7 March 2012

U.S. Department of Homeland Security
Science & Technology Directorate
Chemical - Biological Division
Washington, DC  20528

Attention:  Mr. Christopher Russell
PM, Wide Area Recovery & Resiliency Program (WARRP)

Subject:  WARRP Analytic Support of Emergency Response and Recovery (ASERR)
aka Medical Countermeasures (MCM) Statement of Work
Deliverable:  Presentation Material Findings Brief
IAA#: HSHQDC-11-X-00544
Contract#:  N66001-10-D-0015, T.O. 0019

Dear Mr. Russell:

Enclosed is a deliverable, “Presentation Material Findings Brief”, covering efforts related to Task 1 of the subject Statement of Work under CDRL A008.

If there are any questions concerning this report, please contact me at 619-553-5410 or 6899.

Sincerely,

Douglas R. Hardy
SSC Pacific 53627
53560 Hull Street
San Diego, CA  92152
Findings brief covering an assessment of the current process for distributing and dispensing medical countermeasures (MCM), including pills and vaccines, to an affected population. This assessment included identifying key gaps in the current process, an estimate of distribution and dispensing times associated with these processes including delivery or dispensing failure rates, the impact of delays, composition of population (trust of government, ability to follow directions, trust of medical treatment), impact of the physical pattern of delivery failure, an analysis of the various drug companies involved in the MCM supply chain and their capabilities/vulnerabilities to supply disruptions, and an assessment from an MCM point of view of the U.S. Governments capabilities to respond to multiple simultaneous attacks that would be consistent with a reload scenario.
Analytic Support of Emergency Response and Recovery for the Wide-Area Recovery & Resiliency Program (WARRP)

Task 1: Medical Countermeasures Response

Findings Brief
February 23, 2012

Deliverable: A008 - 4
Submitted by: Stokes Evans Limited
Contract #: N66001-10-D-0015, G2 Software Systems, Inc.
Subcontract #: Stokes Evans Limited-0015-005
Agenda for Today

• Approach
• Findings
  – Themes and Interview Results
  – Top Recommendations
  – Additional Recommendations
• Revised Report Structure
• Detailed Gaps
• Status
  – Schedule
  – Risks
  – Process Model
  – Interviews
  – Research
APPROACH
Recovery is dependent on several response outcomes: saving lives, controlling movement, and swift rehabilitation.

Components of Successful Response:

- **Enable Recovery**
  - Dispense MCM to entire potentially affected population within 96 hour window
  - Positively characterize event as quickly as possible
  - Complete prophylaxis of affected or entire population
  - Monitor effectiveness of antibiotics
  - Treat the sick
  - Minimize re-exposure or secondary exposure
  - Vaccinate?

- **Minimize Morbidity**
  - Positively characterize event as quickly as possible
  - Provide security / maintain confidence in government
  - Communicate with public
  - Offer economic incentives and direct support (food)
  - Vaccinate?

- **Control Flight**
  - Positively characterize event as quickly as possible
  - Minimize re-exposure potential
  - Decontaminate commercial and residential areas
  - Offer economic incentives and direct support
  - Vaccinate?

- **Reoccupy Quickly**
  - Positively characterize event as quickly as possible
  - Minimize re-exposure potential
  - Decontaminate commercial and residential areas
  - Offer economic incentives and direct support
  - Vaccinate?
Our Focus - Reduce Morbidity and Mortality: MCMs must reach as much of the population as possible without delays

Delays in distribution and dispensing have life and death effects

Delays or gaps in dispensing can add tens of billions of dollars to recovery – even in limited planning case

<table>
<thead>
<tr>
<th></th>
<th>Number Dead*</th>
<th>Additional Deaths</th>
<th>Additional Human Cost**</th>
</tr>
</thead>
<tbody>
<tr>
<td>Best Case: 100% prophylaxis with 96 hours</td>
<td>14,400</td>
<td></td>
<td></td>
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<tr>
<td>24 Hour Delay in beginning prophylaxis</td>
<td>21,600</td>
<td>7,200</td>
<td>$56.8 B</td>
</tr>
<tr>
<td>10% “missed” plus 24 hour delay for 30%</td>
<td>26,160</td>
<td>11,760</td>
<td>$92.9 B</td>
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</tbody>
</table>

For 120,000 exposed/infected:
- One lost hour > $2.3 Billion cost
- Missed 1% of population > $8.7 Billion

* Based on exposed population of 120,000
**Based on FDA figure of $7.9 million per life, 2011

Modeling the Incubation Period of Inhalational Anthrax
Dean A. Wilkening, 2008
The end-to-end process model developed for the project helped us identify and classify over 100 potential gaps.

- Gaps were defined as potential areas of process failure or contributors to failure elsewhere in the response or recovery phases:
  - Anything that delayed initial dispensing
    - Decision making
    - Logistics
    - Process coordination
    - Communication
  - Anything that decreased the likelihood of a 100% response
    - Use of contingency systems versus existing systems
    - Departures from normal processes
    - Reliance on the public
    - Lack of redundancy
  - Anything that decreased confidence in government
Analysis of the gaps and a broader system-level assessment helped to form over 25 recommendations.

Recommendations have been prioritized by looking at value and cost trade-offs.

**Value**
- Scope of impact
  - National
  - Individual States / Locals
  - PODs
- Value of outcome

**Cost / Difficulty**
- Cost to implement
- Concentration of authority
  - One decision maker or many?
- Understanding of problem
  - Do we need additional study?
Real world outcomes of MCM Distribution and Dispensing

Value can be affected at many levels, with compounding effects:

- Nation
- Region
- State
- Demographic
- City
- Zip Code
- POD

Results

- Value created
- Desired outcomes

Value = measurable impact on results

- Could be change in outcome or change in likelihood of a desirable result

Value or Output metrics:

- % and # of MCM dispensed in 96 hours
- Total time until 95% MCM dispensed
- % of potentially exposed confirmed as “in or out” within XX hours
- % and # of potentially exposed to get sick
- % and # of potentially exposed to die
- Ratio of those requiring 60 day course to initial potentially exposed population
- Ratio of those requiring 60 day course to those completing 60 day course
- % and # of people fleeing area
- Days from event to XX% repopulation

Processes

- What is supposed to happen
- 8 MCM elements
- Decision making

Systems

- Control / Correct
- Reward
- Automate / Practice
- Redundancy
- Checks / Balances

People

- Communication
- Base needs (fear)
- Skills / Training / Attitude
- Team / Community

Behavior

“What people really do”

Process / behavior metrics:

- % / # of worker no shows
- % / # of late or missed shipments
- % / # PODs delayed or closed
- # of security incidents
- Actual versus expected demand by POD
- #, frequency and severity of stock-outs
- MCM dispensed per hour by POD
We have completed our data gathering and have shifted to analysis and reporting.

- Over 100 Process Gaps have been identified and analyzed
- Outcome measures for the end-to-end response/recovery process have been developed
- Over 25 specific recommendations have been analyzed for impact, cost to implement, and difficulty to implement
- A systems analysis of the overall distribution and dispensing framework has commenced
- Work has started on preparing the draft report
FINDINGS
Findings: Themes and Interview Results

1. No clear answer to “who’s in charge?”

- No clarity as to federal vs. local problem
- No clarity as to roles and responsibilities among federal agencies

Interview quotes:
- “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.”
- “The number one gap in the process is the perceived disconnect among federal agencies. 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?”
- “Locals struggle with understanding the roles and responsibilities during an emergency response. Who’s in charge? What are the legal issues?”

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

- Decision makers may be forced to make a decision with inaccurate, incomplete, or non-existent information

Interview quotes:
- “There is no standardization of plans between feds, states, and locals as far as decision-making during an event.”
- “One of the biggest gaps is looking at a continuum, or looking at the end-to-end process. We are deficient on socializing crisis decision making to leaders – the same leaders that need to be driving critical preparedness steps.”
- “We have not thought enough about the level of consequence of delayed decision making.”
- “We need leaders who are willing to make hard decisions. The best laid plans are going to be futile without this.”
3. State and local plans are developed independently without clear directives, and there is no overarching coordination for response plan execution

- No acceptable venue for sharing information or best practices
- All federal help comes in the form of recommended guidance, which states and locals can choose to accept, or not

Interview quotes:

- “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.”
# Findings: Themes and Interview Results

## 4. A local public health approach does not appreciate the urgency of the situation or the intent of a thinking adversary

- Scientists and PH officials rely on constant data collection and evidence to make high-consequence decisions

**Interview quotes:**
- “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. No planning has been done around post-48 hour response and recovery

- There are no definitive plans for administering completion prophylaxis
- “Recovery” has not been defined, so planners do not know how to achieve that outcome

**Interview quotes:**
- “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.”
## Findings: Themes and Interview Results

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

- Very few stakeholders have pre-scripted communications
- No clear overarching communications guidance from any entity

**Interview quotes:**

- “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 planning is done for one city scenarios with treatable strains

**Interview quotes:**

- “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 more resources as best as they can to address two problems. A double strike and/or antibiotic resistance would cause a real problem.”
## Findings: Themes and Interview Results

### 8. No clear and consistent national plan for leveraging the private sector for distribution and dispensing

- Any agreements with the private sector are done on an ad hoc basis by individual states and localities

**Interview quotes:**
- “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. In a multi-city attack, there may be inadequate amount of product available nationwide in both the SNS and the private sector supply chain

- For these ubiquitous antibiotics, the private sector relies on a just-in-time system due to the predictability of demand; these products are not stockpiled within hospitals or pharmacies

**Interview quotes:**
- “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?”
10. An adequate workforce for both planning and response is a major issue because of the decrease in Departments of Health staffing and heavy reliance on volunteers

- Locals may not have enough resources to respond to an attack of this magnitude on their own

**Interview quotes:**

- “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.”
Findings: Themes and Interview Results

11. Funding cuts 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
- Funding cuts are prevalent across the board in the federal government

Interview quotes:
- “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 bioattack, including MCM distribution and dispensing

- Planning has not been done with the end goal in mind
- Reasonable and practical metrics have not been established to measure the effectiveness of this process

Interview quotes:
- “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.”
## Findings: Top Recommendations

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. <strong>Put the Federal Government in Charge of Bioterrorism Response</strong></td>
<td>Federal government should take responsibility for directing a national response to bioterrorism, including MCM distribution and dispensing</td>
</tr>
<tr>
<td>2. <strong>Assess the Adequacy of Strategic Communications</strong></td>
<td>Review and refine strategic communications to ensure they are correct, consistent, and constant, and that they are distributed to appropriate communication channels pre-event</td>
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<tr>
<td>3. <strong>Develop Plan to Address Multi-Drug Resistant Strain Vulnerabilities</strong></td>
<td>Develop standardized pre-determined response plan for an MDR strain</td>
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</table>
| 4. **Increase Regional and National Use of Retail Drug Stores and Commercial Partners**                                                           | Consider the use of: \(\begin{align*}
\text{• Pre-developed regional retail prescription databases} \\
\text{• Pharmacies as open PODs to supplement public PODs} \\
\text{• Tier 1 - Big Box retailers for mass distribution, Tier 2 - Pharmacies for refilling MCMs}
\end{align*}\) |
| 5. **Expand “Push” Dispensing Models for Initial Antibiotic Dispensing**                                                                        | Expand “Push” dispensing model (including postal model) to additional cities/regions to provide a quick strike and supplement public PODs            |
| 6. **Concurrent Antibiotic Dispensing and Vaccination During the First Several Days**                                                             | Utilize POD model to dispense antibiotics as well as vaccines to affected population during initial response period (vaccination POD and pill POD) |
| 7. **Plan for Providing MCMs for Completion Prophylaxis**                                                                                         | Develop standardized plan included roles and responsibilities for obtaining, distributing, and dispensing MCMs to affected population for completion prophylaxis |
### Findings: Additional Recommendations (not in priority order)

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>Description</th>
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<tbody>
<tr>
<td>Provide Volunteers/Public Servants and Families with Home Med Kits</td>
<td>Reduce time to respond and dispense by ensuring volunteers/public servants (and their families) have antibiotic prophylaxis for immediate use after attack</td>
</tr>
<tr>
<td>Provide Volunteers/Public Servants and Their Families with Pre-Event Vaccination</td>
<td>Reduce time to respond and dispense by ensuring volunteers/public servants (and their families) receive vaccination before attack and can immediately respond</td>
</tr>
<tr>
<td>Develop Flexibility and/or Contingencies to Current Plans</td>
<td>Develop contingency plans to account for unplanned population behavior, delayed timelines, and failure of task execution</td>
</tr>
<tr>
<td>Increase Sharing of MCM Distribution and Dispensing Best Practices Between States</td>
<td>Create additional forums for discussion of common problems and possible solutions for MCM distribution and dispensing as well as to promote general coordination around response processes</td>
</tr>
<tr>
<td>Initiate Exercises to Test/Stress Plans</td>
<td>Plan and conduct exercises to test pre-existing plans under simulated bioterrorism conditions to better train state/local government and responders and identify areas requiring additional resources or contingency plans</td>
</tr>
<tr>
<td>Provide Access to Commercial Home Med Kits to the Population</td>
<td>Develop commercial Med Kits for purchase by the general population pre-event to allow for immediate prophylaxis</td>
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## Findings: Additional Recommendations (cont’d)

<table>
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<tr>
<th>Recommendation</th>
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</thead>
<tbody>
<tr>
<td><strong>Develop Better Definition of Roles, Responsibilities, and Expectations Around Characterization</strong></td>
<td>Delineate roles and responsibilities for entities involved in agent/event characterization and set appropriate expectations around characterization timelines so they may be incorporated in response plans.</td>
</tr>
<tr>
<td><strong>Create Federal Guidance/Training for Recovery Processes</strong></td>
<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>
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<tr>
<td><strong>Develop Real-Time Biological Agent Detection Capabilities</strong></td>
<td>Invest in real-time biological agent detection technologies, particularly environmental.</td>
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<td><strong>Test Ability of Medical Information Systems</strong></td>
<td>Conduct test of medical information systems (e.g. HAN) to keep pace with rapidly developing scenario.</td>
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<td><strong>Universal/Uniform Documentation and Standardization of Dispensing Procedures</strong></td>
<td>Create guidance on best-practice dispensing procedures to allow for quick, standardized decision making, particularly around a regional response.</td>
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<tr>
<td><strong>Develop Real-Time Pre-Symptomatic Diagnostic Capabilities</strong></td>
<td>Invest in development of technologies capable of determining affected population/infected individuals.</td>
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REPORT STRUCTURE
Revised Report Structure

Introduction:
• Current DHS Biological attack Planning Scenario overview including assumptions.
• Comparison of bio threat to other threats. How the bio threat is like/unlike:
  – Other WMD (nuke, chem, rad)
    • Like: National security threat, harmful intent “Clauswitzian” proposition risk of reload
    • Unlike: Latency (delayed effects form time of release to onset of illness) No defined beginning and end, no immediately defined barrier, definitive detection and characterization
  – Explosives
  – Cybersecurity
  – Pandemics
    • Like: Health problem
    • Unlike: Lacking the time sensitivity
• Because the bio threat is not directly analogous to any of these, it should be treated differently than all of them.
  – The bio threat is a WMD threat and should be treated more like a national security problem than a PH problem, because it is caused by ill intent to our nation.
  – However, unlike other WMD threats, the bio threat does not have a defined beginning and end, is easy to proliferate beyond one attack, and is a threat to only human health, not infrastructure.
  – High regret decisions will have to be made with non-existent, inaccurate, or incomplete information. Decision makers cannot afford to waste time collecting data or waiting for information.
• Because of a biological threat’s unique nature, there is a lot of confusion within the government as to how it should be treated:
  – Federal or local problem? Currently no one in charge muddled command and control
  – Which federal agency is ultimately in charge? As so many agencies are involved in the response, who ultimately has the coordinating role?
  – Who is providing resources for response?
  – How do we begin to recover from such an ambiguous threat?

Anthrax as a bio threat:
• One example of a bio threat is anthrax, and we have used it as a case study for our analysis.
  – Specific characteristics of anthrax as an aerosol threat
    • Persistence which complicates recovery
  – In the event of an anthrax attack, there are three steps to ultimate recovery: (what about population management and communication – beyond MCM?)
    • MCM
      • Which MCM prevent or treat inhalational anthrax
      • Distribution and dispensing need to be done quickly
    • Characterization (are you including detection in this step or is it a separate issue?)
      • What areas are affected that require avoidance or remediation?
      • What therapeutics is the strain sensitive to?
    • Remediation
      • Compliance of treatment and/or vaccination
      • Decontamination
• Purpose of Project
  – To examine current response and recovery plans and identify gaps
  – To recommend ways to alter the process to achieve greater efficiency and flexibility

Description of MCM Distribution and Dispensing:
• Origin of current response plans
  – Why POD system? Developed specifically to immunize against smallpox
  – Development of the SNS
• Current standard plan: PODs
  – SNS to RSS to POD model
  – Details are state/county/city specific
• Other potential approaches to dispensing
  – Postal Model
    • Push model involving volunteer postal workers
    • Only in certain cities
  – Other push models
  – Other pull models
Revised Report Structure

**Framework:**
- End-to-end system model
  - Map out the entire process of anthrax response and recovery
  - Identify phases in model:
    - Plan for MCM Dispensing
      - Development of downstream plans
    - Prepare for MCM Dispensing
      - Allocation of resources and placement of materiel
    - Detect and Characterize Event
      - Several methods of detection available
        » We are focused on “large” events detectable by environmental surveillance
      - Decision point for triggering process
    - Initial MCM Distribution
      - Move materiel to affected locations
    - Initial MCM Dispensing
      - Get materiel into the hands of affected population
    - Ongoing MCM Distribution
      - Continual movement of the material to the affected locations beyond the initial response
    - Ongoing MCM Dispensing and Prophylactic Treatment
      - Ensure target population receives completion prophylaxis
      - Ensure affected population completes entire therapeutic course
    - Recover
      - Return to “new normal” state
    - Resilience
      - Prepare for next attack.
  - There are factors within each phase affecting how the phase will perform:
    - Population – those affected by the attack
  - Responders – those who are involved with distribution, dispensing, remediation, or other services
  - Materiel – MCM, other medical supplies
  - Places – Distribution centers, service delivery points
  - Communications – Coordinated messaging for all people involved
  - Decisions - policy, command and control, decision making processes, jurisdictional issues

**Analysis:**
- State end goals and objective of the process:
  - Goal of XX% (90%?) of population receiving MCM
  - Full recovery in 6 months
- There are several gaps in the process that are undefined, or stop or stall the process, preventing the process from achieving its goals:
  - Several “themes” of gaps emerged
  - Gaps are listed by stage in process and by category affected
  - Full list of gaps listed in Appendix XX
- How the process or gaps are affected by several scenarios:
  - **Base:** Single Release, 48 hour detection, antibiotics are effective
  - **Reload:** Initial release detected in 48 hours followed by second release, antibiotics are effective
  - **MDR:** Single Release, 48 hour detection, antibiotics are not effective
  - **MDR / Reload:** Initial release detected in 48 hours followed by second release, antibiotics are not effective
  - Anthrax Planning Scenario 2

**Recommendations:**
- List of priority recommendations:
  - Description of recommendation
  - Gaps addressed
  - Metrics affected
- Full list of recommendations listed in Appendix XX
DETAILED PROCESS GAPS
## Findings: Detailed Gaps for Overall Process

<table>
<thead>
<tr>
<th>Element</th>
<th>Process</th>
<th>Category</th>
<th>Gap</th>
<th>Effect</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall</td>
<td>All modes of dispensing</td>
<td>Materiel</td>
<td>There is no way to track or identify the public with adverse reactions to medications</td>
<td>Public may resort to treatment from hospitals; morbidity or mortality could result from adverse reactions; trust of the government may wane</td>
</tr>
<tr>
<td>Overall</td>
<td>Multiple</td>
<td>Affected population</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 in this decision will erode public confidence and greatly affect response</td>
</tr>
<tr>
<td>Overall</td>
<td>Multiple</td>
<td>All</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>
</tr>
<tr>
<td>Overall</td>
<td>Multiple</td>
<td>Decisions</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>
</tr>
<tr>
<td>Overall</td>
<td>Multiple</td>
<td>Decisions</td>
<td>Public health-oriented thinking is not 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>
</tr>
<tr>
<td>Overall</td>
<td>Multiple</td>
<td>Decisions</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>
</tr>
<tr>
<td>Overall</td>
<td>Multiple</td>
<td>Decisions</td>
<td>Impact of multi-drug resistant agents on response is not understood – particularly need for flexibility and potential for loss of public confidence</td>
<td>Using current response plans for 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>
</tr>
</tbody>
</table>
Findings: Detailed Gaps for Overall Process

<table>
<thead>
<tr>
<th>Element</th>
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<th>Category</th>
<th>Gap</th>
<th>Effect</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall</td>
<td>Multiple</td>
<td>Decisions</td>
<td>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</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 morbidity and mortality may significantly increase</td>
</tr>
<tr>
<td>Overall</td>
<td>Multiple</td>
<td>Decisions</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>
</tr>
<tr>
<td>Overall</td>
<td>Multiple</td>
<td>Decisions</td>
<td>Incubation period not well understood for anthrax</td>
<td>We operate under a 3-5 day assumption, when studies have shown it may be as little as 2 days and as many as 14 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>
</tr>
<tr>
<td>Overall</td>
<td>Multiple</td>
<td>Decisions</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 approximately four days for anthrax; each additional 24 hours can result in 8% more casualties.</td>
</tr>
<tr>
<td>Overall</td>
<td>Multiple</td>
<td>Materiel</td>
<td>Hard or impossible to deploy/redeploy stockpile medications across state lines and once states take possession on 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</td>
</tr>
<tr>
<td>Overall</td>
<td>Multiple</td>
<td>Materiel</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>
</tr>
</tbody>
</table>
## Findings: Detailed Gaps for Overall Process

<table>
<thead>
<tr>
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<th>Process</th>
<th>Category</th>
<th>Gap</th>
<th>Effect</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall</td>
<td>Multiple</td>
<td>Multiple</td>
<td>Funding for preparedness is being cut at all levels and in all agencies</td>
<td>Difficult to address problems or develop plans without the resources available to do so</td>
</tr>
<tr>
<td>Overall</td>
<td>Multiple</td>
<td>Multiple</td>
<td>&quot;Home rule&quot; creates a complicated structure that inhibits response</td>
<td>Different requirements and points of authority for autonomous entities, whether they be at the state, local, or county level; results in hurdles for private sector involvement; authority and decision making is not standardized nationwide</td>
</tr>
<tr>
<td>Overall</td>
<td>Multiple</td>
<td>Responders</td>
<td>There is a tendency to double or triple-count available resources when constructing response plans (e.g., policeman, security guard, National Guard)</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</td>
</tr>
<tr>
<td>Overall</td>
<td>Multiple</td>
<td>Responders</td>
<td>No current plans to incorporate DoD into response</td>
<td>Trained resources will go to waste during a national crisis; DoD will have undefined roles resulted in ad hoc responses, if any at all</td>
</tr>
<tr>
<td>Overall</td>
<td>Multiple</td>
<td>Responders</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>
</tr>
<tr>
<td>Overall</td>
<td>Multiple</td>
<td>Responders</td>
<td>The local ability to decide to request SNS, set up dispensing infrastructure, and allocate resources to dispensing infrastructure may not be timely</td>
<td>Lack of sufficient local resources and/or clear guidelines for decision making may significantly delay or stop the process, resulting in increased morbidity/mortality</td>
</tr>
<tr>
<td>Overall</td>
<td>Multiple</td>
<td>Affected population</td>
<td>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.</td>
<td>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 resort to rioting or violence to obtain them.</td>
</tr>
</tbody>
</table>
## Findings: Detailed Gaps for Overall Process

<table>
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<th>Gap</th>
<th>Effect</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall</td>
<td>Multiple</td>
<td>Affected population</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>
</tr>
<tr>
<td>Overall</td>
<td>Multiple</td>
<td>Decisions</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>
</tr>
<tr>
<td>Overall</td>
<td>Multiple</td>
<td>Materiel</td>
<td>Inventory visibility &amp; tracking 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>
</tr>
<tr>
<td>Overall</td>
<td>Multiple</td>
<td>Responders</td>
<td>Heavy reliance on PH departments for preparedness and response. These departments are experiencing huge amounts of turnover, attrition rates leads to understaffing at PH centers, lack of institutional knowledge. Preparedness is not a priority within most state and local departments.</td>
<td>May result in an uncoordinated, ad hoc response in the event of an emergency — severely limiting ability to provide timely MCMs. Lack of knowledge transfer amongst staff at PH departments. Low staff levels may lead to inability to mount a response.</td>
</tr>
<tr>
<td>Overall</td>
<td>Other</td>
<td>Decisions</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 PH community</td>
</tr>
<tr>
<td>Overall</td>
<td>Overall</td>
<td>Communications</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>
</tr>
</tbody>
</table>
## Findings: Detailed Gaps in Plan for Dispensing MCMs

<table>
<thead>
<tr>
<th>Element</th>
<th>Process</th>
<th>Category</th>
<th>Gap</th>
<th>Effect</th>
</tr>
</thead>
<tbody>
<tr>
<td>Plan for MCM Dispensing</td>
<td>Create National Plans</td>
<td>Decisions</td>
<td>No clear CRI &quot;target population&quot;. No standardization on the use of MSA vs. city limits vs. commuter population as a target for response</td>
<td>Unclear exactly who falls into the target population for response, which will result in inaccurate number of people being planned for and possibly uncoordinated regional response</td>
</tr>
<tr>
<td>Plan for MCM Dispensing</td>
<td>Create National plans</td>
<td>Decisions</td>
<td>Lack of biodefense-defined outcomes, planning assumptions, or requirements at the national level</td>
<td>No defined goals or objectives for the overall process. Lack of common goals leads to ambiguity in planning among national, state, and local stakeholders</td>
</tr>
<tr>
<td>Plan for MCM Dispensing</td>
<td>Create National Plans, Create State Plans</td>
<td>Decisions</td>
<td>Federal guidance comes in the form of recommendations, rather than clear directives</td>
<td>There are multiple guidelines from 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>
</tr>
<tr>
<td>Plan for MCM Dispensing</td>
<td>Create National Plans, Create State/Local Plans</td>
<td>Decisions</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</td>
</tr>
<tr>
<td>Plan for MCM Dispensing</td>
<td>Create State/local plans</td>
<td>Decisions</td>
<td>Animal health planning is mostly absent</td>
<td>First, animals may be used as sentinels if a plan were in place. Second, people may go to great lengths to obtain medications for their pets and/or leave the area if no plan to treat them is in place.</td>
</tr>
<tr>
<td>Plan for MCM Dispensing</td>
<td>Create State/local plans</td>
<td>Decisions</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>
</tr>
<tr>
<td>Plan for MCM Dispensing</td>
<td>Create State/Local Plans</td>
<td>Places</td>
<td>Lack of layered contingency planning for POD locations in event of large area contamination, evacuation, or shelter in place</td>
<td>Ad hoc planning to choose and stand up new sites in case selected sites are compromised by an event</td>
</tr>
</tbody>
</table>
## Findings: Detailed Gaps in Plan for Dispensing MCMs

<table>
<thead>
<tr>
<th>Element: Plan for MCM Dispensing</th>
<th>Process: Create State/Local Plans</th>
<th>Category: Decisions</th>
<th>Gap: 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.</th>
<th>Effect: 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.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Element: Plan for MCM Dispensing</td>
<td>Process: Multiple</td>
<td>Category: Decisions</td>
<td>Gap: Lack of measures for biodefense preparation, response, or outcomes (recovery)</td>
<td>Effect: Ambiguity on what national, state, and local stakeholders need to achieve to be fully prepared to respond to a bioattack</td>
</tr>
<tr>
<td>Element: Plan for MCM Dispensing</td>
<td>Process: Multiple</td>
<td>Category: Decisions</td>
<td>Gap: Lack of widely accepted national biodefense strategy or architecture</td>
<td>Effect: No common way for all stakeholders to approach the biodefense problem</td>
</tr>
<tr>
<td>Element: Plan for MCM Dispensing</td>
<td>Process: Plan</td>
<td>Category: Places</td>
<td>Gap: POD logistics and security have not been stress tested at the local level</td>
<td>Effect: 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.</td>
</tr>
<tr>
<td>Element: Plan for MCM Dispensing</td>
<td>Process: Plan Supply incl. SNS</td>
<td>Category: Materiel</td>
<td>Gap: Antibiotic supply both in the SNS and existing supply chain may be insufficient in reload/multiple attack scenarios</td>
<td>Effect: Some localities may experience MCM 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, and government control will be tested</td>
</tr>
<tr>
<td>Element: Plan for MCM Dispensing</td>
<td>Process: Plan Supply incl. SNS</td>
<td>Category: Materiel</td>
<td>Gap: No clear plan for alternate prophylaxis to address MDR strains.</td>
<td>Effect: 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</td>
</tr>
<tr>
<td>Element: Plan for MCM Dispensing</td>
<td>Process: Plan Supply incl. SNS</td>
<td>Category: Materiel</td>
<td>Gap: Vaccine supply not sufficient for large scale deployment</td>
<td>Effect: Only certain populations will be able to receive the vaccine; those who do not receive it cannot be in affected area; could be a perception of inequity between those who receive the vaccine and who does not; decision makers will have to determine how to segment the population for vaccine administration</td>
</tr>
</tbody>
</table>
# Findings: Detailed Gaps in Prepare for Dispensing MCMs

<table>
<thead>
<tr>
<th>Element</th>
<th>Process</th>
<th>Category</th>
<th>Gap</th>
<th>Effect</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prepare for MCM Dispensing</td>
<td>Create Dispensing Structure</td>
<td>Decisions</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 response, no plan for reaching the targeted population</td>
</tr>
<tr>
<td>Prepare for MCM Dispensing</td>
<td>Create Dispensing Structure</td>
<td>Places</td>
<td>POD network may not be periodically reviewed and updated in all locations</td>
<td>Changing traffic patterns, construction, etc. may prohibit using a planned POD site. May need to change plans temporarily or alter them completely.</td>
</tr>
<tr>
<td>Prepare for MCM Dispensing</td>
<td>Create Distribution Structure</td>
<td>Responders</td>
<td>Distribution structure may rely on volunteers or PH employees to perform operational roles for which they do not have the relevant skills or training</td>
<td>Bottlenecks in the process, increasing response time. Large chance of increase in error rate.</td>
</tr>
<tr>
<td>Prepare for MCM Dispensing</td>
<td>Exercise System</td>
<td>Decisions</td>
<td>There are 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>
</tr>
<tr>
<td>Prepare for MCM Dispensing</td>
<td>Exercise System</td>
<td>Decisions</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>
</tr>
<tr>
<td>Prepare for MCM Dispensing</td>
<td>Exercise System</td>
<td>Decisions</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>
</tr>
<tr>
<td>Prepare for MCM Dispensing</td>
<td>Exercise System</td>
<td>Decisions</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>
<td>Inaccurate representation of a true emergency; preparation for event will be insufficient; hard to spot areas that need improvement and difficult to determine outcomes</td>
</tr>
<tr>
<td>Prepare for MCM Dispensing</td>
<td>Manage Supply</td>
<td>Materiel</td>
<td>Few or no caches of antibiotics at the state or local level mean that MCMs may not be available 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</td>
</tr>
</tbody>
</table>
## Findings: Detailed Gaps in Detect and Characterize Event

<table>
<thead>
<tr>
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<th>Effect</th>
</tr>
</thead>
<tbody>
<tr>
<td>Detect and Characterize Event</td>
<td>Analyze Biological Agent</td>
<td>Materiel</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>
</tr>
<tr>
<td>Detect and Characterize Event</td>
<td>Characterize Event</td>
<td>Responders</td>
<td>Budget cuts are negatively impacting state labs, forcing some to significantly reduce capacity or even close</td>
<td>Relying on state or local capabilities for bioagent identification or characterization may not be an option</td>
</tr>
<tr>
<td>Detect and Characterize Event</td>
<td>Characterize event</td>
<td>Responders</td>
<td>There is a general lack of understanding of level of effort to test and characterize a wide area biological event. Lack of clear plan of how to determine spatial extent of an attack or how long this will take.</td>
<td>This process will take longer than most entities are accounting for in their plans; without a general understanding of the magnitude of the event, recovery will be very difficult.</td>
</tr>
<tr>
<td>Detect and Characterize Event</td>
<td>Characterize Event</td>
<td>Responders</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>
</tr>
<tr>
<td>Detect and Characterize Event</td>
<td>Identify Biological Agent</td>
<td>Decisions</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. Without goals or guidelines, this activity may not have an effect on response.</td>
</tr>
</tbody>
</table>

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**WARRP MCM and Population Response** 32
## Findings: Detailed Gaps in Detect and Characterize Event

<table>
<thead>
<tr>
<th>Element</th>
<th>Process</th>
<th>Category</th>
<th>Gap</th>
<th>Effect</th>
</tr>
</thead>
<tbody>
<tr>
<td>Detect and Characterize Event</td>
<td>Isolate Affected Population</td>
<td>Materiel, Responders, Affected Population, Decisions, Places, Communications</td>
<td>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</td>
<td>Lack of planning for ongoing response including how to target population and the true quantity of medications that will be required</td>
</tr>
<tr>
<td>Detect and Characterize Event</td>
<td>Monitor Environment</td>
<td>Decisions</td>
<td>There is no Phase II sampling plan for BioWatch at the state and local level</td>
<td>No clear method for determining extent of environmental contamination after BioWatch hit is confirmed</td>
</tr>
<tr>
<td>Detect and Characterize Event</td>
<td>Monitor Environment</td>
<td>Materiel</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 large-scale attacks. 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 respiratory distress will be detected in 4 to 4.5 days (2.5 to 3 days + 1.5 days laboratory testing), giving no time to distribute and dispense.</td>
</tr>
<tr>
<td>Detect and Characterize Event</td>
<td>Monitor for Event</td>
<td>Materiel</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>
</tr>
<tr>
<td>Detect and Characterize Event</td>
<td>Monitor Intelligence and Activity</td>
<td>Responders</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 available as quickly as we would like.</td>
</tr>
<tr>
<td>Detect and Characterize Event</td>
<td>Monitor Public Health</td>
<td>Responders</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>
</tr>
<tr>
<td>Detect and Characterize Event</td>
<td>Multiple</td>
<td>Materiel</td>
<td>No integration between national biosurveillance systems</td>
<td>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</td>
</tr>
</tbody>
</table>
Findings: Detailed Gaps in Initial MCM Distribution

<table>
<thead>
<tr>
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<th>Process</th>
<th>Category</th>
<th>Gap</th>
<th>Effect</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial MCM Distribution</td>
<td>Activate SNS</td>
<td>Decisions</td>
<td>Process for requesting SNS activation has many steps requiring many disparate stakeholders.</td>
<td>Lengthy approval process may prevent timely treatment of exposed population. Stakeholder coordination will be very difficult in emergency. Could cause a significant delay in the response process.</td>
</tr>
<tr>
<td>Initial MCM Distribution</td>
<td>Activate SNS</td>
<td>Decisions</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 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>
</tr>
<tr>
<td>Initial MCM Distribution</td>
<td>Activate SNS</td>
<td>Decisions</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>
</tr>
<tr>
<td>Initial MCM Distribution</td>
<td>Activate SNS</td>
<td>Decisions</td>
<td>FDA must issue an EUA for any medications that will be used for post-exposure prophylaxis before SNS can be activated (Doxy has 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>
</tr>
<tr>
<td>Initial MCM Distribution</td>
<td>Distribute MCMs to First Responders</td>
<td>Responders</td>
<td>No standard defined process for providing MCMs to first responders</td>
<td>Delays in responding to scene, while responders await prophylaxis</td>
</tr>
<tr>
<td>Initial MCM Distribution</td>
<td>Distribute MCMs to Open PODs, Closed PODs</td>
<td>Places</td>
<td>Lack of consistency and guidance at state and local levels creates complexity in distribution planning and response</td>
<td>Multiple requests on supply sources can cause confusion for distributors, especially when dealing with autonomous states or localities in one response</td>
</tr>
<tr>
<td>Initial MCM Distribution</td>
<td>Distribute to Public via public POD, Distribute to Public via closed POD</td>
<td>Materiel</td>
<td>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.</td>
<td>People may flood PODs before medicines are made available. May erode public confidence in MCM response if there are no medications to hand out.</td>
</tr>
</tbody>
</table>
### Findings: Detailed Gaps in Initial MCM Distribution

<table>
<thead>
<tr>
<th>Element</th>
<th>Process</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Initial MCM Distribution</td>
<td>Multiple Decisions</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 make 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 increased public panic, morbidity, and mortality.</td>
</tr>
<tr>
<td>Initial MCM Distribution</td>
<td>Where to Distribute?</td>
<td>Affected population</td>
<td>There will be demand for antibiotics outside of the impacted state or locality from people who have traveled 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, as there is no plan to treat people that move out of the area. Worried well start to increase nationally. Cases appearing outside of the affected area may prompt fears of a follow-on attack.</td>
</tr>
<tr>
<td>Initial MCM Distribution</td>
<td>Where to Distribute?</td>
<td>Decisions</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>
<td>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.</td>
</tr>
</tbody>
</table>
## Findings: Detailed Gaps in Initial MCM Dispensing

<table>
<thead>
<tr>
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<tbody>
<tr>
<td>Initial MCM Dispensing</td>
<td>All modes of dispensing</td>
<td>Materiel</td>
<td>FDA-approved information sheet provided with MCMs is only available in English</td>
<td>Non-English speakers will not understand the information sheet, including instructions for taking MCMs or contraindications that may result from the pills</td>
</tr>
<tr>
<td>Initial MCM Dispensing</td>
<td>Dispense to Public via All Models</td>
<td>Places</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>
</tr>
<tr>
<td>Initial MCM Dispensing</td>
<td>Dispense to Public via closed POD</td>
<td>Affected population</td>
<td>Closed PODs may not always be closest location to receive MCMs if target population is located elsewhere during attack</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 plans and supplies</td>
</tr>
<tr>
<td>Initial MCM Dispensing</td>
<td>Dispense to Public via closed POD</td>
<td>Affected population</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>
</tr>
<tr>
<td>Initial MCM Dispensing</td>
<td>Dispense to Public via Postal Model</td>
<td>Affected population</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 others to avoid taking the government-provided MCMs</td>
</tr>
<tr>
<td>Initial MCM Dispensing</td>
<td>Dispense to Public via Postal Model</td>
<td>Decisions</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 make the effort to implement in their city</td>
</tr>
<tr>
<td>Initial MCM Dispensing</td>
<td>Dispense to Public via Postal Model</td>
<td>Decisions</td>
<td>Postal model is completely reliant on HHS grant funding for maintenance and deploying in new cities</td>
<td>Lack of suffiency of funding results in limiting implementation; program could fall apart if HHS withholds grant money</td>
</tr>
<tr>
<td>Initial MCM Dispensing</td>
<td>Dispense to Public via Postal Model</td>
<td>Materiel</td>
<td>Uniform number of pills are 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</td>
</tr>
</tbody>
</table>
## Findings: Detailed Gaps in Initial MCM Dispensing

<table>
<thead>
<tr>
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</tr>
</thead>
<tbody>
<tr>
<td>Initial MCM Dispensing</td>
<td>Dispense to Public via Postal Model</td>
<td>Places</td>
<td>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</td>
<td>Push models are not implemented nationally despite EO guidance. Unused resources will limit response in other cities.</td>
</tr>
<tr>
<td>Initial MCM Dispensing</td>
<td>Dispense to Public via Postal Model</td>
<td>Places</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 traveling. Not designed to reach 100% of the population. Will not reach businesses. Will not necessarily buy the PH department more time to set up PODs.</td>
</tr>
<tr>
<td>Initial MCM Dispensing</td>
<td>Dispense to Public via Postal Model</td>
<td>Responders</td>
<td>Security personnel accompanying postal volunteers are not provided with home med kits for them 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.</td>
</tr>
<tr>
<td>Initial MCM Dispensing</td>
<td>Dispense to Public via Postal Model</td>
<td>Responders</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 make the effort to implement in their city</td>
</tr>
<tr>
<td>Initial MCM Dispensing</td>
<td>Dispense to Public via Postal Model</td>
<td>Responders</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>
</tr>
<tr>
<td>Initial MCM Dispensing</td>
<td>Dispense to Public via public POD</td>
<td>Affected population</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>
</tr>
<tr>
<td>Initial MCM Dispensing</td>
<td>Dispense to Public via public POD</td>
<td>Affected population, Materiel</td>
<td>Off-label use of antibiotics presents additional risks for children because these medications are untested in children</td>
<td>Children may have adverse affects from medication or not take it at all; presents additional burden on parents to correctly give the medication to their children</td>
</tr>
</tbody>
</table>
# Findings: Detailed Gaps in Initial MCM Dispensing

<table>
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</thead>
<tbody>
<tr>
<td>Initial MCM Dispensing</td>
<td>Dispense to Public via public POD</td>
<td>Decisions</td>
<td>PODs present an attractive opportunity for a subsequent attack, especially if there are no alternatives</td>
<td>Potential to increase the amount of fatalities that results from subsequent attacks, and if an attack happens, people will not come to PODs for fear of being attacked</td>
</tr>
<tr>
<td>Initial MCM Dispensing</td>
<td>Dispense to Public via public POD</td>
<td>Responders</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>
</tr>
<tr>
<td>Initial MCM Dispensing</td>
<td>Dispense to Public via public POD</td>
<td>Responders</td>
<td>Some locations do not provide countermeasures to families of responders</td>
<td>Responders may choose not to report for duty if families are not taken care of</td>
</tr>
<tr>
<td>Initial MCM Dispensing</td>
<td>Dispense to Public via public POD, Dispense to Public via closed POD</td>
<td>Affected population</td>
<td>Public may be reluctant to visit PODs for fear of contamination, contagion, repeat attacks</td>
<td>Public may avoid coming to PODs in fear that they are unsafe, limiting their ability to treat the impacted population</td>
</tr>
<tr>
<td>Initial MCM Dispensing</td>
<td>Dispense to Public via public POD, Dispense to Public via closed POD</td>
<td>Materiel</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>
</tr>
</tbody>
</table>
### Findings: Detailed Gaps in Ongoing MCM Distribution

<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td>Ongoing MCM Distribution</td>
<td>Ongoing MCM Distribution</td>
<td>Decisions</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>
</tr>
<tr>
<td>Ongoing MCM Distribution</td>
<td>Ongoing MCM Distribution</td>
<td>Materiel</td>
<td>Assumption that MCMs are ubiquitously available in the market may not have been tested</td>
<td>If MCM supply in the SNS plus the commercial market is inadequate to meet demand, potential for increased number of fatalities in event of an attack</td>
</tr>
<tr>
<td>Ongoing MCM Distribution</td>
<td>Ongoing MCM Distribution</td>
<td>Materiel</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>
</tr>
<tr>
<td>Ongoing MCM Distribution</td>
<td>Ongoing MCM Distribution</td>
<td>Materiel</td>
<td>Surge production unknown, particularly for MCMs for other biological/radiological</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>
</tr>
<tr>
<td>Ongoing MCM Distribution</td>
<td>Ongoing MCM Distribution</td>
<td>Materiel</td>
<td>Jurisdictions may be reluctant to share resources with the initially impacted areas, in fear that they might be attacked as well</td>
<td>In contrast to other disasters where national resources were shared with the affected area, the impacted city may be left with only local resources for ongoing response</td>
</tr>
<tr>
<td>Ongoing MCM Distribution</td>
<td>Ongoing MCM Distribution</td>
<td>Responders</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>
</tr>
<tr>
<td>Ongoing MCM Distribution, Ongoing MCM Dispensing and Completion Prophylaxis</td>
<td>Ongoing MCM Distribution, All modes of dispensing</td>
<td>Multiple</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>
</tr>
</tbody>
</table>
**Findings: Detailed Gaps in Ongoing MCM Dispensing and Completion Prophylaxis**

<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td>Ongoing MCM Dispensing &amp; Completion Prophylaxis</td>
<td>Ongoing MCM Dispensing &amp; Completion Prophylaxis</td>
<td>Affected population</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>
</tr>
<tr>
<td>Ongoing MCM Dispensing &amp; Completion Prophylaxis</td>
<td>Ongoing MCM Dispensing &amp; Completion Prophylaxis</td>
<td>Communications</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>
</tr>
<tr>
<td>Ongoing MCM Dispensing &amp; Completion Prophylaxis</td>
<td>Ongoing MCM Dispensing &amp; Completion Prophylaxis</td>
<td>Materiel</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 system and receiving more doses of medicines, while others do not receive enough (or any) MCMs. Also may result in people taking to much or too little MCM or receiving the incorrect type of antibiotic every time they get the next dose.</td>
</tr>
<tr>
<td>Ongoing MCM Dispensing &amp; Completion Prophylaxis</td>
<td>Ongoing MCM Dispensing &amp; Completion Prophylaxis</td>
<td>Places</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>
</tr>
<tr>
<td>Ongoing MCM Dispensing &amp; Completion Prophylaxis</td>
<td>Ongoing MCM Dispensing &amp; Completion Prophylaxis</td>
<td>Places</td>
<td>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</td>
<td>Schools and other buildings remain closed for up to 60 days?</td>
</tr>
</tbody>
</table>
Findings: Detailed Gaps in Ongoing MCM Dispensing and Completion Prophylaxis

<table>
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<tbody>
<tr>
<td>Ongoing MCM Dispensing &amp; Completion Prophylaxis</td>
<td>Ongoing MCM Dispensing &amp; Completion Prophylaxis</td>
<td>Places, Affected population</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 networ and will not be able to receive follow-on doses</td>
</tr>
<tr>
<td>Ongoing MCM Dispensing &amp; Completion Prophylaxis</td>
<td>Ongoing MCM Dispensing &amp; Completion Prophylaxis</td>
<td>Responders</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 PH staff that participated in the initial response</td>
</tr>
<tr>
<td>Ongoing MCM Dispensing &amp; Completion Prophylaxis</td>
<td>Ongoing MCM Dispensing &amp; Completion Prophylaxis</td>
<td>Responders</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>
</tr>
</tbody>
</table>
## Findings: Detailed Gaps for Recovery

<table>
<thead>
<tr>
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<th>Effect</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recovery</td>
<td>Recovery</td>
<td>Decisions</td>
<td>Coordination with water resource management is mostly absent</td>
<td>Having safe water to drink will be a very important factor in recovering an area. What if the water supply is also affected by the attack?</td>
</tr>
<tr>
<td>Recovery</td>
<td>Recovery</td>
<td>Decisions</td>
<td>No quick reaction or interdiction tools to prevent follow-on attacks</td>
<td>Potential for devastating effects on capabilities, (public) confidence, and morale. Potential for follow-on attacks to occur, consuming more national resources.</td>
</tr>
<tr>
<td>Recovery</td>
<td>Recovery</td>
<td>Responders</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>Difficult to measure with any accuracy. Risk may still be present even when no spores are detected. If goal is achieved, recovery may be significantly delayed. If goal is not achieved, when will the area be safe to reoccupy?</td>
</tr>
<tr>
<td>Recovery</td>
<td>Recovery</td>
<td>Decisions</td>
<td>Decontamination research and development for outdoor biological attacks have not been a national priority. We lack standards and a strategy for mass decontamination, and have only rudimentary capabilities in this area</td>
<td>Affected area may not be sufficiently decontaminated and may have to be permanently vacated, leading to no recovery of the area</td>
</tr>
<tr>
<td>Recovery</td>
<td>Recovery</td>
<td>Decisions</td>
<td>Insufficient guidance and training provided by EPA to state and local health departments on processes and procedures related to decontamination</td>
<td>States and locals may be confused as to their role in recovery and may be skeptical to reoccupy the affected area</td>
</tr>
</tbody>
</table>
STATUS UPDATE
## Medical Countermeasures Response Analysis

<table>
<thead>
<tr>
<th>Task Description</th>
<th>Dates</th>
</tr>
</thead>
<tbody>
<tr>
<td>Task 1A Medical Countermeasures (A004-A)</td>
<td></td>
</tr>
<tr>
<td>Plan - Document In-Scope / Out-of-Scope Activities</td>
<td></td>
</tr>
<tr>
<td>Plan - Define Key Stakeholders</td>
<td></td>
</tr>
<tr>
<td>Plan - Develop interview guide and JEAS</td>
<td></td>
</tr>
<tr>
<td>Assess - Conduct distribution and dispensing interviews</td>
<td></td>
</tr>
<tr>
<td>Assess - Conduct pharma supply capability and vulnerability interviews</td>
<td></td>
</tr>
<tr>
<td>Assess - Model baseline and exceptions</td>
<td></td>
</tr>
<tr>
<td>Assess - Identify baseline and exception to baseline gaps</td>
<td></td>
</tr>
<tr>
<td>Assess - Identify pharma supply vulnerabilities (in A004)</td>
<td></td>
</tr>
<tr>
<td>Results - Address gaps in MCM supply chain</td>
<td></td>
</tr>
<tr>
<td>Draft Task 1A Status Review</td>
<td>March 5, 2012</td>
</tr>
<tr>
<td>Final Task 1A Report (A004-A2)</td>
<td>April 2, 2012</td>
</tr>
<tr>
<td>Task 1B Population Response (A004-B)</td>
<td></td>
</tr>
<tr>
<td>Plan - Develop in-Scope / Out-of-Scope Activities</td>
<td></td>
</tr>
<tr>
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<td></td>
</tr>
<tr>
<td>Plan - Develop interview guide and JEAS</td>
<td></td>
</tr>
<tr>
<td>Assess - Conduct population assessment interviews</td>
<td></td>
</tr>
<tr>
<td>Assess - Conduct response capability interviews</td>
<td></td>
</tr>
<tr>
<td>Assess - Conduct net-centric response interviews</td>
<td></td>
</tr>
<tr>
<td>Assess - Model baseline and exceptions</td>
<td></td>
</tr>
<tr>
<td>Assess - Identify pharma supply vulnerabilities (in A004)</td>
<td></td>
</tr>
<tr>
<td>Assess - Red Team multiple attack scenarios</td>
<td></td>
</tr>
<tr>
<td>Results - Address gaps in distribution and dispensing</td>
<td></td>
</tr>
<tr>
<td>Results - Address gaps in MCM supply chain</td>
<td></td>
</tr>
<tr>
<td>Draft Task 1B Status Review</td>
<td>March 5, 2012</td>
</tr>
</tbody>
</table>

## Report Integration (A-004)

<table>
<thead>
<tr>
<th>Task Description</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Final Report</td>
<td>April 16, 2012</td>
</tr>
</tbody>
</table>
## Status: Project Risks are under control

### Content and Report Associated Risks

<table>
<thead>
<tr>
<th>Risk</th>
<th>Mitigation</th>
<th>Update</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposing Existing Weaknesses May Reduce Stakeholder Support</td>
<td>Complete definition of scope and objectives; exhaustive and well documented research; careful presentation of findings; and development of higher level support</td>
<td>Over 200 research documents reviewed and cataloged. Process models complete and interviews providing independent validation.</td>
</tr>
<tr>
<td>Lack of Relevancy</td>
<td>Position study relative to existing research and cite all sources; complete end to end process model including population behavior</td>
<td>Interview list expanded to include more HHS and other government stakeholders.</td>
</tr>
<tr>
<td>Reducing Usefulness By Creating Classified Work</td>
<td>Remain aware of importance of maintaining FOUO status</td>
<td>No classified documents have been reviewed.</td>
</tr>
</tbody>
</table>

### Programmatic Risks

<table>
<thead>
<tr>
<th>Risk</th>
<th>Mitigation</th>
<th>Update</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lack of Participation From Key Stakeholders</td>
<td>Regular meetings and pre-prepresents of all findings</td>
<td>Bi-weekly updates plus regular working sessions are effective. Web access to documents and process model.</td>
</tr>
<tr>
<td>Lack of Focus From Key Stakeholders</td>
<td>Regular meetings and pre-prepresents of all findings to identified stakeholders</td>
<td>Bi-weekly updates plus regular working sessions are effective.</td>
</tr>
<tr>
<td>Scope Creep</td>
<td>Regular review of Project Plan and outputs with Sponsor and confirmation that planning scenario does not include radiological event</td>
<td>Outline, approach and scope agreed again in “Outline Briefing”. Process model adds definition to scope.</td>
</tr>
<tr>
<td>Lack of Access to SME’s</td>
<td>Leverage sponsor to gain introductions to DHS, HHS, White House, and other experts</td>
<td>No change in mitigation. All SME’s are being cooperative</td>
</tr>
</tbody>
</table>
Process Model: “80% Solution” complete for now

1. Built detailed process flow diagrams for primary processes supporting elements 3, 4, 5, 6, 7 of the model.

2. Gaps were identified through modeling.

3. Gaps were validated through interviews and research; detailed processes were updated.
## Status: 28 Interviews Conducted / Scheduled

### Name | Organization
--- | ---
Richard Danzig | SME
Carter Mecher | VA
Ken Rapuano | MITRE
Sid Baccam | IEM
Nathaniel Hupert | Cornell Medical School
Lisa Koonin | CDC/OID/OD
Eva Lee | Georgia Tech
COL Bob Mauskapf | VA DOH
Matthew Feltman | Kroger/Giant
Michael Robbins | Chicago DOH
Isaac Weisfuse | NYC DOH
Jack Cantlin | Walgreens
John Kavanagh | PwC, Former FBI
Cyndi Lake | Alexandria VA DOH
George Korch | HHS

### Name | Organization
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Greg Burel | Director, DSNS/CDC
Mike Rackley | Target
Bill Raub | SME
Jack Herrmann | NACCHO
Nicki Pesick, Tracee Treadwell | Anthrax Management Team, CDC
Jude Plessas | USPS
David Starr | NYC DOH
Bob Hooks | DHS OHA
Matthew Minson | SNS Houston
James Blumenstock, Gerrit Bakker | ASTHO
Cathy Polley, Rhett Asher | FMI
Alex Adams | NACDS
Stephanie Dulin | CDC
Aggie Leitheiser | MN DOH
Rear Adm Ali Khan | HHS
Status: Research, 232 Documents Reviewed

- **Academic and Research Organizations**
  - **2001 Anthrax Attack**
    - Acad - 2001 Anthrax Attack - 2001/MMWR_Averse Events of Anthrax Prophylaxis
    - Acad - 2001 Anthrax Attack - 2003_Shaffer_Increased prescription trends due to Anthrax USDA
    - Acad - 2001 Anthrax Attack - 2004_Hupert_Patient Requests for Abxin NYC
    - Acad - 2001 Anthrax Attack - 2004_Sanderson_B.Anthracis inhalation in a mail center
    - Acad - 2001 Anthrax Attack - 2005_Belongia_Demand for Abxin 2001 in Unaffected Regions
  - **Acad - Anthrax Scenarios - 2008_Isukapalli_Modeling Number of Infections Based on Attack**
  - **Modeling Anthrax**
    - Acad - Model - Eva Lee - RealOptV5_090429_withjre
    - Acad – Model - Eva Lee - Appendix POD Staffing Guidelines
    - Acad - Model - Eva Lee - MCM Dispensing Multi-Modality and Cost-Effectiveness
    - Acad – Model - Eva Lee - Effective Mass Dispensing RealOpt
    - Acad - Modeling Anthrax - 1994_Meselson_Sverdlovsk Anthrax Outbreak of 1979
    - Acad - Modeling Anthrax - 1994_Sepkowitz _Editorial Response to Meselson Science
    - Acad - Modeling Anthrax - 2001_Brookmeyer_Stat Analysis of truncated data_Sverdlovsk
    - Acad - Modeling Anthrax - 2001_Rickmeier_Bio Warfare Human Response Model
    - Acad - Modeling Anthrax - 2003_Brookmeyer_Modeling Optimum Duration of Anthrax Prophyl
    - Acad - Modeling Anthrax - 2004_Brookmeyer_Vaccination Policies to Contain Anthrax
    - Acad - Modeling Anthrax - 2005_Brookmeyer_Modeling the Incubation Period of Anthrax
    - Acad - Modeling Anthrax - 2006_Wilkening_Sverdlovsk Revisited
    - Acad - Modeling Anthrax - 2008_Coleman_Anhtrax Dose Response & Risk Analysis
    - Acad - Modeling Anthrax - 2008_Drusano_Is 60 Days of Cipro Necessary
    - Acad - Modeling Anthrax - 2008_Kumar_Modeling Antibiotic Effectiveness by Admin
    - Acad - Modeling Anthrax - 2008_Wilkening_Modeling Incubation Period of Inhalation Anthrax
    - Acad - Modeling Anthrax - 2009_Legrand_Estimating Spatial Extent of Covert Anthrax Release
  - **Modeling Antibiotic Distribution and Dispensing**
    - Acad - Modeling Antibiotic Distribution and Dispensing - 2003_Wein_Modeling Emergency Response to Anthrax Attack
    - Acad - Modeling Antibiotic Distribution and Dispensing - 2005_Craft_Analyzing Bioterror Response Logistics for Anthrax
    - Acad - Modeling Antibiotic Distribution and Dispensing - 2005_Fowler_Modeling PEP Strategies Cost-Effectiveness
    - Acad - Modeling Antibiotic Distribution and Dispensing - 2005_Wein_Craft_Follow-up to Baccam Model
    - Acad - Modeling Antibiotic Distribution and Dispensing - 2006_Bravata_Modeling Stockpile & Dispensing MCM
    - Acad - Modeling Antibiotic Distribution and Dispensing - 2007_Hupert_Anticipating Demand for EMS due to ADE after PEP
    - Acad - Modeling Antibiotic Distribution and Dispensing - 2007_Khan_Grad Thesis_Effectiveness of Diverse Dispensing
    - Acad - Modeling Antibiotic Distribution and Dispensing - 2007_Schmitt_Cost Effectiveness of Post-Anthrax Abx Treatment
    - Acad - Modeling Antibiotic Distribution and Dispensing - 2008_Wilkening_Modeling Logistics of Anthrax Response
    - Acad - Modeling Antibiotic Distribution and Dispensing - 2009_Franz_Preparedness for an anthrax attack
    - Acad - Modeling Antibiotic Distribution and Dispensing - 2009_Hupert_Predicting Hospital Surge Post-Anthrax Event
    - Acad - Modeling Antibiotic Distribution and Dispensing - 2011_Updated_Houck_Herrman_Impact of Prepositioned MCM for Anthrax
Status: Research, Cont.

- Acad - Prepositioning - Eva Lee Article
- Acad - Surveys and Polls - Harvard Opinion Poll_Public Response to Anthrax Attack
- Acad - Mass Prophylaxis Dispensing Concerns Traffic
- Acad - Vaccination Policy Options 2007
- Acad - Uncertainty and Ops In Mass Prophylaxis Planning
- Acad – Implementing CRI – 2008_AMA_Implementing CRI_Lessons Learned from Boston
- Acad – Relationship Between Mass Prophylaxis Dispensing and MRAEs_Department of Public Health_Cornell

- HHS Centers for Disease Control (CDC):
  - CDC - Crisis Emergency Risk Communication Basic Guide
  - CDC - Public Perceptions About Trust in Emergency Risk Communication
  - CDC - CERC Pandemic Flu OCT07
  - CDC - SNS_Planning_Guide_V10.02
  - CDC - Points of Dispensing Standards 2008
  - CDC - Burel SNS Planning and Capabilities Update 2011
  - CDC - MCM Dispensing Capability 8
  - CDC – CDC and EPA Interim Clearance Doc
  - CDC – Public Health Preparedness Capabilities
  - CDC - Selected Fed Legal Authorities re PH Emergencies
  - CDC - FAQs Fed PHE Laws

- Critical Incident Analysis Group (CIAG):
  - CIAG - Urban Military Report
  - GMU - 2005 Community Shielding Survey
  - UCLA - Post Katrina Study Vulnerable Populations
  - APHA - 2007 Public Health Preparedness Survey
  - CMU - Predicting Action on an Email Message 2005
  - BJP - 2003 Biochemical terrorism psychological study

- Homeland Security Institute (HSI):
  - BNA – A Realistic Path to Future Medical Countermeasure Development
  - BNA – Bioterrorism Medical Countermeasures
  - DHS - HSI Resilience in Emergency Response
  - BNA – Question 9

- Department of Homeland Security (DHS) and Homeland Security Council (HSC):
  - HSC - National_Planning_Scenarios_ExecSummaries_ver2
  - DHS – ARES – AAR Keys
  - DHS – ARES – ARES Executive Report Final
  - DHS – ARES – ARES R10 TTX Final AAR (15 Dec 10)
  - DHS – ARES – ARES Region 1 AAR
  - DHS – ARES – ARES Region III AAR + IP_Final_100410
  - DHS – ARES – ARES Region V AAR_Final
  - DHS – ARES – AZ ARES 2010 TTX AAR-ip_Final
  - DHS – ARES – FL TTX AAR-IP_Final_18Jan10_v1
  - DHS – ARES – nyc_anthrax_ttx_aar_041509 (Region II NY)
  - DHS – ARES – Region VI ARES AAR FINAL 090810
  - DHS – ARES – WY_ARES TTX_Final_AAR-IP
  - DHS – Anthrax Scenarios - 2008_IOM_DHS Bioterrorism Risk Assessment
  - DHS – Anthrax Scenarios - DHS Anthrax Planning Scenario
  - DHS - Draft Planning Guidance for biological incident recovery
  - DHS - Biodefense Knowledge Management System PIA
  - DHS - SEDI Biodefense Decision Support Tools Feb 2011
  - DHS - SNS Perspective on Pre-positioning MCM Burel IOM Feb 2011
  - DHS - SEDI Biodefense Decision Support System April 2011
  - DHS – A Realistic Path to Future Medical Countermeasure Development
  - DHS – Bioterrorism Medical Countermeasures
  - DHS – Mass Prophylaxis_Casualty

- DOD, Army, USAMRIID:
  - USAMRIID - Blue Book Anthrax Antibiotics
  - USAMRIID - Blue Book 2005 Complete
  - ARMY - Biological Warfare Ch01 History of Bioterrorism
  - ARMY - Biological Warfare Ch03 Epidemiology of Bioterrorism
  - ARMY - Biological Warfare Ch04 Anthrax
  - ARMY - Biological Warfare Ch18 Lab Identification of Bio Threats
  - ARMY - Biological Warfare Ch19 Consequence Mgmt
  - ARMY - Biological Warfare Ch20 Medical Casualties
  - ARMY - Biological Warfare Ch21 MCM
  - ARMY - Biological Warfare Ch22 Biosafety
  - ARMY - Biological Warfare Ch23 Biosurety
Status: Research, Cont.

- ARMY - Biological Warfare Ch25 Emerging and Future Threats
- ARMY - Modeling Anthrax - 1993_Friedlander_PEP Against Experimental Anthrax
- ARMY - Modeling Anthrax - 2007_Heine_Antibiotic Efficiency Against Anthrax in Mice
- ARMY - Modeling Anthrax - 2009_Vietri_Short Course Abx versus Prophylaxis in Anthrax

- Other Federal Government:
  - SEN - Senate Testimony Oct 2011 Anthrax 10 Years Later (DHS, UPMC, FBI)
  - SEN - bio-response-report-card-2011
  - SEN - CNI Comment Grading the Report Card
  - HOUSE - Distribution and Dispensing of MCM 2011
  - GAO - Report National Preparedness for Acquiring MCMs to Threats from Terrorism and Other Sources

- Department of Health and Human Services (HHS):
  - HHS - BARDAStrategicPlan9-28—508
  - HHS - Fed Register HHS PHEMCE Strategy
  - HHS - MCMFactSheetFinal-508
  - HHS - MCMReviewFinalCover-508
  - HHS - Medical Countermeasures Requirements Setting
  - HHS - Pandemic and All Hazards Act of 2006
  - HHS - PHEMCE Implementation Plan 2007
  - HHS - PHEMCE Strategy and HHS PHEMCE Implementation Plan
  - HHS - Project BioShield Annual Report 2010
  - HHS - Strategic National Stockpile
  - HHS - State Distribution and Dispensing Assessments - 2-Dulin_TAR_FactSheet_2009
  - HHS - Anthrax Scenarios - ASPR Anthrax Attack Scenario_HHS Programmatic Responses
  - HHS - PHEP Cooperative Agreement MCM Distribution and Dispensing Composite Measure Guide2011final

- Institute of Medicine of the National Academies (IOM):
  - IOM - Prepositioning Antibiotics for Anthrax
  - IOM - Dispensing MCM Workshop Summary
  - IOM - Public Health Emergency MCM Enterprise
  - IOM - MCM Dispensing Emergency Use and Postal Model

- IOM - Crisis Standards of Care
- IOM - BioWatch and Public Health Surveillance
- IOM - Medical Surge Capacity Workshop Summary

- Dr. Bob Kadlec
  - Kadlec - Modeling Anthrax - 2011_Kadlec January Presentation to Prepositioned MCM Comm
  - Kadlec - HS End-to-End Biodefense Review and Assessment
  - Kadlec - MCM Survey Domestic Preparedness Jan 2011
  - Kadlec – Clinical evaluation and management of persons with possible inhalation anthrax

- NATO
  - NATO - Modeling Anthrax - NATO Threat Assessment B anthracis
  - NATO - Anthrax Scenarios - NATO Modeling_IDA Exercise Dread Night

- National Response Framework (NFR) Documents
  - National Response Framework 2008
  - NRF Emergency Support Functions
  - nrf_BiologicalIncidentAnnex
  - nrf Annexes-all
  - nrf-authorities
  - nrf-PartnerGuideFederal
  - nrf-PartnerGuideLocal
  - nrf-PartnerGuidePrivateSector
  - nrf-PartnerGuideState

- Other Sources
  - Book - Beyond Anthrax The Weaponization of Infectious Diseases
  - Other - Anthrax Scenarios - 2007_Executive Action LLC_3 Anthrax Attack Scenarios & Response
  - Other - Bioterrorisms Deadly Math 2008 article
  - Other – Danzig - A Policymaker’s Guide to Bioterrorism
  - Other – Danzig – After an Attack, Preparing Citizens for Bioterrorism
  - Other – Danzig – Catastrophic Bioterrorism – What is to be done?
  - Other – Danzig – CNAS_AumShinrikyo_Danzig_0
  - Other – Danzig – CNAS_Prediction_Danzig
  - Other – Title II
  - Other – Mass Prophylaxis_American Society of Health-System Pharmacists_2009
Status: Research, Cont.

- Other - Field Testing a Head of Household Method to Dispense Antibiotics_2007
- Other - PhRMA 2010 Anthrax drugs and vaccines in development
- Other - PhRMA infectious disease drugs in development 2010
- Other - Kellman Bioviolence
- Other - Anthrax_Symposium_Report
- Other - CRS - Federal Efforts to Address the Threat of Bioterrorism

• RAND Corporation:
  - RAND - Assessing State and Local CMC Dispensing
  - RAND - Are Communities Ready to Conduct Rapid MCM Distribution
  - RAND - DoD Coordination Meeting Notes
  - RAND - Initial Evaluation of the Cities Readiness Initiative
  - RAND - Response Planning Tool Kit for Special Needs Populations
  - RAND - Bioterrorism with Zoonotic Disease Exercise
  - RAND - Understanding Psychological Consequence of Bioterror 2003
  - RAND – Research Related to Countermeasure Distribution

• State and Local
  - Alaska Guidelines – Anthrax Testing
  - NACCHO - POD-Article-2_utilizing-school-buses
  - NACCHO - POD-Article-3_gated-communities
  - NACCHO - POD-Article-5_nonlinear
  - NACCHO - POD-Article-4_polling-places
  - State Distribution and Dispensing Assessments - 1- Technical Assistance Review (TAR) Tool_CDC Additional Inf
  - State Distribution and Dispensing Assessments - 2009_RAND_Eval of CRI
  - State Distribution and Dispensing Assessments - 2010_Trust for Americas Health_State Preparedness Scores
  - State Distribution and Dispensing Assessments - 2010_CDC_Public Health Preparedness by State
  - State and Local - Kansas City Closed POD Workbook
  - State and Local - WA POD Field Ops Guide
  - State and Local - NJ TOPOFF 3 After Action 2006
  - State and Local - MO Standing Orders Anthrax
  - State and Local – Benton County Mass Dispensing Plan
  - State and Local – Essex Regional Health Commission POD Planning
  - RegionalRecoveryBioAttack201009
  - State and Local -2007_Hawaii Dept of Health_MassMedication Modeling in Response to PH Emergencies_Outcomes of a Drive-Thru Exercise
  - NACCHO – Job Loss Report

• Center for Biosecurity of UPMC:
  - UMPC - 2010 Conference Report
  - UMPC - 2010 Conference Background Reading
  - UMPC - 2010 Conference Attendees

• US Postal Service
  - USPS - Surveys and Polls - Questionnaire to USPS workers in MN Medkit Pilot
  - USPS - DOMPREP Raub
  - USPS - Piessas Presentation
  - USPS - Anthrax Reactions from USPS and PH workers Quinn
  - CRI - Postal Plan Philadelphia Notes
  - USPS - Postal Model Seattle After Action Report
  - USPS - Postal Model Presentation USPS
  - USPS - Minnesota Dept Health Postal Notes
  - CRI - Postal Plan Philadelphia
  - CRI – Postal Plan Synopsis_2009

• Wide Area Recovery and Resiliency Program (WARRP):
  - WARRP Newsletter July 2011
  - WARRP Newsletter March 2011
  - WARRP Newsletter May 2011
  - WARRP Newsletter September 2011
  - WARRP Objectives
  - WARRP overview 27 Oct 2011
  - WARRP TRANSITION White Paper
  - WARRP White Paper APR 2011 FINAL
  - WARRP - Scenario CBR Slides
  - WARRP - Bio Operational Test Eval BOTE Info Brief
  - WARRP - Bio Operational Test Eval BOTE Abstract
  - FEMA - Improvised Nuclear Device Overview_4-14-11
  - WARRP - Bio Scenario MSEL factors
Status: Research, Cont.

- WARRP - Anthrax Background rev 3
- WARRP - Scenario 1pgSum_4
- WARRP - Dec Event Concept Rev4
- WARRP – WARRP_Framework_v2_[3][1]

• Behavior
  - Acad - exposure to bioterrorism and mental health response among staff on capitol hill
  - Acad - lessons learned from those exposed to anthrax
  - Acad - Mitchell Critical Incident Stress Management defined
  - Acad - Psychological Issues Older Adults
  - Acad - Threat of bw prophylaxis mitigation of psych social conseq
  - ASPR - Disaster Behavioral Health
  - COMM - Crisis_Management_Briefings_CMB__Large_Group
  - CSTS - Body Recovery and Media Management
  - CSTS - Body Recovery and Stress Management Relief Workers
  - CSTS - Body Recovery and Stress Management Supervisors
  - CSTS - Business Leadership in Preparedness
  - CSTS - Consult_katrina_mental_health
  - CSTS – Disaster Behavioral Health responders survivors
  - ERHMS - Monitoring Responder Health
  - HHS - Mental Health All-Hazards Disaster Planning Guidance