attack.

• **Gap 73, Initial MCM Distribution:** Response plans may differ significantly across states and localities. Autonomy of jurisdictions can create confusion in the supply chain (e.g., separate demands on distributors).

• **Gap 74, Initial MCM Distribution:** Lack of consistency and guidance at state and local levels creates complexity in distribution planning and response.

• **Gap 90, Initial MCM Dispensing:** Processes and procedures at PODs differ among states and localities (e.g., providing identification, filling out forms, picking up certain amounts). No nationwide directives on POD processes.

**Metrics affected**

A Federally coordinated MCM Response Architecture should include a top-level performance model describing the results to be achieved, which is linked to outcome and process metrics. Without clear, concise, and measurable outcome goals, other elements of the architecture, like the concept of operations, process model, resource model, data model, logistics model, and technology model, cannot be properly scaled, aligned, or measured. All metrics will be affected by the owner of the MCM Response Architecture including:

**Outcome Measures** are the most critical indicators of overall response success and map directly back to the response objectives related to recovery: reducing casualties, controlling unwanted population movements or flight, and enabling rehabilitation. By implementing an architecture and controls, metrics including percentage of affected population to die, percentage to get sick, percentage that flee, and percentage that do not return can all be minimized.

**Compliance Measures** indicate the level of success in getting the public to successfully complete a treatment regimen. Failure of compliance directly leads to degraded outcomes. The key compliance metrics are the percentage of the potentially affected population to seek or acquire antibiotics in the first 96 hours after an event, the percentage of the population that begins
taking the antibiotics without delay, and the percentage of the population that completes a 60-day antibiotic course as directed. Incorporating these metrics into an architecture that addresses compliance should drive improvement in compliance and better outcomes.

**Dispensing Measures** indicate the volume of medical countermeasures successfully transferred to the public within specified time windows, typically within 96 hours of an event. Dispensing failures or delays can have a negative impact on compliance and, in turn, outcomes. Standardization, measurement, better integration, and shared services across jurisdictions driven by an architecture can improve the likelihood of complete dispensing in the 96-hour window and provide resiliency to adapt to setbacks.

**Logistics Measures** are indicators of performance or partial failure of the distribution and dispensing process. These measures are monitored by several levels of incident and dispensing management to make adjustments to ensure the highest rates of dispensing and compliance. Incorporating a complete process and logistics model into the architecture and building out shared services like transportation will help to minimize dispensing failures due to logistics problems. Transportation, personnel, security, inventory, facilities, and tactical communications are all monitored to detect and correct or to contain potential logistics failures.

**Characterization Measures** are indicators of external conditions or limiting factors affecting the distribution, dispensing, and use of medical countermeasures. These measures may affect strategic and tactical decision making or change the potential value of Dispensing and Compliance Measures. For example, better understanding of who has actually been exposed to a threat would adjust expectations of dispensing and compliance. A determination that a particular strain is resistant to antibiotics will also change the approach to dispensing and supporting compliance. Incorporating these measures into decision making processes and analyses is critical to avoiding breakdowns leading to poor outcomes.

**Recommendation 2: Improve the Effectiveness of Strategic Risk Communications**

Communicating with the public will be critical to enacting an efficient response, encouraging population compliance, and ultimately, saving lives. The federal agency in charge of coordinating a national response should review and refine strategic communications to ensure they are correct, consistent and constant, and that they are distributed to appropriate communication channels pre-event. Again, implementation costs should be relatively small.

A properly coordinated Strategic Communications plan will address a number of gaps that this study has identified. Pre-event perception and fears of the public as well as proper communication to volunteers need to be addressed. Special attention should be directed towards special needs groups. Coordinated pre-event preventive measures are key, while concise and clear communications are paramount post-event. Specific communications components are addressed as follows:

**General**

An effective communications strategy can serve as a low-cost/high-impact method for increasing population compliance and reducing morbidity. Currently, communication between federal, state and local authorities is lacking, or is perceived to be lacking. Lack of a well-coordinated communications process can lead to significant delays in high-consequence decision making by both officials and the public. Far too few stakeholders have pre-scripted communications, and there is no clear and overarching communications guidance from any entity. The public will only cooperate if messaging is clear, consistent, timely and authoritative. Additionally, the different communications requirements and decision making styles of population segments must be incorporated into strategic communications plans and execution.

**Population Response**

Psychological and sociological reactions of the public are not adequately addressed. Performance metrics are predicated on a certain response and behavioral assumptions that may
not be the case at the time of the event. This unpredictability heightens the importance of a coordinated point for communication and information. We know that in times of crisis, the public will look to government and other authoritative sources for guidance. The public currently has no expectation of communications methodology, frequency and urgency from the Federal Government. Proper communication from the government will help to build trust and improve compliance. Again, the different needs of various population segments must be understood and addressed. Segmentation goes beyond language capabilities and will change over time, requiring regular testing of assumptions and the use of various communication mediums.

Communications prior to, during, and after an event

Partnership in this element is vital. Blanket communications should be launched via multiple platforms – text, e-mail, emergency broadcast system, etc. Proactive and preventive communications are preferred. Effective communication between the Federal Government and the private sector is also lacking. The Federal Government should consider leveraging existing private sector resources that have expertise in strategic communications and that understand population response. Additionally, the Federal Government should conduct a communications standards review for state and local authorities to ensure consistent and standardized processes.

Shifting decision making from the high pressure environment of an event to pre-event preparations can reduce the variability in compliance by the public. Incorporating decision points and specific preparation alternatives like home MedKits or closed PODs into preparation allows more of the public to “invest” in a solution and relieve anxiety and non-compliance. Communications tied to actions, tailored to segments, and delivered repeatedly by trusted sources including partners other than the Federal Government are more likely to be received and embedded into the public mindset.

Gaps addressed

- **Gap 8, Overall**: Most individuals will be concerned not simply with receiving the requisite drugs within the recommended time, but with receiving them as soon as possible. System not capable of meeting expectations of public in crisis mode.
- **Gap 15, Overall**: Communications to the public are not pre-scripted by some federal, state, or local entities.
- **Gap 109, Ongoing MCM Dispensing and Completion Prophylaxis**: Will be difficult to inform or provide assurance to a population in an affected area that they do not need to participate in completion prophylaxis.

Metrics affected

Outcomes metrics, particularly the rate of death, rate of sickness, and rate of flight, are directly affected by strategic communications. Strategic communication deficiencies can lead to compliance and dispensing failures that lead directly to poor outcomes. By establishing an environment where fear and miscommunication are minimized and trust is built, logistics and dispensing can proceed as planned and the greatest possible percentage of the population will receive, take and complete their MCM course. The public will also be more likely to comply with instructions about evacuation and travel when they are trusting of the government.

**Recommendation 3: Provide Pre-Event Communication to Decision Makers and to the Public**

Pre-event communication is generally high among state and local health departments, as they must comply with CRI requirements, as well as among the portions of the Federal Government that assist states and locals with planning. However, this communication is severely lacking on the top and bottom ends of the spectrum, namely among high-level decision makers and the public. This is particularly disconcerting as the high-level decision makers are the ones that will be making crucial response decisions that will determine the outcome of the event. Also, public
compliance with instructions (e.g., receiving and taking pills) will determine the ultimate survival rate of the affected area.

Roles and responsibilities should be clearly delineated ahead of time, and leaders should be sensitized as to their own roles as well as the roles of every other entity involved. Sensitizing leaders in decision making for this type of event will be critical to an effective response and is very cost-effective. As one interviewee noted, “We are deficient in socializing decision making to leaders – the same leaders that need to be driving critical preparedness steps.”27 Leaders will be forced to make decisions with limited, imperfect or incomplete information during a bioterrorism attack, and they need to be not only aware of this, but also be prepared to act. The same interviewee stated that we “need to understand the importance of crisis decision-making dynamics. How many current leaders have had to make life-and-death decisions in compressed timeframes? This is the crux of the problem in addressing this kind of event.”28

There have been some tabletop exercises, such as TOPOFF, that do aid in giving leaders practice with high-level crisis decision making. However, most exercises do not appreciate the time crunch that decision makers will be under during an actual attack. These exercises tend to focus more on policy discussions vice timely response decisions. One anecdote from an interview was that decision-makers in a table top exercise were so wrapped around the axel of the “evacuate vs. shelter-in-place” decision that they were unable to make other decisions. Decision makers should participate in real-time exercises and drills in order to prepare them for the complexities of the decisions they will have to make in a crisis and for them to appreciate the minimal amount of time they will have to make these decisions.

Also, leaders may not know the people or number of agencies involved. Not only do we need to avoid having these people meeting for the first time around the table responding to a bioterrorism event, but leaders also need to understand roles and responsibilities of everyone involved. Command and control during a bioterrorism attack is already confusing, so it can only be assumed that this will be compounded when a disaster does strike and decisions need to be made quickly. The exercises mentioned above should involve the participation of all key stakeholders so that roles and responsibilities can be exercised as well.

On the other end of the spectrum, the public also lacks pre-event education and generally does not even possess an awareness of the bioterrorism problem. Most preparedness literature focuses on preparedness at the state and local level in terms of public health departments, not in terms of citizens. There is very little work done around general public education.

Richard Danziger notes that:

[N]ational security – protecting the country against enemies – is viewed both by our government and our public as almost exclusively government’s responsibility. The public is implicitly regarded as a vulnerable, dependent population to be protected by the government; in this context, members of the public are not treated as co-equals in ensuring their own personal safety. These differences are reflected in different response paradigms for handling the twin threats of pandemic influenza and bioterrorism. While pandemic influenza planning assumes the need for layperson education and action to contain the spread of disease and reduce risks and consequences, present preparations for bioterrorism follow a professional paradigm with little consideration as to how laypeople could be involved in their own security.29

This excerpt highlights that not only is the public not prepared or educated, but they view it as the government’s responsibility to defend them and provide resources for preparedness.

27 Interview with subject matter expert.
28 Ibid.
Currently, the government is not living up to its responsibility for educating or communicating with the public. In a Harvard survey of the public, they found that “[m]ore than half of people say they are familiar with term ‘inhalation anthrax,’ but roughly 40% of those people also believe it is contagious or don’t know if it is.” The government could easily clarify the characteristics of anthrax with some simple outreach. In addition to knowing the characteristics of the agent, the public should know exactly where to go and what to do in a bioterrorism event. The public should be well aware of the location of the closest POD, information that has not been released because of fear of secondary attacks. They should also know whether or not to evacuate the city or shelter in place, whether the postal service is bringing their medication to them and that it is essential that they take their full course of medication in order to survive. Unless these messages are relayed to the public is a clear and readily accessible way, the public will not comply and morbidity and mortality will increase.

Waiting until an event happens to disseminate information will be too late. It will result in confusion amongst the public and could easily result in chaos and non-compliance. It is important to actively push information to the public before an event happens. The public should not have to go to great lengths to seek out and pull the information they need (e.g., actively visiting a website). They should receive the information in mass mailings, public service announcements, or through any other means that will reach a large amount of the population.

**Gaps addressed**

- **Gap 8, Overall:** Most individuals will be concerned not simply with receiving the requisite drugs within the recommended time, but with receiving them as soon as possible. System not capable of meeting expectations of public in crisis mode.
- **Gap 14, Overall:** No clear policy on evacuation vs. shelter in place during an event.
- **Gap 20, Overall:** High-consequence decision making with limited information is necessary, but many organizations and officials are not prepared, trained, or capable of making timely life-or-death decisions.
- **Gap 32, Plan for MCM Dispensing:** Lack of consistent understanding about rules and laws governing MCM distribution and dispensing at local levels.
- **Gap 48, Prepare for MCM Dispensing:** Public has not been involved in many exercises and there is a lack of public awareness on response processes.
- **Gap 50, Prepare for MCM Dispensing:** There is a lack of exercises that test high-level peri-event decision making.
- **Gap 93, Initial MCM Dispensing:** Public may be reluctant to visit PODs for fear of contamination, contagion, and/or repeat attacks.

**Metrics affected**

As with strategic communications, pre-event communications and engagement can affect all critical outcome metrics. Sensitizing the public and decision makers to the issues they will have to deal with and providing options for them to get involved and take ownership of their personal solution can reduce anxiety and uncertainty during a response. With more people engaged and potentially assisting others, compliance rates may increase and stress on distribution and logistics may be reduced.

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31 Interview with subject matter expert.
Recommendation 4: Use the Federal Government Lead Agency as the One Point-of-Contact for Private Sector Partnerships and Leverage the Relationships Nationally

The private sector is a valuable resource that is underused in response planning to bioterrorism events. They have great expertise and resources to bring to bear, as demonstrated during the H1N1 pandemic. Furthermore, as evidenced by interviews, the private sector wants to be involved. They feel a sense of corporate responsibility to the communities where they are located. They can also help relieve some of the burden on the government and absorb some of the costs.

However, the use of the private sector for response to public health emergencies has been ad hoc and disjointed thus far. Each state or local jurisdiction, depending on the presence of home rule, has developed separate contracts or MOUs with each private sector partner. These have included contracts with third-party distributors to receive and deploy medications from the RSS and MOUs with pharmacies to dispense vaccines during H1N1. The development of these partnerships relies on the initiative of state and local public health officials.

The private sector has been frustrated by the many different processes and procedures that these separate contracts require. For example, one retailer had to submit 150 different reports for H1N1 in one state alone. This inconsistency makes it difficult for private sector partners, many of which operate nationally, to participate in any meaningful way. In interviews with the private sector, they requested that the process be more consistent nationally.

The advantages of using the private sector are numerous. They have the ability to work across state lines. This is opposed to the SNS, which cannot redeploy medications across state lines. Also, the private sector has an existing supply chain which they use every day. These supply chains must operate efficiently at all times, or businesses will fail. They are accustomed to overcoming hurdles that result from emergency situations. Their employees are also trained in their roles. They are more likely to succeed than a government response model where public health staff or volunteers will be asked to perform roles they are not trained to do.

Also, one common theme heard in interviews was the concern about the availability of product both in the SNS and in the private sector. The Federal Government could work with the private sector to increase the amount of antibiotics in the retail supply nationally (e.g., encourage the development of buffer stocks) so that it could be leveraged in the case of a large-scale attack that would otherwise deplete the SNS.

These advantages should demonstrate the need to leverage the private sector for response. This could be accomplished in several ways. First, pharmacies can be used as open PODs to supplement public PODs. If the population decides not to go to PODs, they will most likely report to private sector pharmacies demanding medications anyway. Therefore, the government should equip them to serve in that capacity. Giving the public options for retrieving their medications will increase population compliance.

Second, the private sector could put together pre-developed regional retail prescription databases, as they did during the Katrina event. Many pharmacy chains worked together to develop a database that could be used by all participating chains to track the population and their prescriptions. Victims of the hurricane could then report to any participating pharmacy chain, and their records would be available. This same model could be used by pharmacy chains during a bioterrorism event. This would be an efficient way to track the population and which medications they received in what amounts. This database should be developed prior to an event so that it can be immediately leveraged during an event.

Another option would be a tiering system for private sector dispensing. Tier 1 would be the use of Big Box retailers for mass distribution, and Tier 2 would be using pharmacies for refilling MCMs. Big Box retailers would be the most useful during a mass dispensing campaign because

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32 Interview with private sector retailer.
of parking availability and general space within the stores. Smaller pharmacies could then refill the remainder of the required 60-day course.

The Federal Government should take the initiative to establish contracts or MOUs with the private sector. Each private sector partner should have one agreement with the Federal Government that can be leveraged by states and locals. States and locals should not be allowed to establish their own agreements in place of the federal agreements. The Federal Government can negotiate dispensing fees and set guidelines in place that the private sector should follow. In interviews, the private sector requested that the process be more directive than consultative, with one set of guidelines and standards. This would give an even greater incentive for private sector participation and could aid in establishing an effective national response plan.

The private sector can also be defined in terms of groups that are not part of the Federal Government, such as community or church groups. By using this definition, many groups can be leveraged to serve as closed PODs. These are PODs that have a pre-determined population that they intend to serve. The main advantage of closed PODs is that they can offload a significant portion of the population from public PODs. Groups that should be explored to serve as closed PODs are employer-based PODs, in which an employer would provide medications to their employees and their families; workplace or institutional PODs, such as nursing homes, colleges, or prisons; and community-based PODs, such as churches, neighborhoods, or community groups. Since people generally trust and feel comfortable identifying with these groups, using the closed POD method is likely to increase population compliance.

Gaps addressed

- **Gap 6, Overall**: Inventory visibility and tracking is difficult for the government, especially between different levels of government.
- **Gap 12, Overall**: There is no way to track or identify people with adverse reactions to medications.
- **Gap 13, Overall**: Hard or impossible to deploy/redeploy stockpile medications across state lines once states take possession on SNS materiel.
- **Gap 33, Plan for MCM Dispensing**: Supply of ciprofloxacin and doxycycline in retail market is low since pharmacies and hospitals employ a just-in-time supply chain. Distributers will likely have a low supply due to the just-in-time model as well.
- **Gap 35, Plan for MCM Dispensing**: Antibiotic supply both in the SNS and existing supply chain may be insufficient in reload/multiple attack scenarios.
- **Gap 53, Prepare for MCM Dispensing**: Dependent entirely on volunteers and state/local public health to ensure dispensing to public. Assumption that anywhere from 10-60% volunteers will show up in an actual event.
- **Gap 72, Initial MCM Distribution**: There will be demand for antibiotics outside of the impacted state or locality from people who have travelled from the affected area that are symptomatic or from the worried well.
- **Gap 75, Initial MCM Distribution**: Distribution of medicines to PODs can be a rate limiting step. Some jurisdictions indicate that they can set up PODs faster than medicines may arrive.
- **Gap 91, Initial MCM Dispensing**: PODs are resource-intensive. Inordinate amount of burden placed on volunteers. Duration of shifts unsustainable over long time period.
- **Gap 92, Initial MCM Dispensing**: First delivery of MCMs may not be sufficient to meet full demand before follow-on deliveries arrive.
- **Gap 94, Initial MCM Dispensing**: PODs present an attractive opportunity for a subsequent attack, especially if there are no alternatives for dispensing.
- **Gap 99, Ongoing MCM Distribution**: No process for leveraging supply of MCMs in private sector or what already is in place in the supply chain.

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33 Interview with private sector retailer.
• **Gap 100, Ongoing MCM Distribution**: There is a manpower and budget deficit for planning for and implementing ongoing MCM distribution. Infrastructure for distribution and dispensing is insufficient.

• **Gap 106, Ongoing MCM Dispensing and Completion Prophylaxis**: No way of tracking who receives medicines and how much they receive, so it will be unclear which members of the public need more doses of each MCM.

• **Gap 111, Ongoing MCM Dispensing and Completion Prophylaxis**: No plan or ability to reserve staff for ongoing dispensing activities - staff shortages at public health departments will require all staff to be part of the initial response.

**Metrics affected**

The objective of involving private sector partners more deeply in MCM logistics, dispensing and compliance is to improve the likelihood of positive outcomes across the board. Engaging capable partners in the community to perform functions they are already proficient at reduces logistics and dispensing risk. Providing the population options to work with groups and individuals they already trust should improve compliance and reduce unwanted flight. Innovation in one community may also be efficiently shared across the country by unhindered commercial partners.

**Recommendation 5: Expand “Push” Dispensing Models for Initial Antibiotic Dispensing**

There are two types of dispensing models that can be used during a biological event: “pull” or “push” models. Pull models require the population to report to a designated location, whether it be a public POD or a pharmacy, to receive their medications. This means that a possibly panicked and frightened group of people will have to walk, drive, or take public transportation (if it is still in service) to one location; stand in line; and fight crowds in order to receive medication. When asked in a Harvard Poll if they would go to a dispensing site to get antibiotic pills for themselves within 48 hours of confirmed anthrax, only 68% said they were very likely to do so (84% would go for their children).34 This is not good news if the goal is to somehow get medications to 100% of the population, and these methods will likely contribute to non-compliance.

Push models are a great supplement to reach the population that may not be inclined to use the pull models. Push models have government staff or volunteers bring the medications to the population. This is also the most effective way of reaching homebound populations, or those residing in institutional housing such as nursing homes or prisons, which can increase compliance amongst those segments.

Although there are many push model options, the most common one is the National Postal Model. In this model, postal employees deliver medications to the population as they would the mail. This model is designed to be a “quick strike” while PODs are being set up. In exercises, the postal service has demonstrated that they can deliver medications to tens of thousands of households within 10 hours of receiving medications (38,000 residences in 8 hours in Seattle, 53,000 residences in 9 hours in Philadelphia, 23,000 residences in 6 hours in Boston).35 Also, when the public was asked about their confidence in organizations’ abilities to deliver antibiotic pills, they were most confident in the postal service with 73% of the public saying they trusted that organization over federal public health agencies (60%) and state/local public health


agencies (66%). This model has shown so much promise that Executive Order 13527 states: “The Federal Government shall pursue a national U.S. Postal Service medical countermeasures dispensing model to respond to a large-scale biological attack.”

However, the National Postal Model has not been implemented nationally. It is currently operational in one city, has been activated in another, and is likely to be expanded to three additional cities. This is due to a lack in funding and a concern about the level of security required for implementation (i.e., one security officer for each postal worker).

There are other options besides the National Postal Model for push models. One city indicated that they are deploying volunteers to apartment buildings. They worked with the fire department to gain access to the buildings, and three volunteers were able to deliver to around 300 people in 20 minutes. The implementation of alternative push models is reliant entirely upon the initiative and creativity of state and local public health workers. Another option is to use the private sector for delivery of antibiotics. There are many companies that also provide deliveries to homes every day and also are familiar with their routes.

In its coordinating role, the Federal Government should assist state and local governments in implementing push models. These would serve as a supplement to public PODs in enabling a quick strike and reaching populations that would not be reachable by public PODs.

**Gaps addressed**

- **Gap 8, Overall:** Most individuals will be concerned not simply with receiving the requisite drugs within the recommended time, but with receiving them as soon as possible. System not capable of meeting expectations of public in crisis mode.
- **Gap 78, Initial MCM Distribution:** Time to detect and characterize event, make the decision to mobilize SNS, and then distribute may be significantly longer than planned. Actual time may greater than 48 hours.
- **Gap 79, Initial MCM Dispensing:** Postal Model is very limited in its applicability at this time only being deployable in one city and in the process of being implemented in four more.
- **Gap 84, Initial MCM Dispensing:** Unclear if traffic and/or road closures have been accounted for in distribution and dispensing drills.
- **Gap 85, Initial MCM Dispensing:** No clear communication from CDC to localities as to guidance for Postal Model implementation.
- **Gap 86, Initial MCM Dispensing:** Some localities are not willing to explore implementing Postal Model due to security personnel requirement and their unwillingness to spare security for this purpose.
- **Gap 94, Initial MCM Dispensing:** PODs present an attractive opportunity for a subsequent attack, especially if there are no alternatives for dispensing.

**Metrics affected**

The Postal or a similar push model may be the only practical approach in situations where transportation is compromised, a single day is available for dispensing, or sheltering in place is ordered. In these situations, the Postal Model can improve dispensing performance and may have a slight positive effect on initial compliance, resulting in improved outcomes. The Postal Model would have to be augmented with a POD model to ensure all people in an area are served. Both the Postal and POD models would be susceptible to logistics failures.

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38 Interview with subject matter expert.
Recommendation 6: Plan to Vaccinate During the Initial Response Phase with Concurrent Antibiotic Dispensing

Currently, there is no policy for providing vaccinations as post-exposure prophylaxis in the event of an anthrax attack, despite studies stating that vaccinations plus antibiotics is the most effective strategy with the lowest cost. An antibiotics-alone strategy requires that the affected population take an antibiotic regimen for 60 days from the date of last exposure, which is a long period of time for people to continually take antibiotics. In the case of reload or re-aerosolization, the regimen could be longer than 60 days since the date of last exposure will have changed. Several interviewees have indicated that they assume vaccines will be used as part of the response, but they are not sure how or when that would happen. CDC officials indicated that vaccination would likely start during the second week after the initial attack to facilitate identifying and vaccinating individuals who were indeed likely exposed rather than all individuals at potential risk.

To speed up the recovery process, post-exposure vaccination may only require 30-45 days of antibiotics to be taken in concurrence with the vaccination. This would require that less antibiotic product be consumed, and it would aid in increasing population compliance because of the shorter time period required. It would also allow immunity to be built up in the affected community so that reload or re-aerosolization would no longer be a threat and help persuade the population to confidently re-occupy the affected area quicker without a need to achieve the goal of zero spore decontamination. Re-occupying an area will be crucial to that area’s recovery.

Vaccination will not be possible during the initial dispensing phase; in order to dispense antibiotics to 100% of the affected population within a 48-hour window, responders must focus solely on handing out antibiotics and cannot afford to slow down any part of the process to simultaneously institute a vaccination structure. However, once the first round of medications is handed out, responders will be able to set up a vaccination structure to further provide prophylaxis to the affected population. The assumption is that this will be able to happen 7-10 days after the response is initiated. Interviews have indicated that this time frame is feasible.

To accomplish concurrent vaccine administration and antibiotic dispensing, the Federal Government needs to develop a national vaccine policy. This would involve determining at what point during the response the anthrax vaccine will be released from the national stockpile, at what amounts, and to whom. On which day of the response would the vaccine be released? Would the vaccine be administered in PODs or by the private sector either in health care facilities or in pharmacies? How will the cold chain requirements be addressed? Whatever policy decisions are made should be implemented nationally and should account for the logistics of vaccine distribution.

Currently, there is not enough vaccine in the SNS to support administration for even one large city. Preliminary studies indicate it may be possible to dilute the existing anthrax vaccine several-fold but research needs to be done around vaccine dilution to determine in what dilution amounts it will still be effective. The Federal Government should also evaluate increasing the amount of vaccine in the stockpile if a national vaccine policy is implemented. Since reload is a real possibility, the Federal Government could consider stockpiling enough vaccine to cover the population of three major cities. Because of vaccine development and


production time, and the lack of sufficient vaccine in the stockpile, this recommendation will take time to implement. It will take years to increase the availability of vaccine or longer to develop a new one, and development/production costs are high when compared to other options. Adverse reactions associated with the administration of the anthrax vaccine also present a challenge to be dispositioned, especially as it has not been tested or approved in children and the elderly, and more studies need to be done around the vaccine’s efficacy. However, the implementation of this recommendation would greatly assist in response and recovery, and the Federal Government should take steps now so that this recommendation can be implemented as soon as possible.

**Gaps addressed**

- **Gap 11, Overall**: It is unclear if/when vaccinations will be used, if at all.
- **Gap 21, Overall**: Impact of multi-drug resistant agents on response is not understood, particularly the need for flexibility and the potential for loss of public confidence.
- **Gap 31, Plan for MCM Dispensing**: The current vaccine is not suitable for children and elderly and would require an IND if the government were to administer it to these at-risk populations.
- **Gap 36, Plan for MCM Dispensing**: No clear plan for alternate prophylaxis to address MDR strains.
- **Gap 37, Plan for MCM Dispensing**: Vaccine supply not sufficient for large scale deployment.
- **Gap 61, Detect and Characterize Event**: Time to identify and capture perpetrator may be time consuming such that a subsequent attack may be carried out.
- **Gap 62, Detect and Characterize Event**: EPA and DHS think of biological attacks like a chemical attack in which there are cool, warm and hot zones for decontamination. However, in biological attacks, affected zones may move because of weather or people carrying spores and the threat may exist for a long time.
- **Gap 104, Ongoing MCM Distribution, Ongoing MCM Dispensing and Completion Prophylaxis**: No definition of when prophylaxis can end; the 60-day clock starts from last date of exposure.
- **Gap 114, Recovery**: Goal for recovery is zero spores detected in the environment. What is acceptable elapsed time before re-occupying contaminated areas? Is 100% decontamination possible? Necessary?
- **Gap 115, Recovery**: No quick reaction or interdiction tools to prevent follow-on attacks.
- **Gap 116, Recovery**: Decontamination research and development for outdoor biological attacks have not been a national priority. The U.S. lacks standards and a strategy for mass decontamination and has only rudimentary capabilities in this area.

**Metrics affected**

The coincidental provision of vaccine and antibiotics can improve death and sickness outcomes, particularly when additional exposures are possible. Vaccination will possibly reduce flight and enable faster rehabilitation of affected areas. The additional burden of providing a vaccination may create sufficient stress on PODs as to negatively affect antibiotic dispensing. Misinformation about vaccine performance may also reduce compliance with antibiotic regimens prematurely.

**Recommendation 7: Provide Commercial Home MedKit Access to First Responders and to the Population**

The U.S. Government should work with private sector partners to develop commercial home MedKits for pre-event distribution to emergency first responders and their families, and potentially for purchase by the general population, so that they can begin immediate prophylaxis once the event occurs. Commercial home MedKits are a way to reach at-risk populations such as the homebound, elderly, those in institutional housing, etc, or other segments of the population such as first responders or those in rural areas. This method could also provide an option to the segment of the public that is unwilling or unlikely to report to public PODs, for whatever reasons, to acquire their medications. Home MedKits could be an effective method for
offloading some segments of the population from public PODs, especially some of the population “tails,” or those that fall outside of the middle 80% of the population in terms of demographics. They would also provide a way to increase compliance among the at-risk populations or those who are simply unwilling to visit PODs.

This study recommends a gradual implementation of home MedKits, starting with first responders and their families. This is an especially crucial segment of the population to reach immediately during response. Providing MedKits to first responders will have two important effects. First, it will reduce the time in which first responders can act in the response phase. If the local jurisdiction does not keep caches of medications on hand, then first responders will have to wait for the SNS to arrive. This means that the responders cannot report to the affected area or effectively respond for several hours. If MedKits were immediately available, the response time would be cut drastically. Secondly, by providing MedKits for their families, first responders will be further incentivized to report to duty because they know their family will be cared for and protected.

The Federal Government should make MedKits available to state and local governments for purchase. These entities should be responsible for bearing the cost of providing MedKits to first responders based on their own perceived priorities either using federally-provided grant monies or other funding. State and local governments could also choose to let first responders purchase their own MedKits if the funding is not available for providing them.

From there, the government could work with private sector partners to develop commercial MedKits that could be available for purchase by individuals. These steps would help to offload a portion of the population from public PODs. Once these steps are implemented, the government can then discuss a program for providing MedKits to the population “tails.”

The Biomedical Advanced Research and Development Authority (BARDA) also made a similar recommendation for the implementation of home MedKits to the Federal Drug Administration (FDA) Anti-Infective Drugs Advisory Committee stating:

- “HHS response required for the December 30, 2009, Executive Order (EO) 13527, Establishing Federal Capability for the Timely Provision of Medical Countermeasures Following a Biological Attack. Pre-positioned medkits are just one mechanism for getting critical MCMs to people with the added benefit to potentially decrease the initial stress on PODs.
- Based on recent USPS Emergency Use Authorization (EUA) experience, it is expected that the household antibiotic kits will stay intact, will not be used inappropriately, and will be viable for use during an anthrax event.
- By employing appropriate labeling/packaging, the first responder community will be well informed on the proper storage and disposal of these kits.
- Valuable tools used for traditional drug approvals, such as Risk Evaluation and Mitigation Strategy (REMS) and product registries, already exist for drugs that have a greater potential for inappropriate use.
- We propose taking a measured approach with the initial indication so that medkits would only be available to the first responder community and their household members. First responders will be defined by appropriate professional responder organizations and not dictated by the USG. This proposed indication is a conservative approach that offers a level of vigilance to a population that is fully engaged in preparedness and response activities. The indicated population could be deliberately expanded as knowledge and experience is gained from this initial effort.
- Distribution of medkits would not be done as part of a federal program. A medkit would be a commercially available drug product via prescription and dispensed by a pharmacist.
- To date, a thorough search of the US literature does not provide data that suggest there would be rampant misuse of antibiotics in the medkit by self medication; a
A comprehensive study or studies that span multiple ethnic, educational, and socioeconomic groups is needed to fully understand self-medication practices in the general population. Without such studies, the negative assumption that people will misuse these products cannot be touted fairly."

There are several other advantages associated with the use of home MedKits. First, the time to dispensing would be very short; dispensing during the 48-hour window would not be an obstacle. Dispensing will not be affected by disruptive events, such as road closures, shelter-in-place orders, public transportation closures, etc. Also, families that choose to evacuate would have their supply of medications on hand. This is particularly important as there is no current plan to dispense medications to the segments of the population who flee the affected area.

MedKits also enable pre-screening of a population. Those possessing MedKits would be screened by a medical professional in order to receive the appropriate medications. This could help lessen overall adverse reactions. If MedKits are purchased by a large portion of the population, this could relieve some of the financial burden from the government as they would not be required to supply medications to that portion of the population.

The process of developing home MedKits could be advantageous as well. It would encourage partnerships between the government and private sector during the processes of MedKit formation, purchase and distribution to retail partners. This could serve as an important step in actively involving the private sector in response. Also, confidence and trust in the government may increase if home MedKits are available for purchase. Knowing that the government is taking proactive measures to make drugs available ahead of time could serve to not only increase trust, but also compliance with government instructions.

As with all mass antibiotic dispensing modes, there are potential disadvantages to the use of home MedKits. First, there is a potential for loss or misuse of the medications. Second, the expiration dates of the medications must be carefully managed. This is especially important with doxycycline as it can cause some toxicity when it expires. Third, there is also the possibility an adversary could confer the strain of anthrax used in the attack to be resistant to the antibiotic contained in the MedKit (or the SNS). Finally, funding a program to have the government supply MedKits would be very expensive. If the MedKits were only available commercially, there would be the perception of elitism, as they would only be available to those who could afford them.

Medical groups such as the Infectious Disease Society of America (IDSA) oppose home MedKit implementation. The IDSA has stated: “The incremental benefit of home stockpiling relative to workplace caches, postal distribution systems and other effective dispensing is unclear. The risks of placing a large amount of antibiotic in homes are clearly significant. However, we cannot quantify them with available data.” Additionally, “replacing outdated drug and safe disposal are critical issues that must be addressed. [For example], [f]lushing antibiotics into the sewer system is likely to further drive drug resistance.”

Going forward, Medical associations such as the American Medical Association and the American Pharmacists Association should be consulted for their perspective on home MedKit implementation.

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Despite these challenges, this analysis supports the recommendation to gradually implement home MedKits, starting with first responders on a state and local level. From a national security perspective, the benefits vastly outweigh the costs.

**Gaps addressed**

- **Gap 3, Overall**: No flexibility built in plan/contingency plans to account for population behavior.
- **Gap 7, Overall**: The local ability to decide to request SNS, set up dispensing infrastructure, and allocate resources to dispensing infrastructure may not be timely.
- **Gap 8, Overall**: Most individuals will be concerned not simply with receiving the requisite drugs within the recommended time, but with receiving them as soon as possible. System not capable of meeting expectations of public in crisis mode.
- **Gap 12, Overall**: There is no way to track or identify people with adverse reactions to medications.
- **Gap 33, Plan for MCM Dispensing**: Supply of ciprofloxacin and doxycycline in retail market is low since pharmacies and hospitals employ a just-in-time supply chain. Distributors will likely have a low supply due to the just-in-time model as well.
- **Gap 42, Prepare for MCM Dispensing**: Few or no caches of antibiotics at the state or local level mean that MCMs may not be immediately available to first responders when the event has been announced, preventing their ability to respond before SNS assets arrive.
- **Gap 48, Prepare for MCM Dispensing**: Public has not been involved in many exercises and there is a lack of public awareness on response processes.
- **Gap 72, Initial MCM Distribution**: There will be demand for antibiotics outside of the impacted state or locality from people who have travelled from the affected area that are symptomatic or from the worried well.
- **Gap 76, Initial MCM Distribution**: No standard defined process for providing MCMs to first responders.
- **Gap 82, Initial MCM Dispensing**: Security personnel accompanying postal volunteers are not provided with home MedKits for themselves or their families.
- **Gap 93, Initial MCM Dispensing**: Public may be reluctant to visit PODs for fear of contamination, contagion, and/or repeat attacks.

**Metrics affected**

Making Home MedKits available to segments of the population can directly affect outcomes including the number of sick and dead by bypassing distribution and dispensing during the high-intensity, initial response phase. Offering people the alternative to take control of their own preparation prior to an event may also increase compliance by mitigating perceived security, personal safety, transportation, family separation and government trust issues. First responders, volunteers, and other people with roles in response may be more comfortable performing their duties and helping others knowing their families are cared for, reducing distribution and dispensing failures. Offloading demand from the POD system will also reduce stress and allow for more flexibility with human and MCM resources. Home MedKits will greatly improve outcomes in situations where shelter-in-place conditions are declared, transportation systems are compromised, or PODs are compromised.

**Recommendation 8: Develop a Plan for Providing Completion Prophylaxis**

CRI provides funding for cities to develop a response plan for the first 48-hour response to a biological attack, which is crucial. However, state and local public health departments have not had the funding or bandwidth to plan beyond that initial time frame. As mentioned above, the recommended antibiotic regimen for inhalational anthrax exposure is 60 days from the date of last exposure. Initial response plans account for the dispensing of pills for the first 10 days. However, no confirmed plans for dispensing the remainder of the medications to the public were found. Having no method for dispensing the remaining dose will mean that the population cannot comply, leading to increase morbidity and mortality.
There is considerable speculation as to how dispensing this completion prophylaxis may occur, but a definitive plan for dispensing completion prophylaxis was not found. Many interviewees indicated that they assumed PODs would continue to dispense the remainder of the medications. However, there was no accounting for how they would staff these PODs continually, whether POD sites (e.g. schools) would remain closed for the duration of the dispensing campaign, how many times the public would report to PODs (e.g., To receive five more 10-day doses? One more 50-day dose?), or how the staff would track who in the population had already received which medications or in what amounts.

There are also many assumptions around the post-48 hour response period. First was the thought that the 48-hour response would be the hardest to accomplish and that everything after that would be much easier. Second, there is a belief that epidemiological research will provide enough information to down scope the population to those who are truly affected in the initial 10-day period. Third was that the affected population would return to their local POD to receive further doses of medication.

These are all dangerous assumptions for a problem of this magnitude. It is likely that the epidemiological investigation will, in fact, not be able to significantly down scope the population before the first dose of medication is completed (10 days). So, any plan for completion prophylaxis should account for dispensing to the entire affected population. Depending upon the population’s experience with the PODs during initial dispensing, they may or may not return for follow-on doses. If they did not evacuate the affected city and choose to continue the full dose, they may return to their POD, or they may choose to receive their medications from a health care provider or pharmacy. They also may choose not to take any further medications, especially if they are not symptomatic, which will result in delayed illness for those who have been exposed. The assumption that this follow-on phase will be much easier to accomplish may be the most dangerous. Without a plan in place, any number of interferences could prohibit the medications from getting to the population, decreasing compliance.

To echo the recommendations above, the Federal Government should develop a national completion prophylaxis plan; the lead federal agency should help the state and local governments implement the plan; a clear communications strategy should be developed around the plan to ensure consistent messaging; the private sector, rather than PODs, should be leveraged to dispense the remainder of the medications; and concurrent vaccine administration should occur. Outlining these factors before an event happens will prevent an ad hoc response, which will mostly likely not fulfill the goal of providing a full course of antibiotics to the population of an affected city.

**Gaps addressed**

- **Gap 41, Plan for MCM Dispensing:** No plan for distribution and dispensing for completion prophylaxis.
- **Gap 47, Prepare for MCM Dispensing:** No planned dispensing structure for completion prophylaxis at the federal, state, or local level.
- **Gap 63, Detect and Characterize Event:** Federal, state, and local governments anticipate that they will have epidemiological results within the initial 10-day response period so that they can narrow down population requiring MCMs.
- **Gap 100, Ongoing MCM Distribution:** There is a manpower and budget deficit for planning and implementing ongoing MCM distribution. Infrastructure for distribution and dispensing is insufficient.
- **Gap 101, Ongoing MCM Distribution:** Surge production unknown, particularly for MCMs for other biological/radiological threats.

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43 In the few anthrax cases that have appeared in this century, the timeframe for characterization has far exceeded 10 days. The mailbox where the anthrax letters were mailed from in Sept/Oct 2001 was identified in Aug 2002, several months after the incident (http://www.dailyprincetonian.com/2002/05/17/5202/), and the case took seven years to close. The anthrax case that appeared in Minnesota in Aug 2011 was assumed to be from natural causes, but the source has still not be identified many months later (http://www.startribune.com/lifestyle/wellness/128645438.html?page=1&c=y).
Gap 103, Ongoing MCM Distribution: After the initial SNS request, it is unclear whether the impacted area must request more MCMs or whether the CDC continues to push MCMs to the area.

Gap 105, Ongoing MCM Dispensing and Completion Prophylaxis: If PODs are used for ongoing dispensing, it is unclear who will staff them for the post-48 hour time period.

Gap 106, Ongoing MCM Dispensing and Completion Prophylaxis: No way of tracking who receives medicines and how much they receive, so it will be unclear which members of the public need more doses of each MCM.

Gap 107, Ongoing MCM Dispensing and Completion Prophylaxis: If hospitals are used for ongoing MCM dispensing, there is no plan to surge staff or planned space to conduct dispensing.

Gap 108, Ongoing MCM Dispensing and Completion Prophylaxis: Will be very difficult to ensure a follow-on dose is given to a mobile population.

Gap 109, Ongoing MCM Dispensing and Completion Prophylaxis: Will be difficult to inform or provide assurance to a population in an affected area that they do not need to participate in completion prophylaxis.

Gap 110, Ongoing MCM Dispensing and Completion Prophylaxis: No mechanism for ensuring that affected population will come back to pick up remaining dose for completion prophylaxis or that they will take their medications.

Gap 112, Ongoing MCM Dispensing and Completion Prophylaxis: Since PODs are government buildings like schools, ongoing dispensing from those sites would mean they cannot revert to their original role until after the response is complete.

Metrics affected
Positive outcomes are necessarily dependent on all potentially exposed people completing their prescribed course of antibiotics. Plans for getting people their antibiotics and encouraging them to continue use despite potential or real side effects is absolutely necessary.

Recommendation 9: Develop a Plan to Address Multi-Drug Resistant Strain Vulnerabilities

In a hearing requested by the Senate Committee on Homeland Security and Governmental Affairs in October 2007, it was noted that “Multi-drug resistant (MDR) anthrax is considered a real threat. MDR anthrax was one of 28 agents evaluated by DHS in its 2006 Bioterrorism Risk Assessment (BTRA) and was deemed a significant enough threat for the Secretary of Homeland Security to issue a Material Threat Determination, hence its inclusion in the Public Health Emergency Medical Countermeasures Enterprise Top-Priority Chemical, Biological, Radiological, and Nuclear (PHEMCE) list.” Despite this prioritization in 2007, five years later there is still no plan in any level of government to address a multi-drug resistant strain of anthrax. This means that if a strain of anthrax that is resistant to doxycycline and ciprofloxacin is released, we will be too late in changing strategies to counter the illness in those who are infected, and the mortality level will increase drastically.

In the same testimony mentioned above, Jay Cohen, the then Undersecretary for the Science and Technology Directorate at the Department of Homeland Security, outlined the steps the Federal Government was taking to counter the MDR anthrax threat. Those include “stocking the Strategic National Stockpile with more than one type of antibiotic for treating anthrax; developing and acquiring novel anthrax countermeasures to be used in such a situation; and developing a new laboratory technique for rapidly determining (in about 6 hours after acquiring a pure culture isolate) whether an anthrax sample is antibiotic resistant or not – thereby rapidly informing the response process.” These are all positive steps, and this study recommends that they continue to be pursued and implemented as soon as possible.

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Ibid.
The first two steps are very important, but they will not aid in shortening the timeline to respond to this threat. Having alternative countermeasures is essential, but they will not help if the government cannot get them to the infected population before symptoms begin appearing. It is most crucial to shorten the timeline for providing alternate countermeasures to the public to achieve meaningful results. This can be accomplished by deploying planned and alternative countermeasures simultaneously, by pre-positioning alternative countermeasures throughout the country, or by achieving the third step mentioned in the testimony, which is developing a technique for a rapid determination of antibiotic resistance. Having this type of capability could allow the SNS to deploy alternative countermeasures initially, which means that the affected populations would not have to return to the PODs to pick up new medications after the first round was found to be ineffectual.

Another option for countering MDR anthrax is vaccination. Vaccines are indifferent to whether the strain of anthrax is antibiotic resistant or not. Pre-event vaccination will essentially take the threat “off the table.” Using the vaccine as post-exposure prophylaxis requires concurrent administration with antibiotics, but may be able to buy time for deploying alternative antibiotics to those who are affected.

Regardless of which method is deemed best to address this threat, a path should be chosen and a plan should be put in place. Without a plan, the government has a strong chance of losing credibility. If after the release, the government assures the public that the antibiotics will save their lives and the antibiotics are not effective, why would the public trust the government going forward? It is likely that the public will not report to a POD a second time to receive another antibiotic that may or may not be effective. Ignoring the threat in the planning stage and relying on an ad hoc response will only result in an extraordinarily high number of lives lost.

Gaps addressed

- **Gap 21, Overall:** Impact of multi-drug resistant agents on response is not understood, particularly the need for flexibility and the potential for loss of public confidence.
- **Gap 36, Plan for MCM Dispensing:** No clear plan for alternate prophylaxis to address MDR strains.
- **Gap 60, Detect and Characterize Event:** Time required to determine the strain or characteristics of the bioagent may lag behind distribution of MCMs.
- **Gap 68, Detect and Characterize Event:** Lack of clear goals or guidelines for time to determine pathogen strain and required treatment.

Metrics affected

Multi-drug resistant strains will, absent an alternative plan, negatively impact death and sickness outcomes. Even with perfect logistics, dispensing, and compliance, death rates will be higher than anticipated. An alternative plan with the same outcome metrics but different target performance levels is required. This plan should include metrics for monitoring performance of countermeasures as well as setting revised targets for logistics, dispensing and compliance. The possibility of even greater flight from the affected area, lower levels of trust in government, and degradation in performance of volunteers should be addressed in revised metrics. A plan for MDR will improve outcomes but will probably not equal the outcomes of a standard scenario.

Additional Considerations

The objective for this analysis was to provide recommendations that are cost-effective, would be relatively easy to implement, and provide a high return on investment. The “Top 9” recommendations were the result. However, other recommendations emerged from this analysis that do not necessarily meet these criteria, but are still worth mentioning. The remainder of the recommendations are listed in Appendix III.

Many of the recommendations that did not make the Top 9 list are research and development activities that require a large, sustained investment and have technological and program risks that are hard to quantify. Also, there is no way to assign a timeline for the development of these
tools. However, they could greatly affect the outcome of the distribution and dispensing process if implemented and could aid in reducing morbidity and mortality.

The first category of recommendations revolves around the anthrax vaccine. This study has identified a need for an anthrax vaccine that is safer for at-risk groups, specifically children and the elderly, and more effective. Ideally, it would require only one dose as opposed to the several doses required currently. Also, this vaccine should be developed and licensed for use as both a preventative method and as post-event prophylaxis. Vaccine development is a large and expensive undertaking, but having an effective vaccine that could be administered to a large population (i.e., several MSAs) could take the anthrax threat “off the table.”

The second category is improved diagnostic tools. Currently, the only method for determining if a person is infected with anthrax is through blood culture, which takes 24-48 hours and is untenable for a large population. Real-time diagnostics could aid in separating those who are infected from those who are not before symptoms begin. This would allow public health officials to dispense prophylaxis only to those who are truly infected. This would mean that antibiotic inventories and other medical resources could be used more effectively, and some degree of panic and uncertainty could be mitigated.

Detection of biological agents is another area that needs research and development. The current methods for detection are either environmental detection (BioWatch) or case diagnosis, both of which would take several days for confirmation. This means that the clock on response will start several days after the event occurs, and response time to dispense prophylaxis is shortened. Development of an affordable, real-time detection system would enable quicker detection and would give responders more breathing room to enact the response. Also, the BioWatch system is configured to detect large-scale events, meaning small-scale attacks would fall under the detection threshold. This new detection system should be scalable so that it can detect an attack of any size.

A next generation treatment for symptomatic patients is also needed. Currently, treatment for those patients who develop symptoms from anthrax is very resource-intensive. It involves the patient being hooked up to a ventilator in an ICU with constant plural drainage and IV antibiotics. Even with all these measures applied, the treatment is only 55% effective. Also, hospitals have very few ventilators or ICU space, meaning that many symptomatic patients in a large-scale attack will not have the opportunity to receive treatment, ensuring mortality. The next generation treatment should require the use of fewer resources and should have a higher effectiveness rate.

The additional recommendations identified all fall into a category of more difficult to implement given the investments required and the timeline for development. Some work is already being done in many of these areas. However, their implementation could greatly improve the outcomes of the end-to-end distribution and dispensing process and could aid in decreasing overall morbidity and mortality in the event of an attack.

**Conclusion**

Waiting until an event occurs to address the problems identified in this study is not an acceptable solution. As protecting the public is the ultimate goal, providing them with pre-event education, clear communications during the event, and options for participating in the response will increase their cooperation and compliance, resulting in lower morbidity and mortality rates. Also, it is important to have plans in place to address several scenarios, not just the one-city, treatable-strain scenario. A thinking enemy will do all he can to thwart our responses, so preparedness is paramount at all levels, from senior government decision makers to the public.

The number of gaps identified in this analysis is overwhelming, and improving the outcomes of the end-to-end process seems daunting. However, implementing the nine priority recommendations would be a great step forward in improving the outcomes, including population compliance. While these do not offer the perfect solution, they can aid in creating a
structure that is more flexible and reliable and a national system that is scalable. The implementation starts with a shift in thinking – by acknowledging that this is a national security threat that will affect the entire country and deserves to be treated as an act of war. By taking these steps, the U.S. can be much better prepared to respond to a biological threat, and much of the terror and damage that would be cause by an attack of this type can be mitigated.
Appendix I: Approach and Framework

This appendix describes this study’s approach to the project and the framework around which the data was analyzed. The approach was focused on minimizing morbidity, which ultimately minimizes mortality and leads to recovery, as seen in Figure 5.

Figure 5. Components of Recovering from a Biological Attack

The process for the project is laid out in Figure 6.

Figure 6. Project Process

This study involved reviewing over 200 documents and conducting over 35 interviews in order to assemble an end-to-end process map of the medical countermeasure distribution and dispensing process for anthrax response and recovery. The high-level overview of the process model can be found in Figure 7.
The end to end process was divided into phases, as indicated above. Although the planning and preparing for MCM dispensing phases were technically out of scope, it was determined that these phases were important in ultimately affecting the downstream process. Then, a deep dive into the processes of each phase was conducted. Owners and resources were assigned to each step of the process.

1. **Plan for MCM Dispensing:** This phase includes the development of plans that will be carried out during a response to a biological attack.

2. **Prepare for MCM Dispensing:** Preparing includes the allocation of resources and placement of materiel so that a response can be carried out according to plan.

3. **Detect and Characterize Event:** There are several methods of detection available, and the process was mapped out for each method. Those methods were defined as environmental detection (e.g., BioWatch), case detection, and intelligence and activity detection (i.e., either an intelligence tip or a direct observation of illicit activity). This study focused on “large” events detectable by environmental surveillance as opposed to a small attack that BioWatch may or may not be able to detect.

   This step is the decision point for triggering the response process. Detecting an event sets everything else in motion. Once an event is detected, it requires characterization. Characterization involves defining the agent, strain, affected area, and delivery mechanism.

4. **Initial MCM Distribution:** After detection, the affected state must request medications from the Federal Government. This phase involves the Federal Government activating the Strategic National Stockpile and moving the materiel to affected state. From there, the state is responsible for receiving the medications and parcelling out the appropriate amounts to the affected jurisdiction. The local public health department must then ensure the medications are received by the PODs.

5. **Initial MCM Dispensing:** This phase involves dispensing medications to the public either through public PODs, closed PODs, or the National Postal Model. There are other methods of dispensing used by individual jurisdictions, but as the three aforementioned models are the most common nationwide, these are the models that were mapped.

6. **Ongoing MCM Distribution:** Ongoing distribution is defined as the continual movement of the material to the affected locations beyond the initial response. The initial distribution phase moves enough materiel for the entire population to receive 10 days worth of medication. The ongoing phase delivers the remainder of the 60-day dose from the Federal Government to the affected jurisdiction(s). As there are no documented plans, it was a struggle to build a process map within this phase.

7. **Ongoing MCM Dispensing and Prophylactic Treatment:** This phase involves dispensing completion prophylaxis to the target population and ensuring that the affected population completes the entire therapeutic course. As with ongoing distribution, any evidence stating how this would be carried out was not found. Many assumptions were made based on interviews speculating as to how this would be completed.

8. **Recovery:** Recovery is defined as a return to “new normal” state, including re-occupying the affected area and assuming activities that were present prior to the attack. The impossibility of returning to the exact pre-attack state has been acknowledged, and this study advocates for a return to as many normal activities as possible instead.
Six factors that would ultimately affect the performance of the overall process were also defined, as seen in Figure 8. The definition of each factor is delineated below.

**Figure 8. The Six Performance Factors of the Response and Recovery Process**

- **Affected Public**: The public which is affected by the attack
- **Responders**: Any person, government or volunteer, who is involved with distribution, dispensing, remediation, or other response services
- **Materiel**: MCMs or other medical supplies
- **Places**: Distribution centers, service delivery points, PODs, etc.
- **Communications**: Coordinated messaging whether intragovernmental, to responders, or to the public
- **Decisions**: Policy, command and control, decision-making processes, or jurisdictional issues

**Figure 9. Processes Were Captured and Analyzed Using Interactive Tools**
This process map and the factors were used to identify gaps in the process. Over 115 gaps were identified and this study found that most fell into themes, which are described in the body of report. Recommendations were generated that would best address the gaps most likely to affect the outcome of the process.

The viability (cost and difficulty to implement) and impact (value and scope of effect) of each recommendation was assessed, and the recommendations were prioritized. Greatest weight was given to recommendations that most influenced outcome measures across a national scale with relatively low cost and manageable implementation challenges. Recommendations that were extremely costly, required significant effort at several levels of government, or impacted only small numbers of people were generally weighted less in the prioritization. Nine primary recommendations were selected.

Figure 10. Recommendations Were Evaluated Against Both Value and Cost/Difficulty

Comprehensive metrics for end-to-end distribution, dispensing, and use of medical countermeasures were developed as the process model was captured. Several types of measures, each with different potential utility, were identified:

- **Outcome Measures** are the most critical indicators of success and map directly back to the response objectives related to recovery: reducing casualties, controlling flight, and enabling rehabilitation.
- **Compliance Measures** indicate the level of success in getting the public to fully complete a treatment regimen. Failure of compliance directly leads to degraded outcomes.
- **Dispensing Measures** indicate the volume of medical countermeasures successfully transferred to the public within specified time windows, typically within 96 hours of an event. Dispensing failures or delays can have a negative impact on compliance and, in turn, outcomes.
- **Logistics Measures** are indicators of performance or partial failure of the distribution and dispensing process. These measures are monitored by several levels of incident and dispensing management to make adjustments to ensure the highest rates of dispensing and compliance.
- **Characterization Measures** are indicators of external conditions or limiting factors affecting the distribution, dispensing, and use of medical countermeasures. These measures may affect strategic and tactical decision making or change the potential value of Dispensing and Compliance Measures. For example, better understanding of who has actually been exposed to a threat would adjust expectations of dispensing and...
Biological Attack Response and Recovery: End-to-End Medical Countermeasure Distribution and Dispensing Processes

compliance. A determination that a particular strain is resistant to antibiotics will also change the approach to dispensing and supporting compliance.

Figure 11. Recommendations Were Evaluated Against Both Value and Cost/Difficulty

Once the potential impact of a recommendation on Outcome Measures is identified, the potential to implement the recommendation across the entire nation was assessed. The total population or portion of targeted segments affected by a single implementation of the recommendation was used as a multiplier on the recommendation effect. Additional credit was given if the recommendation was easily scalable and deployable at a national or regional level. Estimation of the cost of each recommendation was limited to rough order of magnitude assumptions.

Figure 12. Recommendations Were Scored Using a Model Weighted Towards Outcomes

<table>
<thead>
<tr>
<th>Type of Measure</th>
<th>Metric</th>
<th>Weight</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Outcome</td>
<td># of People Who Die</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td></td>
<td># of People Who Get Sick</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td></td>
<td># of People Who Flee</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td></td>
<td>% of People Who Come Home</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Compliance</td>
<td>% of People Who Finish Prophylaxis</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td></td>
<td>% of People Who Start Prophylaxis &lt; 96 Hr</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td></td>
<td>% of People Who Seek Prophylactic MCM</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Distribution / Dispensing</td>
<td>% Dispensed &lt; 96 Hr</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td></td>
<td>% Dispensed To People Requiring 60 Day Course</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Characterization</td>
<td>Time to Detect Release</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Time to Diagnose Anthrax</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Impact on MDR Response Capability</td>
<td>1</td>
<td></td>
</tr>
</tbody>
</table>

* Key to Scores: 0 - no effect on metrics, 1 - some effect, 2 - moderate effect, 3 - strong effect, 4 - very strong effect
After an initial scoring of recommendations, the outcome was plotted to identify the best valued, most feasible recommendations. This exercise is not exact, as the scoring model can be biased and some strategic priorities undervalued. For example, the recommendation to promote the National Postal Model or another push dispensing model was recommended as a solution suitable for shelter-in-place scenarios even though it was outscored by less expensive recommendations.

The “Top 9” recommendations were validated with the project sponsor. All additional recommendations were retained in the Appendix III.

Figure 13. Selection of “Top 9” Recommendations Was Based on Analysis and Strategic Needs
### Appendix II: Complete List of Process Gaps

<table>
<thead>
<tr>
<th>Gap ID</th>
<th>Element</th>
<th>Gap</th>
<th>Effect</th>
<th>Reference</th>
</tr>
</thead>
</table>
| 1      | Overall | Heavy reliance on public health departments for preparedness and response. These departments are experiencing huge amounts of turnover; attrition rates lead to understaffing at public health centers and lack of institutional knowledge. Preparedness is not a priority within most state and local health departments. | May result in an uncoordinated, ad hoc response in the event of an emergency – severely limiting the ability to provide timely MCMs. Lack of knowledge transfer amongst staff at public health departments. Low staff levels may lead to inability to mount an effective response. | “The impact of budget cuts has been huge on local health departments, especially in the areas of planning and response. They will probably not have an adequate workforce to carry out response in most cities because of these cuts.” - Subject Matter Expert Interview  
“Public Health Awareness Cooperative Agreement Funding is eroding. This will make it difficult to address preparedness gaps at any level.” - Subject Matter Expert Interview  
“Around 2008, CRI changed the funding algorithm for their grants. These resulted in big cuts that severely impacted budgets.” - Subject Matter Expert Interview  
“There is already a major shortage of trained public health workers and funded positions. There are not enough workers, particularly experts, to effectively respond during public health emergencies. The United States has 50,000 fewer public health workers than it did 20 years ago and one-third of public health workers will be eligible to retire within five years. As baby boomers begin to retire, there is not a new generation of workers being trained to fill the void. Also, under current policies and, in some cases, public health workers in one area are not allowed to be shifted to help in other areas, even during emergencies. The recent budget cuts are intensifying the problem, with a reduction of 15 percent of the local public health workforce since 2008 and, at the same time, health departments around the country are experiencing furloughs or shortened work weeks.” Trust for America’s Health. “Ready or Not? Protecting the Public’s Health from Diseases, Disasters, and Bioterrorism 2011.” Dec 2011: 28. Web. http://www.rwjf.org/files/research/73723.readyornot.12.20.11.pdf. Accessed 01 Mar 2012.  
“Recent declines in both federal preparedness funding and state and local financial resources are directly threatening these gains. Federal funding for state and local public health preparedness programs has declined by 27% since 2005 with a cut of more than $100M since FY2010 alone. That loss, combined with state budget cuts due to the economic downturn, has made it difficult for health departments to maintain newly developed information systems and analytical staff. Significant personnel losses – including trained epidemiologists – have resulted in reduced capacity, including emergency preparedness capacity, in 40% of public health departments nationwide. There are 44,000 fewer persons working in state and local health departments than there were 2 years ago.” Committee on Homeland Security and Governmental Affairs. “Ten Years After 9/11 and the Anthrax Attacks: Protecting Against Biological Threats.” Testimony of Tom Inglesby. Hearing Before the United States Senate. One Hundred Twelfth Congress, First Session, 18 Oct. 2011. Web. https://www.hsdl.org/?view&did=690886. Accessed 04 Jan 2012. |
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<td>2</td>
<td>Overall</td>
<td>Regional response plans are developed on an ad hoc basis depending upon the initiative of the state and local health departments (e.g. VA, MD and DC or NY, NYC, NJ and CT).</td>
<td>Ineffective communication of state and local plans to the public may result in confusion and can erode public confidence in response capabilities; regional coordination is personality-dependent within the public health community.</td>
<td>&quot;As called for by the guidance for the cooperative agreements, all of the states we visited organized their planning on a regional basis, assigning local areas to particular regions for planning purposes. However, the state-defined regions encompassed areas within the state only. A concern for response organization officials was the lack of planning for regional coordination between states and with a neighboring country of the public health response to a bioterrorist attack.&quot; U.S. Government Accountability Office. “Bioterrorism: Preparedness Varied across State and Local Jurisdictions.” Washington, DC: Apr 2003. GAO-03-373. Web. <a href="http://www.gao.gov/new.items/d03373.pdf">http://www.gao.gov/new.items/d03373.pdf</a>. Accessed 27 Jan 2012.</td>
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<td>3</td>
<td>Overall</td>
<td>No flexibility built in plans/contingency plans to account for population behavior.</td>
<td>Population behavior may bottleneck the process at any point.</td>
<td>Most planners assume that the public will follow directions and comply with the government-recommended instructions. There are no options given to the public for alternate courses for obtaining MCMs. Planners need to build in contingency plans and give the public several options during response so that they are more likely to comply. &quot;The predominant planning paradigm therefore considers layperson response as one of a number of post-attack problems, not as a resource. Laypeople are seen, at best, as subjects for control, at worst, obstacles that reduce survival rates and impede recovery operations through ill-informed or self-interested behavior. If people would do what they were told, go where they were sent, and follow directions, the jobs of professionals would be far easier.&quot; Danzig, Richard, Rachel Kleinfeld, and Philippe C. Bleek. “After an Attack: Preparing Citizens for Bioterrorism.” Washington, DC: Center for a New American Security, 2007: 10. Print.</td>
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<td>4</td>
<td>Overall</td>
<td>“Home rule” creates a complicated structure that inhibits a coordinated national response.</td>
<td>Different requirements and points of authority for autonomous entities, whether at the state, local, or county level, results in hurdles for private sector involvement; authority and decision making is not standardized nationwide.</td>
<td>&quot;In [one state] alone, [a retailer] had to submit 150 different reports for H1N1. They are in favor of a nationally standardized reporting system.&quot; - Subject Matter Expert Interview &quot;Whatever process is designed should be consistent across states. The concept of ‘home rule’ makes this exceedingly difficult, since even counties and underlying municipalities often have divergent processes for emergency response.&quot; - Subject Matter Expert Interview</td>
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<td>5</td>
<td>Overall</td>
<td>Metrics exist to measure preparedness, but may not be appropriate to measure system effectiveness once it is stressed. No one has run an end-to-end, unscripted drill. Preparedness does not equate to response capabilities.</td>
<td>Systems (e.g. PODs) may not be able to perform in the event that they are stressed. In a worst-case scenario, the system may become paralyzed and ineffective.</td>
<td>“The current evaluation and rating system is inadequate to determine readiness of localities to complete distribution within two days. The assessment tool that CDC utilizes to determine state and local SNS distribution readiness only assesses planning and management of the stockpile. There is no comprehensive system at the federal level to determine the capacity of state and local jurisdictions to actually deliver SNS countermeasures to affected populations in a specific period of time.” Albright, Penrose, et al. “Net Assessment of the U.S. Biodefense Policy &amp; Programs.” Civitas Group, 2008: 61. Print. *Cited with permission from P. Albright</td>
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<td>6</td>
<td>Overall</td>
<td>Inventory visibility and tracking is difficult for the government, especially between different levels of government.</td>
<td>May result in unfair and unequal distribution of MCMs to general public, as some people may receive more than a full dose of MCMs, while others may receive none at all or not enough. Also may result in unequal distribution of SNS assets to states.</td>
<td>A state or locality may be able to track medications once they receive them from the SNS. However, once they reach the POD level, there is no mechanism for tracking who gets what batch of medications in what quantities. And without asking for identification or collecting some kind of identifying information, tracking becomes impossible at the POD level. &quot;There is very little control of the inventory once the CDC transfers the materiel to the states. The resources can’t be redistributed once they are pushed out.‖ - Subject Matter Expert Interview</td>
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"The CDC has no idea who is getting what in distribution and dispensing and in what amounts. In other words, they do not have an effective inventory management system. It will be very important on the day of the event to know how much medication you have and how much is left. We need to have a clearer picture of what's occurring on the ground.” - Subject Matter Expert Interview

One city "will be tracking the number of medications given out, not the people who receive them. They will not be looking at resident status. They will not be checking identification or anything; the people will be required to fill out a basic form. The form goes back with the client with the medications.” – Subject Matter Expert Interview

"Measurement tools have focused on assessing the existence of personnel, plans, and equipment, not on whether the health system can put these resources into practice in emergency conditions.”


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### Gap ID | Element | Gap | Effect | Reference
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7 | Overall | The local ability to decide to request SNS, set up dispensing infrastructure, and allocate resources to dispensing infrastructure may not be timely. | Lack of sufficient local resources and/or clear guidelines for decision making may significantly delay or stop the process, resulting in increased morbidity/mortality. | "Key potential gaps in distribution capabilities include: · The ability of local authorities to make timely decisions and SNS requests; · The timely ability to set up state and local distribution infrastructure; · The timely ability to allocate SNS inventory to that infrastructure; and · The ability to adequately staff PODs to support a 48 hour distribution requirement." Albright, Penrose, et al. “Net Assessment of the U.S. Biodefense Policy & Programs.” Civitas Group, 2008: 67. Print. *Cited with permission from P. Albright
8 | Overall | Most individuals will be concerned not simply with receiving the requisite drugs within the recommended time, but with receiving them as soon as possible. System not capable of meeting expectations of public in crisis mode. | Erodes public confidence in ability of federal, local or state governments to distribute and dispense MCMs. Public may resort to alternate means to obtain MCMs, and may even resort to rioting or violence to obtain them. | A "gap has been in establishing an evidence base on the timeline that MCMs need to be dispensed (48 hours? 72? 96?). In many cases, the public health infrastructure may not be able to carry out the dispensing in that timeline." - Subject Matter Expert Interview

"A 12-hour timeframe [to distribute SNS assets] sounds great on paper, but when human behavior is added in, the timeframe becomes unrealistic. People will be questioning the government and losing trust when it takes so long to get antibiotics to the city. The media will get a hold of the information once the decision to deploy the SNS is made, and that will start the clock on public awareness." - Subject Matter Expert Interview

"What about the time between when an attack is detected and when a POD is up and running? Panic could easily ensue if pills are not immediately available. Could we stockpile antibiotics in the pipeline of pharmacies so that people could begin getting prophylaxis immediately?" - Subject Matter Expert Interview
### Biological Attack Response and Recovery: End-to-End Medical Countermeasure Distribution and Dispensing Processes

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<td>9</td>
<td>Overall</td>
<td>Rate at which technology is reducing hurdle to creating and deploying biological weapons is not adequately appreciated or reflected in planning.</td>
<td>Creates three planning factors absent today: 1) increased likelihood of a single actor or small event with little chance of detection through intelligence, 2) increased cost efficiency of bioweapons versus other WMD increases likelihood of large event, and 3) increased ability to engineer MDR or difficult-to-identify strains.</td>
<td>&quot;They [Central Intelligence Agency - Directorate of Intelligence, 2003] also noted that ‘the biotechnology underlying the development of advanced biological agents is likely to advance very rapidly, causing a diverse and elusive threat spectrum. The resulting diversity of new BW agents could enable such a broad range of attack scenarios that it would be virtually impossible to anticipate and defend against,’ they say.” Albright, Penrose, et al. “Net Assessment of the U.S. Biodefense Policy &amp; Programs.” Civitas Group, 2008: 11-12. Print. *Cited with permission from P. Albright&quot;</td>
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<td>10</td>
<td>Overall</td>
<td>There is a tendency to double- or triple-count available resources when constructing response plans.</td>
<td>Actual resources to respond in event of an emergency may be less than originally planned, impacting ability to distribute and dispense MCMs in a timely manner or at all.</td>
<td>&quot;Police are often triple-counted: they are not only policemen but also off-duty security guards (including for hospitals) and members of the National Guard.&quot; Danzig, Richard. “A Policymaker’s Guide to Bioterrorism and What to Do about It.” Washington, DC: Center for Technology and National Security Policy, National Defense University, 2009:27. Print. &quot;There is usually an over count in number of volunteers because those who do volunteer tend to sign up for multiple things.&quot; -Subject Matter Expert Interview</td>
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<td>11</td>
<td>Overall</td>
<td>It is unclear if/when vaccinations will be used, if at all.</td>
<td>Any response including vaccinations will be ad hoc, and many decisions surrounding their use will have to be made on the fly.</td>
<td>Most interviewees stated when they “assumed” vaccinations would be used, but there is no current policy to support their use in response to an anthrax attack. &quot;[The CDC plans] to follow the antibiotic response within 10 days with a follow-on vaccination campaign... They could not give the vaccinations in day 1, but they could probably get the materiel there and give the vaccinations by day 7. This could give responders breathing room to line people up to receive vaccines after the first antibiotic wave is over.&quot; - Subject Matter Expert Interview</td>
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<td>12</td>
<td>Overall</td>
<td>There is no way to track or identify people with adverse reactions to medications.</td>
<td>Public may swamp hospitals; morbidity or mortality could result from adverse reactions; trust of the government may wane.</td>
<td>Tracking of medications at the POD level is difficult to impossible. The screening form to determine which medication is given to each person is designed to move people through the POD process quickly, and will most likely not be administered by a health professional. Therefore, a percentage of people are likely to develop adverse reactions, and there is no process for tracking those people and correcting their medication.</td>
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<td>13</td>
<td>Overall</td>
<td>Hard or impossible to deploy/redeploy stockpile medications across state lines once states take possession of SNS materiel.</td>
<td>Once medications are distributed to a state from the stockpile, they are the property of that state and cannot be transferred to another state.</td>
<td>Since states own the inventory after they receive it, they would be unlikely to relinquish their supply to other affected jurisdictions. “There is little control of inventory once the CDC transfers the materiel to the states. Resources cannot be redistributed to other states once they are pushed out.” - Subject Matter Expert Interview</td>
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<td>14</td>
<td>Overall</td>
<td>No clear policy on evacuation vs. shelter in place during an event.</td>
<td>Decision will be made after the event occurs, and any delay or change in this decision will erode public confidence and greatly affect response.</td>
<td>The team heard anecdotes in interviews that this issue consumes a large amount of time at tabletop exercises. Leaders have not been able to build a consensus on this issue. Therefore, it is likely that the decision will be made after an event occurs.</td>
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<td>15</td>
<td>Overall</td>
<td>Communications to the public are not pre-scripted by some federal, state or local entities.</td>
<td>Ineffective or inefficient messaging to the public may result in chaos; will result in governments scripting communications on the fly while they are trying to respond to the event.</td>
<td>Everyone acknowledges that communications at the time of the event will be difficult. However, only one jurisdiction the team spoke with had pre-scripted communications and a playbook. “The Anthrax Management Team at CDC is working on developing questions and answers for anthrax, and they are updating much of the information based on new guidance. They are consolidating public health information on anthrax onto one CDC webpage. They recognize that they have to have the material ready to go at the time of the event. States and locals are free to use the information if they want, but it is not required.” - Subject Matter Expert Interview &quot;The government needs to take a proactive role in telling people what they should do - plan messaging ahead of time and don’t be reactionary.” - Subject Matter Expert Interview</td>
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<td>16</td>
<td>Overall</td>
<td>No clear answer to who’s in charge at the federal, state, or local level, or between levels.</td>
<td>Lack of clear chain of command; lack of clear authority; confusion in coordination.</td>
<td>&quot;There is an issue relating to ownership: the ‘who’s in charge’ question. This flows into all levels of government (local, state, and federal). This issue would be magnified by the magnitude of the incident we’re talking about.” - Subject Matter Expert Interview &quot;We can’t pretend that locals are in charge of in the case of multiple attacks. Who will they lean on? The locals-in-charge model is unrealistic.&quot; - Subject Matter Expert Interview &quot;The number one gap in the process is the perceived disconnect between the federal agencies where DHS, HHS, CDC, ASPR come to play. Locals have trouble understanding and differentiating between federal agency roles, responsibilities, and authorities. Who really is the lead? Who is in charge during what scenario, and what do they bring to the table?” - Subject Matter Expert Interview &quot;Few fully understand when, and how, a transition from an event of local significance to one constituting an event of national significance occurs. No concerted effort has been made to understand where the threshold for dividing Federal responsibility from State/local/private responsibility lies, nor when transitions of responsibility within the Federal government should occur.” Rosenzweig, Paul. &quot;Challenges to Leadership: Responding to Biological Threats.&quot; Center for Technology and National Security Policy, National Defense University. (2011): 1 Web. <a href="http://www.ndu.edu/CTNSP/docUploaded/DTP%2086%20Challenges%20to%20Leadership.pdf">http://www.ndu.edu/CTNSP/docUploaded/DTP%2086%20Challenges%20to%20Leadership.pdf</a>. Accessed 14 Feb 2012. &quot;A multitude of federal agencies - DHS, EPA, HHS, CDC, USDA, and the FBI, among others - all have some responsibility for bioterrorism. It concerns me that so many different federal entities could be scrambling to respond during and after an attack. And, of course, state and local health officials and first responders are part of the system as well. Yet, the Executive Branch does not have one agency or official that is the designated leader on all elements of biodefense....We need a leader who can direct the response and eliminate overlap or redundancy. This official should have the ability to coordinate across federal agencies and harness the assets and expertise of state and local governments, first responders, and the private sector.” Committee on Homeland Security and Governmental Affairs. “Ten Years After 9/11 and the Anthrax Attacks: Protecting Against Biological Threats. Testimony of Senator Susan Collins. Hearing Before the United States Senate. One Hundred Twelfth Congress, First Session, 18 Oct. 2011. Web. <a href="https://www.hsdl.org/?view&amp;did=690886">https://www.hsdl.org/?view&amp;did=690886</a>. Accessed 04 Jan 2012.</td>
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17 | Overall | Funding for preparedness is being cut at all levels and in all agencies. | Difficult to address problems or develop plans without the resources available to do so. | "Historically, funding for emergencies is often substandard until there is an actual emergency, and then there is a call for emergency supplemental support. This dynamic means the country is often unprepared to immediately respond during crises. The current economic difficulties have led to major cuts in federal, state and local support for public health and preparedness, leaving Americans more vulnerable during emergencies. The economic impact of a disaster can also be more significant if the community cannot return to normal after an event. Adequate preparedness allows for a strong and more timely recovery.

- State cuts: 40 states and Washington, D.C. cut funding for public health from fiscal year (FY) 2009-2010 to 2010-2011, 30 of these states cut funding for a second year in a row. According to the Center on Budget and Policy Priorities (CBPP), states have experienced overall budgetary shortfalls of $425 billion since FY 2009.
- Local cuts: Since 2008, 34,400 local public health jobs have been lost, and in the past year, close to half of all local public health departments reported reducing or cutting at least one program altogether.
- Federal cuts: Between FY2005 and 2011, federal support for state and local public health preparedness, including the PHEP cooperative agreements was also cut by 38 percent. Since FY 2010, the grant program will have sustained a $72 million cut.


18 | Overall | No current plans to incorporate DOD into response. | Trained resources will go to waste during a national crisis; DOD will have undefined roles resulting in ad hoc responses, if any at all. | "...the military lacks any command structure or other strong coordination structure for biological events. While various commands have frequently conducted exercises in an effort to develop practical responses to potential biological events, those exercises are often necessarily regional in character – given that most combatant commands are regionally-based. To date, there exists no single center of excellence within DOD’s operational commands to which the military can readily turn for a comprehensive national approach (if one is ever needed)."


"Several jurisdictions have looked at incorporating the National Guard into their response, but they found that it would take up to 48 hours for the National Guard to respond, which is too long a timeframe." - Subject Matter Expert Interview

"Discussions are taking place at the highest level of government on whether DOD assets can be mobilized for logistics, transportation, or security during an emergency public health event." - Subject Matter Expert Interview
### Biological Attack Response and Recovery: End-to-End Medical Countermeasure Distribution and Dispensing Processes

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<td>19</td>
<td>Overall</td>
<td>Public health-oriented thinking is neither sufficient nor appropriate when facing a resourceful adversary.</td>
<td>A scientific approach relying on data collection does not reflect the urgency of the situation. Reliance on local response capabilities during a deliberate attack on the nation will not be sufficient.</td>
<td>Because bioterrorism affects health, it was originally classified as a public health issue. However, the public health system is a disjointed system designed to deal with health issues at a local level. A biological attack would quickly become a national problem, because it would be an attack on the nation that would affect more than one locale due to population movement. Also, public health officials are accustomed to responding to events in longer timeframes (weeks to months), whereas a biological attack will require immediate response. This is not an event where data collection and a slow, thoughtful approach will be appropriate. Leaders will be forced to make decisions with little to no information.</td>
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<td>20</td>
<td>Overall</td>
<td>High-consequence decision making with limited information is necessary but many organizations and officials are not prepared, trained, or capable of making timely life-or-death decisions.</td>
<td>The process may be stalled or crippled by the inability of decision makers to make high-consequence decisions within the time required to save lives.</td>
<td>The U.S. does not educate leaders in high-level response roles to make these kinds of decisions. Unless they have a military background, they likely have not been exposed to this kind of decision making. Tabletop exercises are not run in real time, which would show the consequences of delayed decision making. &quot;We need leaders who are willing to make hard decisions. The best laid plans are going to be futile without this. We need to understand the importance of the crisis decision-making dynamics. How many current leaders have had to make life-and-death decisions in compressed timeframes? This is the crux of the problem in addressing this kind of event.&quot; - Subject Matter Expert Interview</td>
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<td>21</td>
<td>Overall</td>
<td>Impact of multi-drug resistant agents on response is not understood, particularly the need for flexibility and the potential for loss of public confidence.</td>
<td>Using current response plans for combating MDR agents will result in high levels of morbidity and mortality. By the time plans can be altered, the time frame for combating the attack will have expired.</td>
<td>Although a Material Threat Determination for MDR anthrax was issued in 2006 (Committee on Homeland Security and Governmental Affairs. “Six Years After Anthrax: Are we Better Prepared to Respond to Bioterrorism?” Hearing Before the United States Senate. 110th Cong. (2007) Print.), no concrete actions have been taken to further study the issue or combat it. There are no current plans to respond to MDR anthrax.</td>
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<td>22</td>
<td>Overall</td>
<td>Federal resources including incident management, technical, security, logistics, medical, laboratory, environmental, forensic, public assistance, and communications personnel and equipment may all be</td>
<td>Current plans require state and local jurisdictions to ask for assistance in order for federal agencies to supply resources. States and locals may become quickly overwhelmed, and by the time they ask for assistance, public confidence may be lost and</td>
<td>It is likely that local resources will be overwhelmed in a large-scale attack, and locals will look to supplement their capabilities with state and federal resources. Many interviewees indicated that they would expect federal help early on in the response process, especially as state and local public health budgets continue to shrink. If an attack happens in several locations, it is likely that federal resources will be required in all affected locations.</td>
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<td>23</td>
<td>Overall</td>
<td>Targets for reduction in morbidity and mortality due to an attack are not defined. Can the targets be translated into operational targets: “time to dispense drugs to XX% of population”?</td>
<td>100% dispensing is not realistic. Setting unrealistic targets immediately sets decision makers and responders up for failure. Setting realistic targets would enable more effective planning.</td>
<td>“This [reduce mortality and chronic morbidity by 90% for attacks that would otherwise result in at least &gt;3000 casualties] is a critical requirement; to our knowledge the level of acceptable casualties has never been defined, nor the lower bound for scoping the federal response. This requirement is based on a judgment of what is possible, and clearly doing better than this is highly desirable.” Albright, Penrose, et al. “Net Assessment of the U.S. Biodefense Policy &amp; Programs.” Civitas Group, 2008: 13. Print. *Cited with permission from P. Albright</td>
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<td>24</td>
<td>Overall</td>
<td>Incubation period not well understood for anthrax.</td>
<td>The U.S. operates under a 3-5 day assumption, when studies have shown it may be as little as 1 day and as many as 41 days, and may be dose dependent. If the goal is to dispense MCMs to the target population within the incubation period, then this needs further study.</td>
<td>“Because the incubation period range for inhalation anthrax is not well defined, cases may begin to present to EDs as soon as 1-3 days post-release. The widely ranging (1-41 days based on multiple research statistics) incubation period is due to a variety of host factors as well as dose and characteristics of the infecting strain. Higher doses (such as to those people who were immediately outside the convention center during the attack), based on animal data, are likely to result in shorter incubation periods. Determining when the period of risk is over will also be problematic and will entail a considerable environmental evaluation effort.” U.S. Department of Health and Human Services. “Overview of Anthrax Attack Scenario.” Aerosolized Anthrax Response Playbook Website. <a href="http://www.phe.gov/Preparedness/planning/playbooks/anthrax/Pages/scenario.aspx">http://www.phe.gov/Preparedness/planning/playbooks/anthrax/Pages/scenario.aspx</a>. Accessed 20 Feb 2012.</td>
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<td>25</td>
<td>Overall</td>
<td>This process has never been exercised end-to-end, resulting in &quot;best guesses&quot; of the time it will take. It is likely to take much longer than predicted.</td>
<td>Meeting 90% casualty reduction requires 100% prophylaxis in approx four days for anthrax; each additional 24 hours can result in 8% more casualties.</td>
<td>This study assumes that the first 48 hours of an anthrax response dispensing campaign would constitute the 'ramp-up' time to full dispensing capacity, with the actual mass prophylaxis campaign taking over 11 days. Zarić, G., et al. &quot;Modeling the Logistics of Response to Anthrax Bioterrorism.&quot; Medical Decision Making 28.3 (2008): 332-50. Print.</td>
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<td>26</td>
<td>Overall</td>
<td>Experience with powdered anthrax spores in limited indoor settings does not compare to wide-area, covert aerosol attack.</td>
<td>Assumptions based on indoor attacks will not work in an outdoor scenario, and responders will be unprepared and unable to characterize or recover from the attack.</td>
<td>To date, the U.S. only has experience with decontaminating an indoor environment during the Amerithrax attacks. Although decontamination of a wide outdoor area has been discussed in the Federal Government, there is still a lack of understanding and capability related to this type of decontamination. “For large outdoor areas, however, decontamination of biological agents cannot even be achieved at all with current capabilities. Therefore, DHS has also asked Livermore to develop protocols for cleaning a large outdoor area contaminated by a biological agent.”</td>
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| 27    | Plan for MCM Dispensing          | POD logistics and security have not been stress tested at the local level. | PODs may be unmanageable in the event of an actual attack, rendering them ineffective in dispensing MCMs. Locals may have a lack of understanding of what logistics measures or the level of security that will be needed to effectively run a POD. | Albright, Penrose, et al. “Net Assessment of the U.S. Biodefense Policy & Programs.” Civitas Group, 2008: 79. Print. *Cited with permission from P. Albright  
"EPA should develop...a strategy for developing procedures and standards for wide-area (as defined by the postulated attack size) decontamination against the spectrum of threats." Albright, Penrose, et al. “Net Assessment of the U.S. Biodefense Policy & Programs.” Civitas Group, 2008: 89. Print. *Cited with permission from P. Albright |
"In training exercises, the maximum number of PODs set up at one time is about 10. There are not enough volunteers to stress the PODs, so we don’t know what it's really going to feel like when an emergency hits...It would be very educational to set up an exercise where the demand differs between PODs to test the ability to transfer material laterally." - Subject Matter Expert Interview |
| 29    | Plan for MCM Dispensing          | Lack of layered contingency planning for POD locations in event of large area contamination, evacuation or shelter in place. | Ad hoc planning to choose and stand up new sites in case selected sites are compromised by an event. | CRI cities are required to have POD locations identified pre-event. However, the team could find no evidence of contingency plans for alternate POD locations if a POD happens to fall within the affected area. Also, there are no current plans for alternate POD locations outside of the affected city if evacuation is ordered. If shelter in place is ordered, the population will most likely be confused when they are told to shelter in place, but also to report to a POD. Contingency plans should be in place to have flexibility in the event of any scenario. |
Biological Attack Response and Recovery: End-to-End Medical Countermeasure Distribution and Dispensing Processes

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<td>30</td>
<td>Plan for MCM Dispensing</td>
<td>Federal guidance comes in the form of recommendations, rather than clear directives.</td>
<td>There are multiple guidelines from the Federal Government to state and local governments. In the absence of clear directives, states and locals are left to fend for themselves. There is no national capability.</td>
<td>Since the &quot;all-disasters-are-local&quot; mantra is used for a biological event, states and locals do not have to take federal guidance. They are left to develop their own plans and processes. They may take federal recommendations if they wish, but not requiring states to comply with federal directives results in many different processes and procedures across the country. &quot;Each county and state had different reporting requirements [for H1N1]. For future events, the process needs to be more directive than consultative. Tell them how to do it. Provide directives farther than recommendations. In the absence of clear guidance, states and counties did what they wanted to do, resulting in inefficient and ineffective processes.&quot; - Subject Matter Expert Interview</td>
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<td>31</td>
<td>Plan for MCM Dispensing</td>
<td>The current vaccine is not suitable for children and elderly, and would require an IND if the government were to administer it to these at-risk populations.</td>
<td>Children and elderly will only be able to receive the vaccine with IND approval; adverse effects are very likely.</td>
<td>&quot;[If the Secretary of HHS declares a public health emergency following the intentional release of anthrax, the FDA can issue an emergency use authorization (EUA) that allows adults (individuals 18 years and older) to receive AVA as prophylaxis on a voluntary basis. At present, the only way children could receive AVA for any reason before or after exposure to anthrax is if the FDA approves an investigational new drug (IND) protocol, which would allow the administration of AVA to individuals younger than 18 years of age. Multiple state and local public health authorities have told federal officials that there will be an array of logistical, operational, communication, and other challenges in administrating AVA under two differing regulatory mechanisms for different populations (i.e., an EUA for adults and an IND protocol for children).&quot; National Biodefense Science Board (NBSB). “Challenges in the Use of Anthrax Vaccine Adsorbed (AVA) in the Pediatric Population as a Component of Post-Exposure Prophylaxis.” Draft, 2011. Web. <a href="http://www.phe.gov/Preparedness/legal/boards/nbsb/meetings/Documents/ava-pediatric-execsun.pdf">http://www.phe.gov/Preparedness/legal/boards/nbsb/meetings/Documents/ava-pediatric-execsun.pdf</a>. Accessed 04 Feb 2012.</td>
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<td>32</td>
<td>Plan for MCM Dispensing</td>
<td>Lack of consistent understanding about rules and laws governing MCM distribution and dispensing at local levels.</td>
<td>Most local responders will not understand FDA approvals; credentialing for distribution and dispensing may also be a hurdle.</td>
<td>&quot;Tim Conley, director of preparedness and planning for the Village of Western Springs Department of Fire/EMS Services and Emergency Management in Illinois noted that most first responders have never heard of EUAs. ‘In general there is a huge lack of understanding and training in the first responder community when it comes to public health. They do not know what they are facing,’ he said. ‘We would run into a fire, point, go. They will go. They will chase the bad guys down the street, getting shot at. They will run at them, they will go. [But] they do not understand a biological event.’‖ IOM (Institute of Medicine). “Medical Countermeasures Dispensing: Emergency Use Authorization and the Postal Model: Workshop Summary.” Washington, DC: The National Academies Press. 2010:49. Print.</td>
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<td>33</td>
<td>Plan for MCM Dispensing</td>
<td>Supply of ciprofloxacin and doxycycline in retail market is low since pharmacies and hospitals employ a just-in-time supply chain. Distributers will likely have a low supply as well.</td>
<td>There will be a limited ability for the government to rely on private sector if SNS stocks run low.</td>
<td>All private sector partners indicated that these ubiquitous antibiotics are part of a just-in-time system, and the retail bubble for these products is not very large. &quot;They are concerned if there is sufficient amount of material in the SNS or in the commercial market.” - Subject Matter Expert Interview</td>
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<td>Doxycycline and Ciprofloxacin are very much a part of a just-in-time system. In his experience, there is not very much quantity on the shelves. He would be suspicious of the assumption that there are plenty of antibiotics in the system.” - Subject Matter Expert Interview</td>
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<td>34</td>
<td>Plan for MCM Dispensing</td>
<td>Lack of widely accepted national biodefense architecture.</td>
<td>No common way for all stakeholders to approach the biodefense problem.</td>
<td>Without a leader or an understanding of federal roles and responsibilities, the development of an architecture will make no headway. The current National Strategy for Countering Biological threats is too high-level, and there needs to be a more implementable strategy at a lower level. “[W]hat is missing from the current bio-threats strategy is any sense of the need for a significant coordination role within the Federal Government. This shortfall can be observed in at least two distinct situations: 1) the lack of a strong Federal coordinator at the White House and 2) the lack of clarity in the respective roles of the Secretaries of Health and Human Services and Homeland Security in preparing for and preventing a biological attack, as well as their role in interacting with other Federal institutions such as DOJ/FBI and the IC.” National Biodefense Science Board (NBSB). “Challenges in the Use of Anthrax Vaccine Adsorbed (AVA) in the Pediatric Population as a Component of Post-Exposure Prophylaxis.” Draft, 2011. Web. <a href="http://www.phe.gov/Preparedness/legal/boards/nbsb/meetings/Documents/ava-pediatric-execsum.pdf">http://www.phe.gov/Preparedness/legal/boards/nbsb/meetings/Documents/ava-pediatric-execsum.pdf</a>. Accessed 04 Feb 2012.</td>
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<td>35</td>
<td>Plan for MCM Dispensing</td>
<td>Antibiotic supply both in the SNS and existing supply chain may be insufficient in reload/multiple attack scenarios.</td>
<td>Some localities may experience antibiotic shortages; fear of further exposure at the national level will restrict movement of buffer stocks and/or result in hoarding; life-and-death rationing decisions will have to be made in real time; government control will be tested.</td>
<td>&quot;In planning SNS assets, they found that a three major city scenario would have taxed the SNS, and the five city scenario would bring it to its knees.” – Subject Matter Expert Interview &quot;Reload is not as much of a part of the conversation as it should be. It is a real concern for bio.” – Subject Matter Expert Interview &quot;Since the [Amerithrax] attacks, HHS has amassed enough antibiotics in the SNS to provide 60 days of treatment for 60 million people, according to the WMD Center report. Still, the report’s general verdict was that the nation has an adequate supply of medical countermeasures to blunt 'small-scale attacks' with anthrax or several other likely pathogens but possibly not enough for a large-scale attack.” Roos, Robert. &quot;Anthrax Countermeasures Better than in 2001, but Work Remains.” Center for Infectious Disease Research &amp; Policy. University of Minnesota, 18 Oct. 2011. Web. <a href="http://www.cidrap.umn.edu/cidrap/content/bt/anthrax/news/oct1811anthrax.html">http://www.cidrap.umn.edu/cidrap/content/bt/anthrax/news/oct1811anthrax.html</a>. Accessed 01 Mar 2012.</td>
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| 36 | Plan for MCM Dispensing | No clear plan for alternate prophylaxis to address MDR strains. | No MCM alternatives identified to ensure that prophylaxis is available for multi-drug resistant strains; in the event of an MDR strain, plans will have to be changed during the response. | No interviewee could express any plan for combating MDR anthrax other than releasing a different antibiotic when the strain was identified. By the time the characterization occurs, it will be too late for a new antibiotic to be effective as prophylaxis. “The U.S. Strategic National Stockpile does not have countermeasures for agents that are resistant to our known antibiotic stockpile (ciprofloxacin and doxycycline), nor does it have countermeasures for engineered threats (e.g. ‘chimera’ agents that add lethal factors from one agent to the genome of a second agent), except for a very small stockpile aimed at anthrax.” Albright, Penrose, et al. “Net Assessment of the U.S. Biodefense Policy & Programs.” Civitas Group, 2008. 45. Print. *Cited with permission from P. Albright
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<td>38</td>
<td>Plan for MCM Dispensing</td>
<td>Animal health planning is mostly absent.</td>
<td>&quot;Overall, according to our classification taxonomy, the strength of the recommendation that animals could provide early warning of an acute bioterrorism attack seems to be, at best, 'fair' because of the inconsistency of the evidence. A somewhat more consistent level of evidence appeared to support the recommendation that animals could be markers for ongoing exposure risk and also that animals could play a strong role in propagating outbreaks caused by particular agents. At the same time, our ability to assess the overall strength of evidence for such recommendations was hampered by large gaps in current knowledge.&quot; - Rabinowitz, Peter, et al. &quot;Animals as Sentinels of Bioterrorism Agents.&quot; Emerging Infectious Diseases. Publication. Centers for Disease Control and Prevention 4.2 (2006): 651. Print.</td>
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<td>39</td>
<td>Plan for MCM Dispensing</td>
<td>State, local and county plans may differ significantly. Operational plans, rules, regulations, requirements may differ during an event. The concept of &quot;home rule&quot; further complicates response capabilities. Planning is autonomous at the state, local, regional and county level with no firm directives. No clear delineation of who's in charge. No overall coordinating body. Each jurisdiction has to &quot;re-invent the wheel&quot; by implementing independent plans.</td>
<td>&quot;Whatever process is designed should be consistent across states. The concept of 'home rule' makes this exceedingly difficult since even counties and underlying municipalities often have divergent processes for emergency response.&quot; - Subject Matter Expert Interview &quot;The state adopts a lot of city policies. They are in the process of reviewing the state guidance to identify the areas of conflict between the city and the state.&quot; - Subject Matter Expert Interview &quot;One of the biggest challenges we have encountered in the last decade is the lack of common national approaches and effective coordination among governments, health and response systems, and communities.&quot; - Committee on Homeland Security and Governmental Affairs. “Ten Years After 9/11 and the Anthrax Attacks: Protecting Against Biological Threats. Testimony of Nicole Lurie. Hearing Before the United States Senate. One Hundred Twelfth Congress, First Session, 18 Oct. 2011. Web. <a href="https://www.hsdl.org/?view&amp;did=690886">https://www.hsdl.org/?view&amp;did=690886</a>. Accessed 04 Jan 2012.</td>
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<td>Plan for MCM Dispensing</td>
<td>Lack of measures for biodefense preparation, response or outcomes (recovery).</td>
<td>Ambiguity on what national, state and local stakeholders need to achieve to be fully prepared to respond to a bioterrorism attack. &quot;Further examples include the lack of any articulated measures of effectiveness for the biodefense effort, and hence any consequent performance flow down to needed capabilities; lack of a well-analyzed and defensible effort for staffing the medical response capability; desultory investments in clean-up capabilities, or in the development of triage tools; and, in general, any overarching system construct that, matched against measures of effectiveness, highlights gaps in capability and (ultimately) resource needs.&quot; Albright, Penrose, et al. &quot;Net Assessment of the U.S. Biodefense Policy &amp; Programs.” Civitas Group, 2008: 22. Print. *Cited with permission from P. Albright</td>
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<td>41</td>
<td>Plan for MCM Dispensing</td>
<td>No plan for distribution and dispensing for completion prophylaxis.</td>
<td>There will be an ad hoc response for completion prophylaxis with no plan for reaching the targeted population. No interviewee could provide evidence of a completion prophylaxis plan, and most had not even thought it through. This has not been a priority in comparison to the first 48-hour response. &quot;Dispensing of continued countermeasures would be accomplished through other sources (including pull mechanisms). In the case of anthrax, continued countermeasure dispensing would be needed to ensure that the remainder of the necessary 60-day course of prophylaxis was administered to the at-risk populations. One single innovation is unlikely to fit all communities.” IOM (Institute of Medicine). “Dispensing Medical Countermeasures for Public Health Emergencies: Workshop Summary.” Washington, DC: The National Academies Press; 2008: 14. Print.</td>
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<td>42</td>
<td>Prepare for MCM Dispensing</td>
<td>Few or no caches of antibiotics at the state or local level mean that MCMs may not be immediately available to first responders when the event has been announced, preventing their ability to respond before SNS assets arrive.</td>
<td>Public panic if MCMs are not available when the media first reports the attack; inability of first responders to go into the affected area without PPE; forces a waiting game for SNS to arrive. Some localities have caches to treat first responders. However, the team could not assess how prevalent this is nationally. These caches often constitute a large investment for public health departments, especially as their budgets shrink. These caches also do not fall under the federal Shelf Life Extension Program (SLEP), so jurisdictions cannot extend expiration dates, resulting in high cache turnover.</td>
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<td>43</td>
<td>Prepare for MCM Dispensing</td>
<td>Little research into treatment for children, elderly and other at-risk groups.</td>
<td>These at-risk groups may experience more adverse or side effects from the current treatments, or the treatments may not work at all. Doxycycline and ciprofloxacin are not recommended for use in children, and little effort is made to find alternate treatments. Also, the anthrax vaccine has not been tested, and is not recommended for use, in children and the elderly. There are no current acceptable solutions for treating these at-risk groups should an attack occur.</td>
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<td>44</td>
<td>Prepare for MCM Dispensing</td>
<td>Decision point or process for replenishing SNS undefined (e.g. when is SNS replenishment initiated after shipments are sent out?).</td>
<td>In reload scenario, SNS supply of MCMs may be depleted as a result of response to first attacks. Sufficient MCMs may not be available for subsequent attacks or completion prophylaxis.</td>
<td>There is no current plan for replenishing the SNS quickly if product is depleted. Therefore, the U.S. will rely on product within the private sector supply chain should supply in the SNS run out. Also, the SNS has no plan to replenish quickly in a multiple attack scenario.</td>
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| 45     | Prepare for MCM Dispensing | Exercises to date have never focused on truly stressing the system. Focus has been on data collection and local process optimization instead of end-to-end improvements and outcomes. | Inaccurate representation of a true emergency; preparation for event will be insufficient; hard to spot areas that need improvement and difficult to determine outcomes. | "In training exercises, the maximum number of PODs set up at one time is about ten. There are not enough volunteers to stress PODs, so we don't know what it's really going to feel like when an emergency hits." - Subject Matter Expert Interview  
"It is very difficult to test run PODs at capacity and stress individual elements; you end up just stressing the whole POD." - Subject Matter Expert Interview  
"POD exercises included quantitative metrics on throughput, but difficulties in recruiting large numbers of mock patients often limits the extent to which the PODs being tested were actually stressed." - Willis, Henry, et al. “Initial Evaluation of the Cities Readiness Initiative.” Santa Monica, CA: RAND, 2009: 44. Print. |
<p>| 46     | Prepare for MCM Dispensing | POD network may not be periodically reviewed and updated in all locations. | Changing traffic patterns, construction, etc. may prohibit using a planned POD site. May need to change plans temporarily or alter them completely. | The team found no evidence that POD locations are reviewed and updated on a regular basis. Jurisdictions should account for changes in infrastructure that may prohibit the use of the POD network as planned. |</p>
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<td>47</td>
<td>Prepare for MCM Dispensing</td>
<td>No planned dispensing structure for completion prophylaxis at the federal, state or local level.</td>
<td>Ad hoc response for completion prophylaxis; will have to plan and set up dispensing structure in the middle of the initial response; no plan for reaching the targeted population.</td>
<td>When asked about days 11-60 dispensing, all interviewees indicated that there was no plan. Many speculated as to what it would look like, but no one could give a definitive answer. This is assumed to be &quot;easy&quot; after the 48-hour response; therefore, no one has made an effort to tackle the problem ahead of time.</td>
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<td>Prepare for MCM Dispensing</td>
<td>Public has not been involved in many exercises, and there is a lack of public awareness on response processes.</td>
<td>Public confusion during the response phase due to lack of awareness; possible panic, disorderly conduct and non-compliance.</td>
<td>Exercises run on the local level are conducted quite apart from the public. The team heard of one vaccination POD during H1N1 that was run like a bioterrorism response POD, but that was an isolated instance. In most jurisdictions, the public is not involved in exercises, do not know where their nearest POD is located, and might not even know what a POD is. Public awareness on response processes for a bioterror event is low.</td>
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<td>49</td>
<td>Prepare for MCM Dispensing</td>
<td>Distribution and dispensing structure relies volunteers or public health employees to perform operational roles for which they may not have the relevant skills or training.</td>
<td>Bottlenecks in the process, increasing response time. Large chance of a high error rate.</td>
<td>&quot;Utilizing people for distribution or dispensing who do the job on a daily basis will cut down on distribution/dispensing time instead of relying on volunteers who at best are receiving just-in-time training.&quot; - Subject Matter Expert Interview</td>
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<td>50</td>
<td>Prepare for MCM Dispensing</td>
<td>There is a lack of exercises that test high-level, peri-event decision making.</td>
<td>High-level decision makers will be ill prepared to make tough decisions in a crisis, especially in situations with inaccurate or incomplete data.</td>
<td>TOPOFF exercises bring together top officials, and they exercise response to a catastrophic WMD event. However, very few exercises run in real time and involve decision makers at all levels. According to anecdotes from interviewees, these exercises often provide a forum for policy debates rather than truly exercising timely decision making.</td>
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<td>51</td>
<td>Prepare for MCM Dispensing</td>
<td>Exercises focus only on isolated and specific pieces of the process (e.g. setting up one POD).</td>
<td>No preparation or training for full execution of response; no confidence in the ability to carry out a response from end to end for an event of this magnitude.</td>
<td>POD testing is equated to concerto practice. &quot;In a concerto, a musician practices the difficult parts one at a time, then they put the whole process together. POD elements should be tested one-off to perfect each piece, and then the pieces can be put together.&quot; - Subject Matter Expert Interview</td>
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Most "exercises have been functional exercises that test only a single component of mass prophylaxis. All exercises are very well-planned, using professional contractors who provide scripts of a predetermined agent and sufficient and pre-designated POD staff who are generally trained in advance." - Khan, Sinan. "Multi Attribute Decision Analysis in Public Health - Analyzing the Effectiveness of Alternate Modes of Dispensing." Thesis. Naval Postgraduate School, 2007: 15. Print.
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<td>52</td>
<td>Prepare for MCM Dispensing</td>
<td>No surety of public health or preparedness funding across all levels of government in every response entity. Restricts the capacity of the system.</td>
<td>Inability for states to maintain staff due to inconsistency of funding; de-prioritization of preparedness and planning; public health lab funding decreases cause either lack of laboratory resources or closures; federal funding cuts result in inability to plan or lead.</td>
<td>There is no guarantee that the grant money provided at the federal level to address public health preparedness will continue to be available. Public health jobs at the state and local level are being cut, laboratory capacity is decreasing, and the SNS budget is being cut. Therefore, response capacity is severely diminished. &quot;State and local health departments are on the verge of shutting down due to lack of funding.&quot; - Subject Matter Expert Interview &quot;Public Health Awareness Cooperative Agreement funding is eroding. This will make it difficult to address preparedness gaps at any level.&quot; - Subject Matter Expert Interview</td>
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<td>53</td>
<td>Prepare for MCM Dispensing</td>
<td>Dependent entirely on volunteers and state/local public health staff to ensure dispensing to public. Assumption that anywhere from 10-60% volunteers will show up in an actual event.</td>
<td>Without full staff, there will be an inability to effectively run all PODs and achieve the throughputs estimated in exercises. This would result in greatly increased time for affected public to receive medications, if they receive them at all.</td>
<td>&quot;The biggest gap is not having enough volunteers to staff PODs.&quot; - Subject Matter Expert Interview One public health official &quot;expects that 50% of volunteers will show up for response.&quot; - Subject Matter Expert Interview &quot;The biggest weakness or downfall of the POD is manpower. Huge numbers are needed to run them, most of which will be volunteers. We assume that only 10% of volunteers will show up.&quot; - Subject Matter Expert Interview</td>
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<td>54</td>
<td>Prepare for MCM Dispensing</td>
<td>Biodefense budget is fragmented and not aligned to required preparation, response and potential recovery.</td>
<td>Misaligned resources result in misaligned and uncoordinated response. Without targeted resources, stakeholders are unable to set up appropriate measures for response and recovery.</td>
<td>Budgets and allocations for biodefense are at several federal agencies including the Departments of Health and Human Services, Defense, Homeland Security, Agriculture, Commerce, and State; the Environmental Protection Agency; and the National Science Foundation. Funding is provided for programs that address multiple public health, healthcare, national security, and international security issues in addition to biodefense. (Franco, Crystal and Tara Kirk Sell. “Federal Agency Biodefense Funding, FY2011-FY2012.” Biosecurity and Bioterrorism 9.2 (2011):117-137. Print.) There is also funding at the state and local level to public health departments, laboratories, and first responders. No one oversees all biodefense funding and appropriately allocates it to where it is needed most.</td>
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<td>55</td>
<td>Prepare for MCM Dispensing</td>
<td>Little investment in clinical diagnostics or triage methods to quickly identify those infected with a biological agent.</td>
<td>Inability to quickly identify those infected with anthrax. Rely on either blood cultures or appearance of symptoms, both of which can take</td>
<td>DHS and DOD invest some money into this area, but it is not a priority, and little if any progress has been made. &quot;Another pressing need in surveillance is the development of technologies to improve the accuracy and speed with which we diagnose sick people. Rapid diagnostics are our best hope for detecting outbreaks early. Although 10 years have elapsed since the anthrax attacks, the diagnosis of this deadly disease is still dependent on assessing a patient’s symptoms (which can be imprecise)</td>
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<td>56</td>
<td>Prepare for MCM Dispensing</td>
<td>Little research in improving treatment types or outcomes.</td>
<td>Until more research into treatment is done, the U.S. must rely on a 60-day treatment of antibiotics, which can produce many side or adverse effects in the population.</td>
<td>The SNS stockpiles doxycycline and ciprofloxacin for anthrax. There is also a limited amount of AVA vaccine. Little research is being done into new treatments or vaccines for anthrax.</td>
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<td>57</td>
<td>Detect and Characterize Event</td>
<td>There are multiple organizations involved in collecting event information (including JTTF, CDC, FBI). Process owner is ambiguous. Responsibility and accountability is also ambiguous. There is no clear coordinating body for all the collected event information.</td>
<td>Potential for uncoordinated response and limited information sharing, which can delay determination/dissemination of event information. Delays in event characterization can negatively impact ability of responders to treat affected population in a timely manner. Locals may be relying on federal resources while feds are relying on local response and capabilities.</td>
<td>States and locals collect BioWatch samples around the surrounding areas to determine extent of contamination. IOM (Institute of Medicine). “BioWatch and Public Health Surveillance: Evaluating Systems for the Early Detection of Biological Threats.” Washington, DC: National Academies, 2011: 82-83. Print. &quot;FBI deploys the Hazardous Materials Response Team comprised of FBI and DOE to collect and analyze samples.” - Subject Matter Expert Interview &quot;FBI and JTTF collect overall crime scene event information to try and attribute the attack to a perpetrator.” - Subject Matter Expert Interview &quot;EPA and CDC sample to determine environmental contamination.” U.S. Department of Health and Human Services, Centers for Disease Control and Prevention (CDC) and the Environmental Protection Agency (EPA). &quot;Joint Interim Clearance Strategy for Environments Contaminated with Bacillus Anthracis.” 2011. Print. &quot;Forensic sample collection techniques are not standardized and hence are not uniform across the relevant agencies. In general, those people collecting samples are not cognizant of analysis techniques, and hence, as is the case with other technical forensics capabilities, there is a need to standardize techniques in a manner that optimizes the value of the samples.” Albright, Penrose, et al. “Net Assessment of the U.S. Biodefense Policy &amp; Programs.” Civitas Group, 2008: 62. Print. *Cited with permission from P. Albright</td>
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<td>58</td>
<td>Detect and Characterize Event</td>
<td>Lag time between when event happens and when it is confirmed is significant. Mechanisms for detection are largely reactive and time consuming. No real-time detection technology.</td>
<td>The longer the event takes to detect, the less time the locale will have to respond; longer detection time means more people adversely affected by attack.</td>
<td>Most interviewees indicated that they would be behind the curve, that detection was the rate-limiting step. &quot;We may lose 24-72 hours in the detection phase due to delays in detection technologies.&quot; - Subject Matter Expert Interview &quot;We do not have an effective anthrax surveillance system currently because we don’t need it (due to the low rate of cases).&quot; - Subject Matter Expert Interview BioWatch will probably take 10-36 hours to detect, and then confirmatory testing will have to be done to validate. Cases will take 2-4 days to appear depending on the incubation period. IOM (Institute of Medicine). “BioWatch and Public Health Surveillance: Evaluating Systems for the Early Detection of Biological Threats.” Washington, DC: National Academies, 2011: 54-166. Print.</td>
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<td>59</td>
<td>Detect and Characterize Event</td>
<td>Physicians are not inclined to think bioterror in diagnosing – first cases may be overlooked.</td>
<td>Longer detection time, thus more compressed response time.</td>
<td>&quot;Many pathogens produce early symptoms that mimic naturally occurring diseases. Some findings are so ubiquitous that a rare provider orders further laboratory or radiographic tests early in the course of the disease, unless significant physiologic derangements are present or the index of suspicion is raised due to prior intelligence information. Most physicians have not evaluated or treated patients with many of the diseases produced by these agents. Since a delay occurs between exposure and symptoms, patients present at various times, to various care providers, rather than simultaneously to one location.&quot; - Jagminas, L. and J, Mothershead. &quot;CBRNE - Biological Warfare Mass Casualty Management.&quot; Medscape Reference. WebMD, 02 May 2011. Web. <a href="http://emedicine.medscape.com/article/831529-overview#aw2aab6b4">http://emedicine.medscape.com/article/831529-overview#aw2aab6b4</a>. Accessed 01 Mar 2012.</td>
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<tr>
<td>60</td>
<td>Detect and Characterize Event</td>
<td>Time required to determine the strain or characteristics of the bioagent may lag behind distribution of MCMs.</td>
<td>Distributed MCMs may not be appropriate to combat identified strain, potential for significant increase in morbidity and mortality.</td>
<td>&quot;At the time of the event you will not know what you are dealing with. You need a primary strategy where you assume it’s not MDR.&quot; - Subject Matter Expert Interview &quot;As laboratory testing of antibiotic susceptibility is likely to take more than 2 days, antibiotic distribution and dispensing efforts in response to an anthrax attack would be initiated before the susceptibility profile of the attack strain was known.” - IOM (Institute of Medicine). “Prepositioning Antibiotics for Anthrax.” Washington, DC: The National Academies Press, 2011: 46. Print.</td>
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<td>61</td>
<td>Detect and Characterize Event</td>
<td>Time to identify and capture perpetrator may be time consuming, such that a subsequent attack may be carried out.</td>
<td>Because of the ability to grow large amounts of bioagents, subsequent attacks are more likely. Characterization techniques are time consuming, and the information to identify the perpetrator may not be</td>
<td>Amerithrax took seven years to identify the source and perpetrator, and questions still remain. U.S. Department of Justice. “Amerithrax Investigative Summary”. 19 Feb. 2010. Web. <a href="http://www.justice.gov/amerithrax/docs/amx-investigative-summary.pdf">http://www.justice.gov/amerithrax/docs/amx-investigative-summary.pdf</a>. Accessed 05 Dec 2011. &quot;There are challenges ahead&quot;, adds Budowle, who retired in 2009 from the U.S. Federal Bureau of Investigation (FBI), where he was involved in the anthrax studies as a senior scientist in the laboratory division: ‘In a lot of ways, we’ve got a long way to go... We haven’t grown in the interpretation of the results and what they might mean.’” Dance, Amber. &quot;Ten Years on from Anthrax Scare, Analysis Lags behind Sequencing.” Nature</td>
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Detect and Characterize Event

EPA and DHS think of biological attacks like a chemical attack in which there are cool, warm and hot zones for decontamination. However, in biological attacks, affected zones may move because of weather or people carrying spores, and the threat may exist for a long time.

No clarity around affected site determination, decontamination, clean-up and recovery.

"One frustrating point [about the Dark Zephyr exercise] was that people were talking about the bio event as if it were a chemical event in terms of contamination and decontamination. There will be no 'hot', 'warm', and 'cool' zones for bio since the spores and people will spread." - Subject Matter Expert Interview

"Although a site can be divided into as many zones as necessary to ensure minimal employee exposure to hazardous substances, the three most frequently identified zones are the Exclusion Zone ('Hot Zone'), the Contamination Reduction Zone ('Warm Zone'), and the Support Zone ('Cold Zone'). In effect, those areas recognized as 'cold' have been 'cleared' as free from contamination." - U.S. Department of Homeland Security. "Planning Guidance for Recovery Following Biological Incident." Draft. Biological Decontamination Standards Working Group. Subcommittee on Decontamination Standards and Technology Committee on Homeland and National Security. 2009: 55. Web. http://www.trivalleycares.org/comments/DHSDraftGuidance.pdf. Accessed 11 Nov. 2011.

Federal, state and local governments anticipate that they will have epidemiological results within the initial 10-day response period so that they can narrow down population requiring MCMs.

Lack of planning for ongoing response, including how to target population and how to determine the true quantity of medications that will be required.

Several interviewees noted that they "hoped" or "have been told" that the characterization would happen within the 10-day window to narrow down the target population. However, this is all based on assumption, and there is no evidence to support it.

No integration between national biosurveillance systems.

Could receive disparate signals, and the lag time for event confirmation could be significant; no way to see the big picture nationally to mount a coordinated, national response.


"These efforts [BioWatch, BWICS, NBIS, ESSENSE] are intended to address a wide range of potential biological threat events, from large-scale releases of biological agents to small-scale releases that affect a smaller area or fewer people. Domestically, these efforts must be undertaken in collaboration with State and local jurisdictions whose health professionals will often be the first to identify outbreaks. The efforts must also include coordination with the private sector—the hospitals where infected individuals will present themselves for treatment and the network of public health laboratories responsible for handling and analyzing the clinical samples related to
### Biological Attack Response and Recovery: End-to-End Medical Countermeasure Distribution and Dispensing Processes

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<td>67</td>
<td>Detect and Characterize Event</td>
<td>No environmental detection system available for small attacks or attacks outside sensor network cities. Minimum detectable attack driven by density of installation and threshold of detection of sensor. How can smaller attacks, defined as affecting less than X,XXX people, be differentiated from larger scale attacks? How will response differ?</td>
<td>Detection mechanisms that can detect large-scale attacks may not be able to detect small-scale attacks. The result is incomplete coverage in detection. Small attacks, below BioWatch threshold, can still cause great damage and more than 10,000 deaths. No mechanism other than epidemiological data to detect these events – detection with initial symptoms is unlikely, but fully developed respiratory distress will be detected in 4 to 4.5 days (2.5 to 3 days). The only U.S. Government-accepted domestic environmental detector is BioWatch. DOD has some smaller scale detectors, but they are only deployed in war zones, not domestically. &quot;A key gap in this area is the need to address the timely detection of small attacks. Specifically, current plans for environmental sensing imply minimum detectable attacks (at appropriate detection probability) that significantly exceed the attack size below which the combination of detection through medical surveillance and treatment of infected could result nevertheless in an effective response. Analysis estimates the upper bound for an effective strategy based on medical surveillance and treatment to be attacks that infect between ~7,500 to ~10,000; these numbers could be driven yet lower depending on the effectiveness of triage and the prevalence at the time of the attack of naturally occurring respiratory ailments in the population.&quot; Albright, Penrose, et al. “Net Assessment of the U.S. Biodefense Policy &amp; Programs.” Civitas Group, 2008: 26. Print. *Cited with permission from P. Albright&quot;</td>
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Biological Attack Response and Recovery: End-to-End Medical Countermeasure Distribution and Dispensing Processes

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<tr>
<td>68</td>
<td>Detect and Characterize Event</td>
<td>Lack of clear goals or guidelines for time to determine pathogen strain and required treatment.</td>
<td>The assumption is that this will happen before dispensing of follow-on doses is to occur, but no entity has set reasonable expectations.</td>
<td>Several interviewees noted that they &quot;hoped&quot; or &quot;have been told&quot; that the characterization would happen within the 10-day window. There are no current guidelines or policies relating to goals or timelines for agent characterization.</td>
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<td>69</td>
<td>Initial MCM Distribution Process for requesting SNS activation has many steps, requiring the participation of many disparate stakeholders.</td>
<td>Lengthy approval process may prevent timely treatment of exposed population. Stakeholder coordination will be very difficult in an emergency. Could cause a significant delay in the response process.</td>
<td>South Carolina’s documentation provides an example of the process for activating the SNS: &quot;The decision to deploy the Strategic National Stockpile will be a collaborative effort between local, state, and federal officials. After the recognition of a potential or actual Weapons Mass Destruction event or a major natural or technological disaster that may or will exceed local medical supplies, the local Health Department along with the Region Health Director will contact the Office of Public Health Preparedness Director of Emergency Management...A strategic policy group comprised of the Governor, the South Carolina Emergency Management Director, and the Commissioner of the Department of Health and Environmental Control will be convened to determine if the Strategic National Stockpile should be requested. If federal assets are required the Commissioner of the Department of Health and Environmental Control with the consent of the governor will submit a form request to the Centers for Disease Control and Prevention for the deployment of the Strategic National Stockpile in South Carolina. Once the Department of Health and Environmental Control Commissioner, or designee, has requested Strategic National Stockpile assets, the Centers for Disease Control and Prevention (CDC) Director’s Emergency Operations Center (DEOC) will initiate a conference call to the Commissioner of the Department of Health and Environmental Control and other Federal, state and local officials to determine if an event threatens the public’s health and that the on-site capacity and resources have or will be strained or exhausted a request will be made for a copy of the SC Strategic National Stockpile Plan. Upon receipt of the SC Strategic National Stockpile Plan, the Secretary of the Department of Health and Human Services or his designee will order the deployment of the Strategic National Stockpile ‘12-Hour Push Package’ to the SC Strategic National Stockpile Receiving, Staging and Storage (RSS) site as designated by the Commissioner of the Department of Health and Environmental Control.” - South Carolina. South Carolina Department of Health and Environmental Control. &quot;Annex 1, Appendix 5: Strategic National Stockpile. South Carolina Emergency Operations Plan,” Nov. 2008. Web. <a href="http://www.scdhec.gov/administration/ophp/docs/Strategic-National-Stockpile-Emergency-Operations-Plan.pdf">http://www.scdhec.gov/administration/ophp/docs/Strategic-National-Stockpile-Emergency-Operations-Plan.pdf</a>. Accessed 04 Jan 2012.</td>
<td>&quot;CDC has an activation protocol. It requires the governor or governor surrogate to make a request...&quot;</td>
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<td>70</td>
<td>Initial MCM Distribution</td>
<td>No defined process/feedback loop for how Federal Government will use state plan to augment capabilities and fill state gaps.</td>
<td>Responsibility for analyzing state plan requested for SNS activation is unclear, and there is no strategy to augment state response, if needed. Risk that state will not receive adequate federal support.</td>
<td>In South Carolina’s response planning document (South Carolina. South Carolina Department of Health and Environmental Control. “Annex 1, Appendix 5: Strategic National Stockpile. South Carolina Emergency Operations Plan,” Nov. 2008. Web. <a href="http://www.scdhec.gov/administration/ophp/docs/Strategic-National-Stockpile-Emergency-Operations-Plan.pdf">http://www.scdhec.gov/administration/ophp/docs/Strategic-National-Stockpile-Emergency-Operations-Plan.pdf</a>. Accessed 04 Jan 2012.), South Carolina notes that states are required to submit their plans in the Activate SNS process, but the team could not find evidence of what was done with the plan once submitted. (“If the Secretary of the Department of Health and Human Services or his designee decides that the event threatens the public’s health and that the on-site capacity and resources have or will be strained or exhausted a request will be made for a copy of the SC Strategic National Stockpile Plan. Upon receipt of the SC Strategic National Stockpile Plan, the Secretary of the Department of Health and Human Services or his designee will order the deployment of the Strategic National Stockpile ‘12-Hour Push Package’ to the SC Strategic National Stockpile Receiving, Staging and Storage (RSS) site as designated by the Commissioner of the Department of Health and Environmental Control.”)</td>
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<td>71</td>
<td>Initial MCM Distribution</td>
<td>Process for activating SNS for neighboring states/localities unclear in a regional attack.</td>
<td>Potential for delays in distributing MCMs to localities where they are required and/or each locality would have their own separate response and interactions with the Federal Government.</td>
<td>CDC indicated that they would push appropriate levels of antibiotics to the entire region, but the process is not defined. “Each state has a different set of authorities for requesting SNS, regulations differ from state to state.” - Subject Matter Expert Interview</td>
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<td>72</td>
<td>Initial MCM Distribution</td>
<td>There will be demand for antibiotics outside of the impacted state or locality from people who have travelled from the affected area that are symptomatic or from the worried well.</td>
<td>The lack of plans to address the out-of-area population will result in increased morbidity/mortality... Worried well will start to increase nationally. Cases appearing outside of the affected area may prompt fears of a follow-on attack.</td>
<td>&quot;Setting up evacuation or remote PODs needs to be in the plans to account for those that have travelled or that leave the area.&quot; - Subject Matter Expert Interview One interviewee said that he &quot;does not know of any plans to address people who flee the city and will not be near PODs.&quot; - Subject Matter Expert Interview &quot;The fact that the population will disperse after an event is so intuitive, but it is not reflected in any planning documents.&quot; - Subject Matter Expert Interview</td>
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| 73    | Initial MCM Distribution | Response plans may differ significantly across states and localities. Autonomy of jurisdictions can create confusion in the supply chain (e.g., separate demands on distributors). | Differences in response plans across states and localities may cause confusion in the supply chain during plan execution and can lead to possible delays in MCM distribution. Distributors will likely be delivering to a number of states/localities and may not be aware of or comply with differences in plans. | "How do distributors prioritize who they give medications to during an emergency? This should not necessarily be a competitive structure during mass dispensing." - Subject Matter Expert Interview  
"During H1N1, there was a unique process for every jurisdiction, no consistency. Everyone was trying to figure out their game plan. Some states/counties asked the retailer to pick up MCMs from the stockpile. Others delivered MCMs to the stores when they weren't expecting it. Some states received medicines and controlled them from a state level. Others pushed the responsibility to the county level. This lack of a standardized approach greatly complicated the management of activities." - Subject Matter Expert Interview |
| 74    | Initial MCM Distribution | Lack of consistency and guidance at state and local levels creates complexity in distribution planning and response. | Multiple requests on supply sources can cause confusion for distributors, especially when dealing with autonomous states or localities in one response. | "Each county and state had different reporting requirements. In the absence of clear guidance, states and counties did what they wanted to do, resulting in inefficient and ineffective processes." - Subject Matter Expert Interview  
"Whatever process is designed should be consistent across states. The concept of 'home rule' makes this exceedingly difficult, since even counties and underlying municipalities often have divergent processes for emergency response." - Subject Matter Expert Interview  
"During H1N1, the process for ordering medications and the paperwork required was different across the country." - Subject Matter Expert Interview |
| 75    | Initial MCM Distribution | Distribution of medicines to PODs can be a rate limiting step. Some jurisdictions indicate that they can set up PODs faster than medicines may arrive. | People may flood PODs before medicines are made available. May erode public confidence in MCM response if there are no medications to hand out. | "Difficult to obtain contracted vehicles for transportation of materiel to PODs in a moment's notice." - Subject Matter Expert Interview  
"They are concerned about the delay in delivery time of SNS assets." - Subject Matter Expert Interview  
One state is "concerned about the throughput from and traffic around the RSS site." - Subject Matter Expert Interview  
"Policymakers have taken significant steps to accumulate supplies of some critical drugs and vaccines. But present distribution mechanisms are not likely to be fast, fair, or credibly safe. They are especially vulnerable to further terrorist attack and inadequately prepared to cope with likely transportation, staffing, and psychological obstacles." - Danzig, Richard, Rachel Kleinfeld, and Philippe Bleek. "After an Attack: Preparing Citizens for Bioterrorism." Washington, DC: Center for a New American Security, 2007: 4. Print. |
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<td>76</td>
<td>Initial MCM Distribution</td>
<td>No standard defined process for providing MCMs to first responders.</td>
<td>Delays in responding to scene while responders await prophylaxis.</td>
<td>Process differs amongst states and localities. Some jurisdictions have caches for this purpose. Others do not, and they rely on the SNS to provide the medications. In those cases, the process for providing MCMs to the first responders is unclear. &quot;Based on the available evidence and expert judgment, the committee finds that it is important to consider how to provide antibiotics for those who will be expected to report to work and stay at work during an attack in order to respond and maintain critical functions within the community.” IOM (Institute of Medicine). “Prepositioning Antibiotics for Anthrax.” Washington, DC: The National Academies Press, 2011: 215. Print.</td>
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<td>77</td>
<td>Initial MCM Distribution</td>
<td>FDA must issue an EUA for any medications that will be used for post-exposure prophylaxis before SNS can be activated (Doxycycline is the one exception as it has a pre-issued EUA).</td>
<td>This adds to the lengthy process to activate the SNS, involves another government agency, and could prolong the distribution of MCMs to the affected locations.</td>
<td>&quot;FDA would have to issue an EUA at the decision to activate the SNS.&quot; - Subject Matter Expert Interview &quot;They will still need to go through FDA to get approval to use these medications for prophylaxis, and this process is entirely unclear in estimating the timeframe.” - Subject Matter Expert Interview &quot;Obtaining EUAs for MCMs that are not yet licensed should not be left until a crisis is at hand. To the extent that some CBRN incidents are anticipatable, the U.S. Government needs to do a better job of assembling additional mockup pre-EUA dossiers and data sets, especially for the unlicensed or unapproved MCMs most likely to be needed or whose availability would be most valuable to society.” - National Biodefense Science Board (NBSB). “Where Are the Countermeasures? Protecting America’s Health from CBRN Events.” March 2010. Web. <a href="http://www.phe.gov/Preparedness/legal/boards/nbsb/meetings/Documents/nbsb-mcmreport.pdf">http://www.phe.gov/Preparedness/legal/boards/nbsb/meetings/Documents/nbsb-mcmreport.pdf</a>. Accessed 02 Mar 2012.</td>
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<td>78</td>
<td>Initial MCM Distribution</td>
<td>Time to detect and characterize event, make decision to mobilize SNS, and then distribute may be significantly longer than planned. Actual time may be greater than 48 hours.</td>
<td>Time delays on the front end of the process will significantly delay the back end. This will result in increase public panic, morbidity, and mortality.</td>
<td>&quot;CRI requires awardees to develop the ability to dispense life-saving antibiotics to 100 percent of the population of a metropolitan region (usually referred to as a metropolitan statistical area, or MSA) within 48 hours of the decision to do so.” (Willis, Henry, et al. “Initial Evaluation of the Cities Readiness Initiative.” Santa Monica, CA: RAND, 2009:1. Print.) This does not account for the time to detect an event or the time to make the decision to mobilize the stockpile. If detection happens via BioWatch, it will take 10-36 hours to recognize an event.</td>
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<td>79</td>
<td>Initial MCM Dispensing</td>
<td>Postal Model is very limited in its applicability at this time, only being deployable in one city and in early stages in four more.</td>
<td>Push models are not implemented nationally despite Executive Order guidance. Potential resources are not being used for response.</td>
<td>&quot;The Postal Model is a very limited program with very limited funding. It is going to 4 new cities: Louisville, Philadelphia, Boston, and San Diego in addition to the program in Minneapolis.” - Subject Matter Expert Interview</td>
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<td>80</td>
<td>Initial MCM Dispensing</td>
<td>Postal Model only delivers to home addresses in certain zip codes.</td>
<td>May raise issues related to fairness of dispensing, especially for commuter populations or those that are travelling. Not designed to reach 100% of the population in an MSA. Will not reach businesses.</td>
<td>&quot;Bottles of antibiotics from the SNS and an information sheet developed by local or state public health will be delivered to all residences in a set geographical area, defined in terms of ZIP Code (within a jurisdiction with a pre-existing Plan adapted from the Model).&quot; - Plessas, J. The Postal Model. PPT. Web. <a href="http://www.authorstream.com/Presentation/aSGuest58704-459527-plenary-plessas/">http://www.authorstream.com/Presentation/aSGuest58704-459527-plenary-plessas/</a>.</td>
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<td>81</td>
<td>Initial MCM Dispensing</td>
<td>Uniform number of pills is provided to all households, regardless of household size.</td>
<td>For large households, MCMs provided through Postal Model may not buy sufficient time before follow-on dose is required. Will not necessarily buy the public health department more time to set up PODs.</td>
<td>&quot;The items for delivery include unit-of-use bottles of antibiotics (current limit: 2 bottles) and an information sheet (developed by public health). The delivery will be made to residential delivery points. Every point of delivery will receive the same number of items.&quot; - Plessas, J. The Postal Model. PPT. Web. <a href="http://www.authorstream.com/Presentation/aSGuest58704-459527-plenary-plessas/">http://www.authorstream.com/Presentation/aSGuest58704-459527-plenary-plessas/</a>.</td>
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<td>82</td>
<td>Initial MCM Dispensing</td>
<td>Security personnel accompanying postal volunteers are not provided with home MedKits for themselves or their families.</td>
<td>Huge disincentive to participation because of concern of being exposed to anthrax and being unable to care for their family. Perception of inequity between postal carriers and security personnel.</td>
<td>&quot;Police organizations have not applied for the same EUA as the MedKits for postal workers, so they are not supplied with MedKits as postal workers are.&quot; - Subject Matter Expert Interview</td>
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<td>83</td>
<td>Initial MCM Dispensing</td>
<td>In Postal Model, no screening of population for adverse reactions before dispensing.</td>
<td>Potential for negative side effects associated with taking MCMs, especially for children. Instances of adverse effects reported in the media could cause</td>
<td>&quot;The items for delivery include unit-of-use bottles of antibiotics (current limit: 2 bottles) and an information sheet (developed by public health). The delivery will be made to residential delivery points. Every point of delivery will receive the same number of items [and the same items].&quot; U.S. Department of Health and Human Services. Centers for Disease Control and Prevention (CDC). &quot;Cities Readiness Initiative Postal Plan Synopsis.&quot; September 2009:1. Print.</td>
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<td>84</td>
<td>Initial MCM Dispensing</td>
<td>Unclear if traffic and/or road closures have been accounted for in distribution and dispensing drills.</td>
<td>In actual event, road closures and heavy traffic may impact ability to dispense MCMs in a timely manner, for getting MCMs to public PODs, for postal delivery, and for getting the public to the PODs.</td>
<td>Several reports acknowledge that traffic may worsen as people flee the city (Baccam, Prasith, et al. “Mass Prophylaxis Dispensing Concerns: Traffic and Public Access to PODs.” Biosecurity and Bioterrorism 9.2 (2011): 139-151. Print.), but the team was unable to find any reports citing mitigation strategies or preparation for traffic or road closures in distribution and dispensing processes.</td>
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<td>85</td>
<td>Initial MCM Dispensing</td>
<td>No clear communication from CDC to localities as to guidance for Postal Model implementation.</td>
<td>Postal Model is not implemented nationally, and many jurisdictions will not take steps to implement in their city.</td>
<td>“CDC directed the city to plan as if the postal plan did not exist.” - Subject Matter Expert Interview</td>
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<td>86</td>
<td>Initial MCM Dispensing</td>
<td>Some localities are not willing to explore implementing Postal Model due to security personnel requirement and their unwillingness to spare security for this purpose.</td>
<td>Postal Model is not implemented nationally, and many jurisdictions will not take steps to implement in their city.</td>
<td>“The state has not been able to crack the Postal Model because law enforcement requirement is too big - locales not willing to give up enough policemen.” - Subject Matter Expert Interview</td>
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<td>87</td>
<td>Initial MCM Dispensing</td>
<td>Uniformed officers escorting postal employees may not be provided with N-95 masks.</td>
<td>Creates perception of inequity; disincentive for uniformed officers to report to duty; has the potential to cause public panic if postal workers are seen with masks.</td>
<td>“N-95 masks for postal volunteers only.” Raub, William. “Pre-Event Deployment of Antibiotic Kits in Homes and Workplaces of Postal First Responders.” DomPrep Executive Briefing. National Press Club, 24 Jan. 2011. Print.</td>
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<td>88</td>
<td>Initial MCM Dispensing</td>
<td>Closed PODs may not always be closest location to receive MCMs if target population is located.</td>
<td>People may be unwilling to travel back to their closed POD (either work or home) if they are at the other location. Need redundant</td>
<td>This is especially true with commuter populations who travel long distances between work and home.</td>
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<td>89</td>
<td>Initial MCM Dispensing</td>
<td>Closed PODs may not provide medications to entire families (e.g. federal workplaces only provide medications to employees).</td>
<td>Will not offload the desired percentage of the population; people may be unwilling to participate. Need redundant plans and supplies.</td>
<td>&quot;For federal employers, at the moment, they only plan to dispense only to the employees.&quot; - Subject Matter Expert Interview</td>
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<td>90</td>
<td>Initial MCM Dispensing</td>
<td>Processes and procedures at PODs differ among states and localities (e.g., providing identification, filling out forms, picking up certain amounts). No nation-wide directives on POD processes.</td>
<td>Some people may not have identification; forms in English will be hard to fill out for non-English speakers; will require critical decisions to be made by volunteers during dispensing; will leave many questions to be answered and directions to be given to the public before they come to a POD.</td>
<td>&quot;Whether or not a POD requires identification depends on the locale.&quot; - Subject Matter Expert Interview</td>
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<td>91</td>
<td>Initial MCM Dispensing</td>
<td>PODs are resource-intensive. Inordinate amount of burden placed on volunteers. Duration of shifts unsustainable over long time period.</td>
<td>Volunteers may not show up in event of an emergency, impacting ability to dispense MCMs in a timely manner. Placing too large of a burden on any POD may cause error rate to increase or POD staff to drop out.</td>
<td>Most jurisdictions have not calculated the number of volunteers they will need to carry out their plans. Since most public health departments do not have large staffs, the majority of responders will need to be volunteers.</td>
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<td>&quot;The POD model of countermeasure distribution is extremely personnel intensive, particularly with a 48 hour distribution requirement. If we are to assume that POD throughput is about 500 patients/POD/hour (San Francisco test data; LA County and Houston planning); and that each POD requires 220 staff (2 shifts, 110/shift) per POD (LA county, Houston planning); then more than 9,000 staff and volunteers are needed to distribute therapeutics in two days.&quot; Albright, Penrose, et al. “Net Assessment of the U.S. Biodefense Policy &amp; Programs.” Civitas Group, 2008: 67. Print. *Cited with permission from P. Albright</td>
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<td>92</td>
<td>Initial MCM Dispensing</td>
<td>First delivery of MCMs may not be sufficient to meet full demand before follow-on deliveries arrive.</td>
<td>Potential for chaos in event that PODs run out of MCMs before they are able to receive more medications. Safety of volunteers may be in jeopardy. Ration system may create black market for MCMs.</td>
<td>It is unclear how many 10-day unit of use bottles are in the stockpile and how much will need repackaging. Depending on the size of the event, the initial delivery may not cover a sufficient part of the population before the drugs run out and panic ensues.</td>
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| 93    | Initial MCM Dispensing | Public may be reluctant to visit PODs for fear of contamination, contagion, and/or repeat attacks. | Public may avoid coming to PODs for fear that they are unsafe, limiting the ability to treat the impacted population. | "Major reasons people are unlikely or only somewhat likely to go to dispensing site within 48 hours to get antibiotics, % of adults who are unlikely or only somewhat likely to go saying “major reason” was that they were: worried that officials will not be able to control crowds (48%); worried about the safety of the antibiotic pills, including side effects (43%); worried about being exposed to anthrax from other people sick with it at site (42%); worried about getting exposed to anthrax left on buildings, people or transportation (40%); would wait to get antibiotic pills until sure exposed to anthrax (40%)."
| 94    | Initial MCM Dispensing | PODs present an attractive opportunity for subsequent attacks, especially if there are no alternatives for dispensing. | Potential for increase of the amount of fatalities if subsequent attacks occur, and if a secondary attack happens, people will not come to PODs for fear of being attacked. | The team been told in many interviews that the locations for the PODs are sensitive for fear of subsequent attack.
"Public health departments are uneasy about sharing plans ahead of time. They think that the more they reveal about their plans, the more vulnerable they are to attack." - Subject Matter Expert Interview
"The city has been in debates about whether or not to make POD locations secret; they do not want them to be secondary targets, and need the flexibility to change the locations of the PODs if necessary." - Subject Matter Expert Interview |
| 95    | Initial MCM Dispensing | Off-label use of antibiotics presents additional risks for children because these medications are untested in children. | Children may have adverse affects from medications or not take them at all; presents additional burden on parents to correctly give the medication to their children. | “Many of these MCMs are not studied in children.” - Subject Matter Expert Interview
“We do not have good data in children or know what to do in children. “ - Subject Matter Expert Interview |
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| 96    | Initial MCM Dispensing | FDA-approved information sheet provided with MCMs is only available in English. | Non-English speakers will not understand the information sheet, including instructions for taking MCMs or contraindications that may result from the pills. | "FDA came up with an acceptable 8 1/2 x 11 sheet to accompany the pills. CDC is working with FDA to try to get it into more easily understood language. Right now the info sheet is just in English." - Subject Matter Expert Interview  
"Translation of the fact sheets into Spanish or other languages is not a condition of the EUA and, therefore, is not required. At this time, FDA has not translated the four exhibits provided in the EUA. CDC or a stakeholder may provide accurate translations of the fact sheets in other languages. CDC is currently developing its version of the recipient fact sheet taking into account readability level; this fact sheet will then be translated into the top 50 languages and will be available for the stakeholders on a DVD for reproduction. Stakeholders are the most familiar with the language needs of their communities and should ensure that translated materials are prepared and made available as necessary." - U.S. Food and Drug Administration (FDA), United States Department of Health and Human Services. “Interim Questions and Answers: Emergency Use Authorization for Oral Formulations of Doxycycline for Post-Exposure Prophylaxis of Inhalational Anthrax.” 23 Aug. 2011. Web. http://www.fda.gov/EmergencyPreparedness/Counterterrorism/ucm269226.htm#doxycyclineeu. Accessed 27 Feb 2012.  
"The drug fact sheets included in the EUA MedKits distributed in the Minneapolis-St. Paul postal model pilot are lengthy and written at a high reading level, and translations to other languages are not available. The content of these fact sheets is specified by the EUA and may not be altered for readability or comprehensibility. Similarly, drug product labels are FDA-approved materials that may not be altered." - IOM (Institute of Medicine). “Prepositioning Antibiotics for Anthrax.” Washington, DC: The National Academies Press, 2011: 147. Print. |
| 97    | Initial MCM Dispensing | Postal Model is completely reliant on HHS grant funding for maintenance and deploying in new cities. | Lack of surety of funding results in limited implementation; program could fall apart if HHS withholds grant money. | "Funding limitations will impact the number of agreements entered/deployments launched each year. The Postal Model is not funded through CRI, though cities who participate in the CRI will have priority due to threat feasibility. HHS/ASPR currently has a limited annual budget for deployments of the Postal Model."  
"HHS covers the expenses of the Postal Model program." - Subject Matter Expert Interview |
| 98    | Ongoing MCM Distribution | Assumption that antibiotics are ubiquitously available in the market has not been tested. | If antibiotic supply in the SNS plus the commercial market is inadequate to meet demand, potential for increased number of fatalities in event of an attack. | "They are concerned if there is sufficient amount of material in the SNS or in the commercial market." - Subject Matter Expert Interview  
"In the event of an anthrax emergency, there may not be enough retail supply to meet demand. Inventory is just in time. They do not maintain huge buffers in stores." - Subject Matter Expert Interview  
"Doxy and cipro are very much a part of a just-in-time system. In his experience, there is not very |
## Biological Attack Response and Recovery: End-to-End Medical Countermeasure Distribution and Dispensing Processes

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<td>99</td>
<td>Ongoing MCM Distribution</td>
<td>No process for leveraging supply of MCMs in private sector or what already is in place in the supply chain.</td>
<td>No organization currently responsible for coordinating with private sector to leverage supplies in market. May result in stockpiles of MCMs that are not used in emergency response.</td>
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<td>Currently, the plan is to solely use SNS assets. However, if availability of product runs low, or if the product cannot get to the intended location in time, it might be prudent to have a plan to leverage what supply is in the private sector supply chain.</td>
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<td>100</td>
<td>Ongoing MCM Distribution</td>
<td>There is a manpower and budget deficit for planning for and implementing ongoing MCM distribution. Infrastructure for distribution and dispensing is insufficient.</td>
<td>Insufficient personnel and resources can delay distribution of completion prophylaxis to public.</td>
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<td>Most grants for preparedness require cities to be able to respond in the 48-hour window. There are no funding requirements for processes beyond initial dispensing.</td>
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<td>“They will need fairly substantial personnel to carry out operations in days 11-60. Local personnel will be burned out by the end of day 10. They will need trained staff to come in from other locations and help with days 61-90.”</td>
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<td>101</td>
<td>Ongoing MCM Distribution</td>
<td>Surge production unknown, particularly for MCMs for other biological/radiological threats.</td>
<td>Potential that MCMs are not available to treat entire affected population in sufficient time can increase number of fatalities that result from attack.</td>
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<td>Most of the active ingredient for ciprofloxacin and doxycycline is produced overseas. Therefore, production capacity depends on the availability of those products, which may or may not be immediately available during an emergency.</td>
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<td>102</td>
<td>Ongoing MCM Distribution</td>
<td>Jurisdictions may be reluctant to share resources with the initially impacted areas for fear that they might be attacked as well.</td>
<td>In contrast to other disasters where national resources were shared with the affected area, because they were isolated incidents, the impacted city may be left with only local resources for ongoing response.</td>
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<td>“But Katrina was much easier to handle than a biological attack would be: the hurricane was largely predicted; as a result, evacuation (reducing the numbers of those affected) and preparation were possible; hurricanes and floods are familiar events and, though the New Orleans experience was extreme, it created well understood needs; the hurricane and related flooding peaked at a recognizable moment; restoration activities were not impeded as they would be if terrorist attacks were repeated, or by the spread of substantial contagion; and, perhaps most significantly, in the weeks after Katrina, the rest of the country was not afraid that it, too, would experience the same disaster, so there was a generous outpouring of support, intake of refugees, and largely unimpeded movement to the damaged city. By contrast, a bioterrorist attack on one city would raise the prospect of attacks on others. These differences all move in the same direction: they reinforce an assessment that citizens of a city stricken by bioterrorist attack will have to rely on their own resources to a degree not known in modern America.”</td>
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### Biological Attack Response and Recovery: End-to-End Medical Countermeasure Distribution and Dispensing Processes

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<tr>
<td>103</td>
<td>Ongoing MCM Distribution</td>
<td>After the initial SNS request, it is unclear whether the impacted area must request more MCMs or whether the CDC continues to push MCMs to the area.</td>
<td>Could result in a delay in receiving ongoing shipments if there is not a clear delineation of roles and expectations or if there is not a clear forecast for how many doses are needed.</td>
<td>No evidence was found to explain whether a push or pull model would take effect after the initial SNS distribution. It is unclear whether the CDC would continue to push medications to the affected location in large enough amounts to cover the entire population, or whether the jurisdictions would continue to request specified amounts of medications from the SNS. “States need supply and resupply strategies. Initiating the VMI has not been tested. In a true emergency, would they be able to resupply PODs?” - Subject Matter Expert Interview</td>
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<td>104</td>
<td>Ongoing MCM Distribution, Ongoing MCM Dispensing and Completion Prophylaxis</td>
<td>No definition of when prophylaxis can end; the 60-day clock starts from last date of exposure.</td>
<td>Ongoing distribution and dispensing could last much longer than people currently think, requiring more resources to be used for this response.</td>
<td>Since the 60-day clock starts when people are last exposed, any re-aerosolization or reload can restart the clock. Since re-aerosolization is not well understood, re-exposure may be difficult to define.</td>
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<td>105</td>
<td>Ongoing MCM Dispensing &amp; Completion Prophylaxis</td>
<td>If PODs are used for ongoing dispensing, it is unclear who will staff them for the post-48 hour time period.</td>
<td>May not have sufficient resources to staff PODs, especially if relying on volunteers or the same public health staff that participated in the initial response.</td>
<td>“They will need fairly substantial personnel to carry out operations in days 11-60. Local personnel will be burned out by the end of day 10. They will need trained staff to come in from other locations and help with days 11-60.” - Subject Matter Expert Interview</td>
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Since there are no completion prophylaxis plans established, this aspect of the plan has not been thought through.
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<tr>
<td>106</td>
<td>Ongoing MCM Dispensing &amp; Completion Prophylaxis</td>
<td>No way of tracking who receives medicines and how much they receive, so it will be unclear which members of the public need more doses of each MCM.</td>
<td>May result in people gaming the system and receiving more doses of medicines, while others do not receive enough (or any) MCMs. Also may result in people taking too much or too little MCMs or receiving the incorrect type of antibiotic every time they get the next dose.</td>
<td>&quot;There is no system for tracking people who have received medication through the POD system.&quot; - Subject Matter Expert Interview One city public health official noted, &quot;They will be tracking the number of medications given out, not the people who receive them. They will not be checking identification; the people will be required to fill out a basic form. The form goes back with the client with the medications.&quot; (Subject Matter Expert Interview) This means that in addition to not tracking medications in the initial dispensing phase, the patient will be required to remember which medication they received or to bring back their form to ensure they even receive the same medication.</td>
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<td>107</td>
<td>Ongoing MCM Dispensing &amp; Completion Prophylaxis</td>
<td>If hospitals are used for ongoing MCM dispensing, there is no plan to surge staff or planned space to conduct dispensing.</td>
<td>Hospitals will be already be oversubscribed and will be unable to undertake this task. May negatively impact ability to provide treatment to those who are already sick.</td>
<td>It is unlikely that hospitals will be used for ongoing dispensing due to their lack of surge capacity during an event of this magnitude. However, since there are no completion prophylaxis plans, all options were considered.</td>
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<td>108</td>
<td>Ongoing MCM Dispensing &amp; Completion Prophylaxis</td>
<td>Will be very difficult to ensure a follow-on dose is given to a mobile population.</td>
<td>Those that choose to flee the area or travel will be out of the reach of the POD network and will not be able to receive follow-on doses.</td>
<td>&quot;Strong need to plan for evacuation or remote PODs to be in place (account for those that have travelled or left the area).&quot; - Subject Matter Expert Interview &quot;The fact that the population will disperse after an event is so intuitive, but is not reflected in any planning documents.&quot; - Subject Matter Expert Interview</td>
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<td>109</td>
<td>Ongoing MCM Dispensing &amp; Completion Prophylaxis</td>
<td>Will be difficult to inform or provide assurance to a population in an affected area that they do not need to participate in completion prophylaxis.</td>
<td>Unaffected public may be wary of the government's instructions and wonder why they no longer need to take the medications; the &quot;worried well&quot; may be a greater amount of the population than expected.</td>
<td>&quot;There is a great possibility of a credibility gap. In days 11-60, there will be messaging saying that only a certain population needs to continue to receive countermeasures because they were exposed and others were not. This will cause a problem with public questioning and trusting the government. Convincing the rest of the population not to take countermeasures will be challenging.&quot; -- Subject Matter Expert Interview</td>
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## Biological Attack Response and Recovery: End-to-End Medical Countermeasure Distribution and Dispensing Processes

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<tr>
<td>110</td>
<td>Ongoing MCM Dispensing &amp; Completion Prophylaxis</td>
<td>No mechanism for ensuring that affected population will come back to pick up remaining dose for completion prophylaxis or that they will take their medications.</td>
<td>Morbidity and mortality rates could increase if affected population does not receive completion prophylaxis.</td>
<td>There is no method for ensuring or tracking public compliance to response measures. In a Harvard Survey, they asked about public views on whether they would start taking antibiotic pills right away or hold onto them, and 23% of adults who are likely to go to dispensing site saying they would be most likely to hold onto them for the foreseeable future. 10% of those polled say they were not likely to go to the dispensing site at all. If the population is unlikely to pick up or take medications initially, they will be less likely to go back and pick up follow-on doses and comply with the instructions for completing the 60-day course. - SteelFisher, Gillian and Robert Blendon. “The Public’s Response to Biological Terrorism: A Possible Scenario Involving the Release of Anthrax in an Unidentified Location.” Harvard Opinion Research Program: Harvard School of Public Health. 01 Feb. 2011. PPT.</td>
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<td>111</td>
<td>Ongoing MCM Dispensing &amp; Completion Prophylaxis</td>
<td>No plan or ability to reserve staff for ongoing dispensing activities - staff shortages at public health departments will require all staff to be part of the initial response.</td>
<td>Staff will likely suffer fatigue and may be unable or unwilling to continually staff PODs for completion prophylaxis.</td>
<td>Since public health staff is decreasing nationally because of budget cuts, there will be an inability to reserve any staff for completion prophylaxis planning or dispensing. “They will need fairly substantial personnel to carry out operations in days 11-60. Local personnel will be burned out by the end of day 10. They will need trained staff to come in from other locations and help with days 11-60.” - Subject Matter Expert Interview</td>
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<td>112</td>
<td>Ongoing MCM Dispensing &amp; Completion Prophylaxis</td>
<td>Since PODs are mostly government buildings like schools, ongoing dispensing from those sites would mean they cannot revert to their original role until after the response is complete.</td>
<td>Schools and other public buildings remain closed for up to 60 days.</td>
<td>“Those buildings serving as PODs would remain closed to their normal function for the duration of the response.” - Subject Matter Expert Interview</td>
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<td>114</td>
<td>Recovery</td>
<td>Goal for recovery is zero spores detected in the environment. What is acceptable elapsed time before re-occupying contaminated areas? Is 100% decontamination possible? Necessary?</td>
<td>&quot;We need to know if the 2001 standard of zero viable spores is necessary, or if there is a less rigid standard that is reasonable and acceptable. There are some research efforts underway to examine these issues, and these should be supported and encouraged.&quot; Committee on Homeland Security and Governmental Affairs. &quot;Ten Years After 9/11 and the Anthrax Attacks: Protecting Against Biological Threats.&quot; Testimony of Tom Inglesby. Hearing Before the United States Senate. One Hundred Twelfth Congress, First Session, 18 Oct. 2011. Web. <a href="https://www.hsdl.org/?view&amp;did=690886">https://www.hsdl.org/?view&amp;did=690886</a>. Accessed 04 Jan 2012. &quot;Despite these discussions and the suggested frameworks proposed by the NAS committee and CRS, no broad federal decisions have been made on the issue of a biological decontamination standard, particularly for a large outdoor biological release. Currently, the issue is unresolved and has been left to policymakers to settle in the midst of the next biological event. Furthermore, it is unclear where in the federal government these decisions lie.&quot; Franco, Crystal, and Nidhi Bouri. “Environmental Decontamination Following a Large-Scale Bioterrorism Attack: Federal Progress and Remaining Gaps.” Biosecurity and Bioterrorism 8.2 (2010) Print.</td>
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<td>115</td>
<td>Recovery</td>
<td>No quick reaction or interdiction tools to prevent follow-on attacks.</td>
<td>&quot;The United States has improved forensic capabilities that will facilitate long-term criminal investigation, but has not developed quick reaction and interdiction tools to prevent follow-on attacks. The inability to prevent follow-on attacks will have even more debilitating effects on capabilities, confidence, and morale than the initial attack.&quot; Danzig, Richard, Rachel Kleinfeld, and Philippe C. Bleek. “After an Attack: Preparing Citizens for Bioterrorism.” Washington, DC: Center for a New American Security, 2007: 4. Print.</td>
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<td>116</td>
<td>Recovery</td>
<td>Decontamination research and development for outdoor biological attacks have not been a national priority. The U.S. lacks standards and a strategy for mass decontamination and has only rudimentary capabilities in this area.</td>
<td>&quot;Environmental microbiology needs much more research. What is the risk of contracting a disease from a contaminated environment? After an attack, we will be left with having to describe what the risk is from secondary aerosolization. What do you tell the public? There is a big gap in the science. What do people do to ‘clean’ their private residences? What do you tell individuals to reduce risk in their private spaces?” - Subject Matter Expert Interview &quot;EPA will focus on critical infrastructure, but there is a gap in the science in secondary aerosolization (spores will last for decades in the environment).” - Subject Matter Expert Interview &quot;Much research has been conducted on decontamination of an indoor environment; not much has been done on outdoor environments.&quot; - Subject Matter Expert Interview &quot;Because there are few historical examples of aerosolized releases, we have limited information regarding the level of infectivity and aerosol dynamics of anthrax spores deposited on surfaces. We don’t know how likely B. anthracis spores are to cause disease in humans after resuspension, and we do know the probability of re-suspension can differ depending on surface (i.e., concrete,</td>
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**Appendix III: List of Additional Recommendations**

The following table provides a list of the remainder of the recommendations from this analysis. The recommendations are not listed in priority order.

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<th>Recommendation</th>
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| **Provide First Responders and Their Families with Pre-Event Vaccination**    | Reduce time to respond and dispense by ensuring first responders (and their families) receive vaccination before attack and can immediately respond.                                                                                                                                                                                                                                                                                                                                              | • **Gap 12, Overall**: It is unclear if/when vaccinations will be used, if at all.  
• **Gap 42, Prepare for MCM Dispensing**: Few or no caches at the state or local level mean that MCMs may not be immediately available to first responders when the event has been announced, preventing their ability to respond before SNS assets arrive.  
• **Gap 76, Initial MCM Distribution**: No standard defined process for providing MCMs to first responders.  
• **Gap 82, Initial MCM Dispensing**: Security personal accompanying postal volunteers are not provided with home MedKits for themselves or their families.  
• **Gap 87, Initial MCM Dispensing**: Uniformed officers escorting postal employees may not be provided with N-95 masks.  
• **Gap 104, Ongoing MCM Distribution and Completion Prophylaxis**: No definition of when prophylaxis can end; the 60-day clock starts from last date of exposure. |
| **Develop a Safe Vaccine for Children, the Elderly, and Other At-Risk Populations** | The current vaccine has not been tested or deemed safe for use in at-risk groups, such as children and the elderly. A vaccine needs to be developed that is safe and effective in these groups.                                                                                                                                                                                                                                                                                               | • **Gap 12, Overall**: There is no way to track or identify people with adverse reactions to medications.  
• **Gap 31, Plan for MCM Dispensing**: The current vaccine is not suitable for children and elderly, and would require an IND if the government were to administer it to these at-risk populations.  
• **Gap 43, Prepare for MCM Dispensing**: Little research into treatment for children, elderly, and other at-risk groups.                                                                                                                                                                                                 |                                                                                                                                                                          |
| **Increase the Quantity of Vaccine in the SNS to Cover Demand in Several Large MSAs** | Currently, the SNS possesses enough vaccine to cover approximately one large MSA. In the event of reload or a multi-city attack, vaccine will be scarce. The U.S. should                                                                                                                                                                                                                                                                                                                                 | • **Gap 11, Overall**: It is unclear if/when vaccinations will be used, if at all.  
• **Gap 37, Plan for MCM Dispensing**: Vaccine supply not sufficient for large-scale deployment.                                                                                                                                                                                                                                                                                                           |
have enough vaccine to cover several large MSAs to combat these scenarios.

- **Gap 102, Ongoing MCM Distribution:** Jurisdictions may be reluctant to share resources with the initially impacted areas for fear that they might be attacked as well.

### Invest in the Development of New Vaccines that are Safer and Can be Administered in a Single Dose

The current anthrax vaccine requires the initial dose with several boosters for immunity to take effect and can have many side effects. A new vaccine should be developed which only requires one dose and is safer for wide administration.

- **Gap 12, Overall:** There is no way to track or identify people with adverse reactions to medications.

- **Gap 56, Prepare for MCM Dispensing:** Little research in improving treatment types or outcomes.

- **Gap 106, Ongoing MCM Dispensing and Completion Prophylaxis:** No way to track who receives medicines and how much they receive, so it will be unclear which members of the public need more doses of each MCM.

- **Gap 108, Ongoing MCM Dispensing and Completion Prophylaxis:** Will be very difficult to ensure a follow-on dose is given to a mobile population.

- **Gap 110, Ongoing MCM Dispensing and Completion Prophylaxis:** No mechanism for ensuring that affected population will come back to pick up [or receive] remaining dose for completion prophylaxis or that they will take their medications.

### Develop Real-Time Pre-Symptomatic Diagnostic Capabilities

Invest in development of technologies capable of rapidly determining affected population/infected individuals.

- **Gap 55, Prepare for MCM Dispensing:** Little investment in clinical diagnostics or triage methods to quickly identify those infected with a biological agent.

- **Gap 63, Detect and Characterize Event:** Federal, state and local governments anticipate that they will have epidemiological results within the initial 10-day response period so that they can narrow down population requiring MCMs.

- **Gap 109, Ongoing MCM Dispensing and Completion Prophylaxis:** Will be difficult to inform or provide assurance to a population in an affected area that they do not need to participate in completion prophylaxis.

### Develop Scalable Real-Time Biological Agent Detection Capabilities

Invest in affordable real-time biological agent detection technologies, particularly environmental and/or technologies that can detect small- and large-scale attacks.

- **Gap 58, Detect and Characterize Event:** Lag time between when event happens and when it is confirmed is significant. Mechanisms for detection are largely reactive and time consuming. No real-time detection technology.

- **Gap 59, Detect and Characterize Event:**
Physicians are not inclined to think bioterror in diagnosing – first cases may be overlooked.

- **Gap 67, Detect and Characterize Event**: No environmental detection system available for small attacks or attacks outside sensor network cities. Minimum detectable attack driven by density of installation and threshold of detection of sensor. How can smaller attacks, defined as affecting less than X.XXX people, be differentiated from larger scale attacks? How will response differ?

- **Gap 78, Initial MCM Distribution**: Time to detect and characterize event, make decision to mobilize SNS, and then distribute may be significantly longer than planned. Actual time may be greater than 48 hours.

<table>
<thead>
<tr>
<th>Develop Next Generation Treatments for Symptomatic Population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Post-symptomatic treatment is highly resource-intensive, requiring respirators and plural drainage, and is only 55% effective. New treatments should be developed that require fewer resources and less hospital capacity and that have a higher effectiveness rate.</td>
</tr>
</tbody>
</table>

- **Gap 43, Prepare for MCM Dispensing**: Little research into treatment for children, elderly and other at-risk groups.

- **Gap 56, Prepare for MCM Dispensing**: Little research in improving treatment types or outcomes.

<table>
<thead>
<tr>
<th>Develop Response and Recovery Contingency Plans</th>
</tr>
</thead>
<tbody>
<tr>
<td>Develop contingency plans to account for unplanned population behavior, delayed timelines, unexpected hurdles, and failure of task execution.</td>
</tr>
</tbody>
</table>

- **Gap 3, Overall**: No flexibility built in plans/contingency plans to account for population behavior.

- **Gap 10, Overall**: There is a tendency to double- or triple-count available resources when constructing response plans.

- **Gap 21, Overall**: Impact of multi-drug resistant agents on response is not understood, particularly the need for flexibility and the potential for loss of public confidence.

- **Gap 29, Plan for MCM Dispensing**: Lack of layered contingency planning for POD locations in event of large area contamination, evacuation or shelter in place.

- **Gap 36, Plan for MCM Dispensing**: No clear plan for alternate prophylaxis to address MDR strains.

- **Gap 46, Prepare for MCM Dispensing**: POD network may not be periodically reviewed and updated in all locations.

- **Gap 53, Prepare for MCM Dispensing**: 
Dependent entirely on volunteers and state/local public health staff to ensure dispensing to the public. Assumption that anywhere from 10-60% of volunteers will show up in an actual event.

- **Gap 84, Initial MCM Dispensing**: Unclear if traffic and/or road closures have been accounted for in distribution and dispensing drills.
- **Gap 91, Initial MCM Dispensing**: PODs are resource-intensive. Inordinate amount of burden placed on volunteers. Duration of shifts unsustainable over long time period.

### Increase Information Sharing Between States and Localities to Enable Better Communication and Collaboration in Preparation and Event Response

<table>
<thead>
<tr>
<th>Gap</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1, Overall</td>
<td>Heavy reliance on public health departments for preparedness and response. These departments are experiencing huge amounts of turnover; attrition rates lead to understaffing at public health centers; lack of institutional knowledge. Preparedness is not a priority within most state and local health departments.</td>
</tr>
<tr>
<td>2, Overall</td>
<td>Regional response plans are developed on an ad hoc basis depending upon the initiative of the state and local health departments (e.g., VA, MD, and DC or NY, NYC, NJ, and CT).</td>
</tr>
<tr>
<td>39, Plan for MCM Dispensing</td>
<td>State, local and county plans may differ significantly. Operational plans, rules, regulations, requirements may differ during an event. The concept of “home rule” further complicates response capabilities.</td>
</tr>
<tr>
<td>73, Initial MCM Distribution</td>
<td>Response plans may differ significantly across states and localities. Autonomy of jurisdictions can create confusion in the supply chain (e.g., separate demands on distributors).</td>
</tr>
<tr>
<td>74, Initial MCM Distribution</td>
<td>Lack of consistency and guidance at state and local levels creates complexity in distribution planning and response.</td>
</tr>
<tr>
<td>90, Initial MCM Dispensing</td>
<td>Processes and procedures at PODs differ among states and localities (e.g., providing identification, filling out forms, picking up certain amounts). No nationwide directives on POD processes.</td>
</tr>
</tbody>
</table>

### Develop Uniform Documentation and Standardization of

<table>
<thead>
<tr>
<th>Gap</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>2, Overall</td>
<td>Regional response plans are developed on an ad hoc basis depending upon the initiative of the state</td>
</tr>
</tbody>
</table>
### Biological Attack Response and Recovery: End-to-End Medical Countermeasure Distribution and Dispensing Processes

#### Dispensing Procedures at the State and Local Levels

<table>
<thead>
<tr>
<th>Gap 4, Overall:</th>
<th>“Home rule” creates a complicated structure that inhibits a coordinated national response.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gap 39, Plan for MCM Dispensing:</td>
<td>State, local and county plans may differ significantly. Operational plans, rules, regulations, requirements may differ during an event. The concept of “home rule” further complicates response capabilities.</td>
</tr>
<tr>
<td>Gap 90, Initial MCM Dispensing:</td>
<td>Processes and procedures at PODs differ among states and localities (e.g., providing identification, filling out forms, picking up certain amounts). No nationwide directives on POD processes.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Gap 5, Overall:</th>
<th>Metrics exist to measure preparedness, but may not be appropriate to measure system effectiveness once it is stressed. No one has run an end-to-end, unscripted drill. Preparedness does not equate to response capabilities.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gap 20, Overall:</td>
<td>High-consequence decision making with limited information is necessary, but many organizations and officials are not prepared, trained or capable of making timely life-or-death decisions.</td>
</tr>
<tr>
<td>Gap 25, Overall:</td>
<td>This process has never been exercised end-to-end, resulting in “best guesses” of the time it will take. It is likely to take much longer than predicted.</td>
</tr>
<tr>
<td>Gap 27, Plan for MCM Dispensing:</td>
<td>POD logistics and security have not been stress tested at the local level.</td>
</tr>
<tr>
<td>Gap 45, Prepare for MCM Dispensing:</td>
<td>Exercises to date have never focused on truly stressing the system. Focus has been on data collection and local process optimization instead of end-to-end improvements and outcomes.</td>
</tr>
<tr>
<td>Gap 48, Prepare for MCM Dispensing:</td>
<td>Public has not been involved in many exercises, and there is a lack of public awareness on response processes.</td>
</tr>
<tr>
<td>Gap 50, Prepare for MCM Dispensing:</td>
<td>There is a lack of exercises that test high-</td>
</tr>
</tbody>
</table>

#### Develop More Comprehensive Exercises to Test/Stress Plans

| Plan and conduct exercises to test pre-existing plans under simulated bioterrorism conditions to better train state/local governments, responders, and high-level decision makers. Identify areas requiring additional resources, contingency plans, or completely different plans. |
| --- | --- |
| Gap 5, Overall: | Metrics exist to measure preparedness, but may not be appropriate to measure system effectiveness once it is stressed. No one has run an end-to-end, unscripted drill. Preparedness does not equate to response capabilities. |
| Gap 20, Overall: | High-consequence decision making with limited information is necessary, but many organizations and officials are not prepared, trained or capable of making timely life-or-death decisions. |
| Gap 25, Overall: | This process has never been exercised end-to-end, resulting in “best guesses” of the time it will take. It is likely to take much longer than predicted. |
| Gap 27, Plan for MCM Dispensing: | POD logistics and security have not been stress tested at the local level. |
| Gap 45, Prepare for MCM Dispensing: | Exercises to date have never focused on truly stressing the system. Focus has been on data collection and local process optimization instead of end-to-end improvements and outcomes. |
| Gap 48, Prepare for MCM Dispensing: | Public has not been involved in many exercises, and there is a lack of public awareness on response processes. |
| Gap 50, Prepare for MCM Dispensing: | There is a lack of exercises that test high- |
Develop Better Definition of Roles, Responsibilities, and Expectations of Event Characterization

Delineate roles and responsibilities for all entities involved in agent/event characterization, and set appropriate expectations around characterization timelines so they may be incorporated in response plans.

- **Gap 51, Prepare for MCM Dispensing:** Exercises focus only on isolated and specific pieces of the process (e.g., setting up one POD).

- **Gap 57, Detect and Characterize Event:** There are multiple organizations involved in collecting event information (including JTTF, CDC, FBI). Process owner is ambiguous. Responsibility and accountability is also ambiguous. There is no clear coordinating body for all the collected event information.

- **Gap 60, Detect and Characterize Event:** Time required to determine the strain or characteristics of the bioagent may lag behind distribution of MCMs.

- **Gap 63, Detect and Characterize Event:** Federal, state and local government anticipate that they will have epidemiological results within the initial 10-day response period so that they can narrow down population requiring MCMs.

- **Gap 66, Detect and Characterize Event:** There is a general lack of understanding of the level of effort to test and characterize a wide-area biological event. Lack of a clear plan of how to determine spatial extent of an attack or how long this will take.

- **Gap 68, Detect and Characterize Event:** Lack of clear goals or guidelines for time to determine pathogen strain and required treatment.

- **Gap 78, Initial MCM Distribution:** Time to detect and characterize event, make decision to mobilize SNS, and then distribute may be significantly longer than planned. Actual time may be greater than 48 hours.

Test Capability of Medical Information Systems

Conduct test of medical information systems (e.g. HAN) to keep pace with rapidly developing scenario.

- **Gap 58, Detect and Characterize Event:** Lag time between when event happens and when it is confirmed is significant. Mechanisms for detection are largely reactive and time consuming. No real-time detection technology.

- **Gap 59, Detect and Characterize Event:** Physicians are not inclined to think bioterror in diagnosing – first cases may be overlooked.

- **Gap 60, Detect and Characterize Event:**
<table>
<thead>
<tr>
<th>Time required to determine the strain or characteristics of the bioagent may lag behind distribution of MCMs.</th>
</tr>
</thead>
<tbody>
<tr>
<td>• <strong>Gap 64, Detect and Characterize Event</strong>: No integration between national biosurveillance systems.</td>
</tr>
<tr>
<td><strong>Create Federal Guidance/Training for Recovery Processes</strong></td>
</tr>
<tr>
<td>Develop and provide standardized guidance and training around roles, responsibilities, expectations and tasks involved in recovery process to federal, state, and local stakeholders.</td>
</tr>
<tr>
<td>• <strong>Gap 30, Plan for MCM Dispensing</strong>: Federal guidance comes in the form of recommendations, rather than clear directives.</td>
</tr>
<tr>
<td>• <strong>Gap 114, Recovery</strong>: Goal for recovery is zero spores detected in the environment. What is acceptable elapsed time before re-occupying contaminated areas: Is 100% decontamination possible? Necessary?</td>
</tr>
<tr>
<td>• <strong>Gap 116, Recovery</strong>: Decontamination research and development for outdoor biological attacks have not been a national priority. The U.S. lacks standards and a strategy for mass decontamination and has only rudimentary capabilities in this area.</td>
</tr>
<tr>
<td>• <strong>Gap 117, Recovery</strong>: Insufficient guidance and training provided by EPA to state and local health departments on processes and procedures related to decontamination.</td>
</tr>
</tbody>
</table>
Appendix IV: List of Primary Interviewees

The following is a partial list of individuals who were interviewed for the purpose of this report. Affiliations listed reflect the individual’s primary association as of the date of the interview. Additional follow-on interviews and group meetings were held with multiple representatives of stakeholder organizations including DHS Office of Health Affairs and HHS Office of the Assistant Secretary for Preparedness and Response.

Alex Adams, National Association of Chain Drug Stores
Parney Albright, Lawrence Livermore National Laboratory
Rhett Asher, Food Marketing Institute
Sid Baccam, Innovate Emergency Management, Inc.
Gerritt Bakker, ASTHO
James Blumenstock, ASTHO
Ted Brown, President Ketch Consulting
Greg Burel, Strategic National Stockpile, CDC
Jack Cantlin, Walgreens
Richard Danzig, SME, Center for a New American Security
Stephanie Dulin, Strategic National Stockpile, CDC
Gerald Epstein, DHS Policy
Matthew Feltman, Kroger/Giant
Jack Herrmann, NACCHO
Bob Hooks, Office of Health Affairs, DHS
Nathaniel Hupert, CDC and Weill Medical College, Cornell University
John Kavanagh, PwC, former Federal Bureau of Investigation
Ali Khan, Office of Public Health Preparedness and Response, CDC
Lisa Koonin, Office of Infectious Diseases, CDC
George Korch, Office of the Assistant Secretary for Preparedness and Response, HHS

Cyndi Lake, City of Alexandria Department of Health
Eva Lee, Georgia Institute of Technology, Georgia Tech University
Carter Mecher, Veterans Administration
Matthew Minson, Texas A&M University, former Office of the Assistant Secretary for Preparedness and Response, HHS
Bob Mauskapf, Virginia Department of Health
Nicki Pesik, Anthrax Management Team, CDC
Jude Plessas, United States Postal Service
Cathy Polley, Food Marketing Institute
Mike Rackley, Target
Bill Raub, Former HHS
Ken Rapuano, MITRE
Michael Robbins, Chicago Department of Public Health
Daniel Sosin, Coordinating Office of Terrorism Preparedness and Emergency Response, CDC
David Starr, New York City Department of Health and Mental Hygiene
Tracee Treadwell, Anthrax Management Team, CDC
Isaac Weisfuse, New York City Department of Public Health and Mental Hygiene
Appendix V: Acronym List

The following acronyms were used in this report.

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>ASPR</td>
<td>Office of the Assistant Secretary for Preparedness and Response</td>
</tr>
<tr>
<td>AVA</td>
<td>Anthrax Vaccine Adsorbed</td>
</tr>
<tr>
<td>BARDA</td>
<td>Biomedical Advanced Research and Development Authority</td>
</tr>
<tr>
<td>BNA</td>
<td>Biodefense Net Assessment</td>
</tr>
<tr>
<td>BTRA</td>
<td>Bioterrorism Risk Assessment</td>
</tr>
<tr>
<td>BWICS</td>
<td>Biological Warning and Incident Characterization System</td>
</tr>
<tr>
<td>CBPP</td>
<td>Center on Budget and Policy Priorities</td>
</tr>
<tr>
<td>CBRNE</td>
<td>Chemical, Biological, Radiological, Nuclear, Explosive</td>
</tr>
<tr>
<td>CDC</td>
<td>Centers for Disease Control and Prevention</td>
</tr>
<tr>
<td>CRI</td>
<td>Cities Readiness Initiative</td>
</tr>
<tr>
<td>DEOC</td>
<td>Director’s Emergency Operations Center</td>
</tr>
<tr>
<td>DHS</td>
<td>Department of Homeland Security</td>
</tr>
<tr>
<td>DOD</td>
<td>Department of Defense</td>
</tr>
<tr>
<td>DOE</td>
<td>Department of Energy</td>
</tr>
<tr>
<td>DOJ</td>
<td>Department of Justice</td>
</tr>
<tr>
<td>EAU</td>
<td>Emergency Use Authorization</td>
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<tr>
<td>ED</td>
<td>Emergency Department</td>
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<tr>
<td>EO</td>
<td>Executive Order</td>
</tr>
<tr>
<td>EPA</td>
<td>Environmental Protection Agency</td>
</tr>
<tr>
<td>ESSENSE</td>
<td>Electronic Surveillance System for the Early Notification of Community-based Epidemics</td>
</tr>
<tr>
<td>FBI</td>
<td>Federal Bureau of Investigation</td>
</tr>
<tr>
<td>FDA</td>
<td>Food and Drug Administration</td>
</tr>
<tr>
<td>FEMA</td>
<td>Federal Emergency Management Agency</td>
</tr>
<tr>
<td>HAN</td>
<td>Health Alert Network</td>
</tr>
<tr>
<td>HHS</td>
<td>Department of Health and Human Services</td>
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<tr>
<td>IC</td>
<td>Intelligence Community</td>
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<tr>
<td>ICU</td>
<td>Intensive Care Unit</td>
</tr>
<tr>
<td>IND</td>
<td>Investigational New Drug</td>
</tr>
<tr>
<td>Acronym</td>
<td>Definition</td>
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<td>---------</td>
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<tr>
<td>IOM</td>
<td>Institute of Medicine</td>
</tr>
<tr>
<td>IV</td>
<td>Intravenous</td>
</tr>
<tr>
<td>JTTF</td>
<td>Joint Terrorism Task Force</td>
</tr>
<tr>
<td>MCM</td>
<td>Medical Countermeasures</td>
</tr>
<tr>
<td>MDR</td>
<td>Multi-Drug Resistant</td>
</tr>
<tr>
<td>MOU</td>
<td>Memorandum of Understanding</td>
</tr>
<tr>
<td>MSA</td>
<td>Metropolitan Statistical Area</td>
</tr>
<tr>
<td>MSP</td>
<td>Minneapolis/St. Paul</td>
</tr>
<tr>
<td>NAS</td>
<td>National Academy of Sciences</td>
</tr>
<tr>
<td>NBIC</td>
<td>National Biosurveillance Integration Center</td>
</tr>
<tr>
<td>NBIS</td>
<td>National Biosurveillance Information System</td>
</tr>
<tr>
<td>PHEMCE</td>
<td>Public Health Emergency Medical Countermeasures Enterprise</td>
</tr>
<tr>
<td>PHEP</td>
<td>Public Health Emergency Preparedness</td>
</tr>
<tr>
<td>POD</td>
<td>Points of Dispensing</td>
</tr>
<tr>
<td>RSS</td>
<td>Receiving, Staging and Storage</td>
</tr>
<tr>
<td>SLEP</td>
<td>Shelf Life Extension Program</td>
</tr>
<tr>
<td>SNS</td>
<td>Strategic National Stockpile</td>
</tr>
<tr>
<td>TAR</td>
<td>Technical Assistance Review</td>
</tr>
<tr>
<td>TOPOFF</td>
<td>Top Officials</td>
</tr>
<tr>
<td>UA</td>
<td>Universal Adversary</td>
</tr>
<tr>
<td>USDA</td>
<td>United States Department of Agriculture</td>
</tr>
<tr>
<td>USG</td>
<td>United States Government</td>
</tr>
<tr>
<td>USPS</td>
<td>United States Postal Service</td>
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<tr>
<td>VMI</td>
<td>Vendor Managed Inventory</td>
</tr>
<tr>
<td>WARRP</td>
<td>Wide Area Recovery and Resiliency Program</td>
</tr>
<tr>
<td>WMD</td>
<td>Weapons of Mass Destruction</td>
</tr>
</tbody>
</table>
Appendix VI: Bibliography

The following bibliography demonstrates the depth and scope of the documents analyzed for this study:


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