Obstacles to Public Health and Health Care System Preparedness and Response in Our Nation’s Directly Funded Cities

Report to the Blue Ribbon Study Panel on Biodefense

March 12, 2015

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*In coordination with*

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Introduction
In New York City and nationwide, there exist known gaps in the capacity of public health departments to respond to and assist their communities in recovering from public health emergencies, particularly in the context of bioterrorism and naturally occurring disease outbreaks. Many of the obstacles that will impede a robust response to such incidents in New York City and other densely populated urban areas can be mitigated now by appropriate federal action.

Along with its counterparts in Chicago, Los Angeles, and the District of Columbia, the New York City Department of Health and Mental Hygiene ("NYC Health Department") encourages the Blue Ribbon Study Panel on Biodefense to consider the following recommendations when developing its spring 2015 Report to Congress.

Summary of Recommendations
1. Federal budgets designed to support public health and health care system preparedness and response must be increased and sustained to maintain and improve critical components of our country's national security infrastructure. Concurrently, funding allocations should be risk-based in a manner that reflects the scale of the response and the magnitude of illness and death faced by high-threat, high-density urban areas during and after a biological incident.

2. Congress should mandate the forward deployment of Strategic National Stockpile (SNS) medication in reasonable quantities in or near high-threat, high-density, urban jurisdictions that have demonstrated an ability to stand up Points of Dispensing (PODs) faster than SNS medications can be delivered to jurisdictions to ensure timely delivery of life-saving medication to the public.

3. Congress should evaluate and implement appropriate interventions to authorize, encourage, and facilitate the training and rapid deployment of non-mission-essential federal employees in support of state and local responses to a broad range of emergencies.

4. Congress should mandate the creation of a federal, interagency BioWatch planning workgroup, overseen by a single lead agency with ongoing, active collaboration with state and local government partners, whose primary objectives are to clarify and coordinate the response and recovery goals, objectives and activities of federal agencies following the detection of a biological incident.

5. The federal government should work to reduce the cost of doxycycline, including calling upon the FDA to investigate and determine ways to mitigate the cost increase.

Each of these recommendations is discussed in more detail below.
Background
Our nation’s public health and healthcare infrastructure plays a critical role protecting our citizens by quickly detecting bioterrorism or naturally occurring outbreaks, containing the spread of disease, and otherwise mitigating the public health impacts of emergencies. Public health and healthcare capabilities noticeably expanded and improved after 9/11 when there was an influx of federal public health and healthcare system preparedness funding via the Centers for Disease Control and Prevention (CDC) Public Health Emergency Preparedness (PHEP) and the Assistant Secretary for Preparedness and Response (ASPR) Hospital Preparedness Program (HPP) cooperative agreements. With these funds, state and local health departments and healthcare systems continue to invest in staff, plan development, training programs, exercises to test plans, and equipment so that skilled and experienced personnel are equipped to respond to a broad range of emergencies. Our reliance upon such qualified personnel and the importance of sustaining them to accomplish our core functions cannot be overstated.

Most local health departments receive PHEP and HPP funds through their respective states. In contrast, New York City, Chicago, Los Angeles County and the District of Columbia receive PHEP and HPP awards directly from the federal government. Each “Directly Funded City,” or DFC, is a high-population, high-density urban area. Collectively, the four DFCs are home to almost 22 million people (8% of the U.S. population), with dramatic increases in daytime populations supplemented by large tourist and commuter populations. Additionally, each DFC is host to countless high-profile events, home to numerous high-value targets such as prominent buildings and national monuments, and each serves as an international travel hub with critical regional transportation infrastructure. A biological attack or emerging infectious disease outbreak on a large scale in any of these four jurisdictions will have a significant impact on global health, the economy, political stability, and security as well as transportation systems.

Based upon these factors, the DFCs are uniquely positioned to make targeted recommendations that will have a broad impact on the lives of millions of Americans in the event of a far-reaching biological incident. Key challenges we face and our accompanying recommendations are set forth below.

Recommendations

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<td>Relentless cuts in federal funding have hampered the preparedness and response efforts of Directly Funded Cities, all of whom are at heightened risk for acts of bioterrorism and the rapid spread of emerging infectious disease outbreaks.</td>
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<td>Recommendation # 1</td>
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<td>Federal budgets designed to support public health and healthcare system preparedness and response must be increased and sustained to maintain and improve critical components of our country’s national security infrastructure. Concurrently, funding allocations should be risk-based in a manner that reflects the scale of the response and the magnitude of illness and death faced by high-threat, high-density urban areas during and after a biological incident.</td>
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Health departments and healthcare systems of all sizes play a key role in detecting threats and responding to a broad range of emergencies, including the consequences of bioterrorism and emerging infectious disease outbreaks such as Ebola virus disease (EVD). State and local health departments throughout the nation rely upon federal funding to prepare for and respond to emergencies, and as is the case for each DFC, federal funding is typically the primary and only source of funding for such purposes. Unfortunately, significant and repeated cuts to the PHEP and HPP budgets jeopardize existing response capabilities and impede efforts to address known gaps in both public health and healthcare system preparedness.
In NYC alone, PHEP funding has decreased 35% from its peak in FY2005. The most drastic impact of this loss has been a 43% reduction in NYC’s public health preparedness and response workforce since 2005, with similar reductions in the other DFCs. In fact, jurisdictions nationwide have eliminated positions for epidemiologists, information technology experts, laboratorians, preparedness planners and others due to funding cuts. The erosion of a skilled, dedicated workforce threatens to compromise the ability of disease control programs to conduct surveillance, analyze data, monitor trends, investigate cases, facilitate diagnostic testing at public health laboratories when warranted, assess public health impacts and initiate measures to thwart disease outbreaks. In NYC, for example, the Public Health Lab now has limited ability to respond to after-hours lab testing needs, which is critical to the 24x7 response needed for pandemic influenza, EVD and bioterrorism. PHEP investment in the public health workforce must be reinvigorated to reverse the deterioration in biosurveillance capabilities that exists throughout the local and state public health sector.

Like the PHEP cuts that compromise core public health capabilities, relentless HPP cuts have impeded preparedness and response efforts necessary to shore up our nation’s health care sector. The cuts to HPP are particularly consequential because federal funding levels were inadequate from the start. As an example, HPP funding to NYC has decreased 39% from its peak in FY2004. When coupled with a lack of other funding sources for health care sector preparedness, HPP cuts hinder efforts by jurisdictions to implement corrective measures, such as hardening of healthcare facilities, which was identified as a critical gap in NYC after Superstorm Sandy in 2012. Additionally, in the DFCs and more broadly, the EVD and measles outbreaks have highlighted the gaps and importance of a prepared healthcare system.

In order to address specific emergencies, jurisdictions have occasionally received one-time funding opportunities to supplement the PHEP and HPP grants, as is happening now with EVD. However, these singular funding allocations are not an adequate substitute for sufficient and sustained base funding. Additionally, these funds are typically awarded after significant local public health expenditures for response activities have been made, require For example, the NYC Health Department currently has no means of reimbursement for its Ebola response (as of December 2014 estimated to be over $7 million). Not only must baseline awards be increased nationwide, PHEP and HPP budgets should be reflective of the inherently higher risk of biological incidents faced by high-threat, high-density urban jurisdictions such as the DFCs. Since September 11, 2001, there have been 16 known terrorist plots against New York City alone.1 This level of risk is unparalleled elsewhere in the U.S., and funding formulas should reflect the threat, the scale of potential illness and death, and the magnitude of other human, economic and social impacts of emerging infectious disease outbreaks and bioterrorism in our nation’s largest and densest jurisdictions. Other federal grant programs take such factors into consideration, including the Urban Areas Security Initiative, the HPP and even the EVD supplemental funding (which accounts for percentage of travelers returning from EVD-affected countries, jurisdictions with enhanced screening at airports (such and Chicago and NYC), and those with large West African populations). Now is the time for a transparent, defensible risk-based funding methodology for all federal preparedness grants. In particular, PHEP funding, should align with other federal funding programs to further incorporate risk.

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<td>The estimated delivery time of medication from the Strategic National Stockpile (SNS) to NYC during certain public health emergencies will delay the dispensing of life-saving medication.</td>
<td>Congress should mandate and provide the necessary funding to support the forward deployment of SNS assets in reasonable quantities to high-threat, high-density urban areas that have demonstrated an ability to stand up PODs faster than SNS medications can be delivered to jurisdictions and subsequently distributed to PODs.</td>
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PHEP funding requires and supports the mission of local health departments to develop and execute plans for the mass dispensing of medication in response to a biological attack. For example, in the case of a widespread, aerosolized attack with *Bacillus anthracis* (anthrax) spores, all potentially exposed people must begin taking antibiotics within 48 hours of exposure to prevent inhalation anthrax and death. The primary method of rapidly dispensing medication in DFCs and jurisdictions nationwide is through Points of Dispensing (PODs), which are temporary emergency sites established to provide free medication to large numbers of people to prevent them from becoming sick.

Notably, local health departments rely upon the federal Strategic National Stockpile (SNS), managed by the CDC, as the sole source of medication that will be dispensed at PODs. Traditionally, deployment of SNS medication has been promised within 12 hours of the “federal decision to deploy.” However, as jurisdictions such as NYC become increasingly adept in their ability to rapidly set up PODs, this timeframe for delivery of SNS assets becomes the most significant rate-limiting factor in their ability to open PODs to the public.

In an effort to close this gap, the NYC Health Department repeatedly asked the CDC in recent years to forward deploy an appropriate quantity of antibiotics that could be immediately accessed and dispensed in the event of an aerosolized anthrax attack in NYC. Rather than storing the medication at remote and undisclosed federal warehouses, the medication would be stored at a NYC-contracted warehouse, yet still remain in the custody and control of the CDC.

While the CDC has met with us numerous times regarding our request, they have cited various concerns, including budget cuts that prevent the purchase of additional medication. The CDC also indicated that re-allocating existing assets would force it to alter its response profile nationwide and affect its ability to support other jurisdictions.

NYC renewed its request for forward-deployed assets following an unprecedented, full-scale, no-notice exercise in August 2014, which definitively demonstrated NYC’s ability to rapidly open 30 PODs citywide in less than 8 hours after NYC’s decision to do so. Many PODs were ready to open—fully set up and staffed—within 6 hours *but for the delivery of medication from the SNS*. All were ready in less than 8 hours—up to 4 hours before medications from the SNS would even arrive at NYC warehouses. Yet, despite this critical delay in medication delivery which would potentially result in increased morbidity and mortality, federal progress to address this gap has been slow.

In order to facilitate earlier public access to life-saving medication during an emergency in which time is of the essence, Congress should mandate and provide the necessary funding to support the forward deployment of SNS assets in reasonable and useful quantities to high-threat, high-density urban areas that have demonstrated an ability to stand up PODs faster than SNS medications can be delivered to jurisdictions. The consequence of the failure to forward-deploy SNS assets may ultimately be measured in the numbers of lives lost.

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<td>Federal agencies are not authorized to permit non-mission-essential federal employees to supplement the response and recovery efforts of local health departments during emergencies.</td>
<td>Congress should evaluate and implement appropriate interventions to authorize, encourage, and facilitate the training and rapid deployment of non-mission-essential federal employees in support of state and local responses to a broad range of emergencies.</td>
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There are many areas in which federal staff could be utilized to augment the response efforts of local jurisdictions during a large-scale emergency affecting the public health. One such opportunity is in the context of PODs. In NYC alone, prophylaxis on a citywide scale will require 33,000 POD staff to support 48 hours of dispensing operations. In
order to fulfill this demand, NYC pre-trains leadership staff and pre-assigns staff to PODs based on proximity to their home address. In anticipation of “role abandonment” or failure to report, NYC has made great efforts to staff each site with several layers of depth, particularly in core leadership positions. The NYC Health Department seeks to bolster this strategy by augmenting its POD staffing pool with non-mission-essential federal employees. This proposal is consistent with section three of the 2009 Presidential Executive Order (EO) 13527: Establishing Federal Capability for the Timely Provision of Medical Countermeasures Following a Biological Attack, which directs the federal government to “…anticipate and immediately supplement the capabilities of affected jurisdictions to rapidly distribute [medication] following a biological attack.”

Notably, the NYC Health Department has learned that during recent disasters in NYC, federal agencies have placed non-mission-essential employees on administrative leave for up to five days while the impact on their agency operations was evaluated. If this is standing policy, after a biological attack non-mission-essential federal employees based in NYC and other DFCs could remain idle at home while nearby PODs struggle to dispense medication due to inadequate staffing levels. In an effort to tap this potential resource, the NYC Health Department worked in recent years with NYC-based federal agencies and the NYC Federal Executive Board (FEB) to develop a proposal through which NYC-based, non-mission-essential federal employees could voluntarily participate at a NYC POD. If the proposal is approved, willing federal employees would receive training and be pre-assigned to a POD in the same manner as NYC employees. These federal employees would be notified and activated by NYC in the first hours of a mass prophylaxis response to work at their assigned PODs distributing medication to the public. Notably, federal employees who work at a NYC POD would be, like all POD staff, eligible to receive life-saving medication for themselves and up to 5 others before the POD opens to the public.

The voluntary participation of non-mission-essential federal employees would significantly augment NYC’s response capacity, not just in POD operations now but more broadly in the future. Unfortunately, the NYC Health Department cannot incorporate federal employees into its response plans, POD or otherwise, because it has not been able to obtain federal approval. Despite the seemingly enthusiastic support of the NYC FEB and NYC-based federal agency representatives, along with section three of the 2009 Presidential Executive Order (EO) 13527, the issues of payroll and authorization by federal agencies to release their employees both for training and for response at the time of an incident remain unresolved. All manner of conversation with NYC’s federal partners in this regard has stalled and the NYC Health Department believes the proposal is currently sitting with the federal Office of Personnel Management (OPM). Congress should consider appropriate interventions to authorize, encourage, and facilitate the inclusion of non-mission-essential federal employees in support of state and local responses to a broad range of emergencies.

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<td>Active, ongoing collaboration between local, state and federal agencies in BioWatch planning is critical to a robust and timely response to a biological incident; however, there has been insufficient interagency planning of this kind.</td>
<td>Congress should mandate the creation of a federal, interagency BioWatch planning workgroup, overseen by a single lead agency with ongoing, active collaboration with state and local government partners, whose primary objectives are to clarify and coordinate the response and recovery goals, objectives and activities of federal agencies following the detection of a biological incident.</td>
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BioWatch is a vital public health surveillance tool designed to provide early warning of a catastrophic release of a biological threat agent. In the event of a BioWatch Actionable Result (BAR) or other method of detection, the nation and jurisdictions affected by a biological incident of national significance will seek to implement a rapid and coordinated response by local, state and federal public health, environmental, and law enforcement agencies. It is
critical that the roles and responsibilities of various agencies be made clear, well in advance of an incident. However, an effective and efficient interagency response cannot happen in the absence of concerted intergovernmental collaboration that produces comprehensive emergency response plans. While there have been some good examples of this in recent years (e.g., the 2008 Interagency Biological Restoration Demonstration – IBRD – project in Seattle and the current Biological Remediation and Re-Occupancy Framework project in NYC), they unfortunately have been the exceptions. If there has been comprehensive interagency planning among federal stakeholders, then state and local health departments are unaware or appear to have been excluded.

No matter the reason, the DFCs are cognizant of critical gaps in preparedness, response, and recovery planning that could be remedied by more robust and coordinated intergovernmental planning. To date, each federal agency seemingly defaults to its own responsibilities rather than working together to solve the difficult, multi-disciplinary issues that will arise following confirmation of a biological incident of national significance. For example, critical questions remain unanswered including: how clean is clean and who has the authority to declare that a facility is safe to reoccupy? If critical infrastructure facilities are compromised, delay and uncertainty around remediation and re-occupancy become untenable at best. Jurisdictions are eager for consequence management recommendations from federal stakeholders on a variety of issues, including remediation standards, mass transit closures, and assessment of ongoing risk following a BAR, or if a biological incident of national significance is detected by other means.

Congress should identify a lead agency to oversee a federal interagency workgroup for BioWatch response planning (which will have utility for any biological response) and ensure that it includes ongoing collaboration with state and local government partners, including the DFCs and other BioWatch jurisdictions. The goals of the workgroup should be coordinating planning, clarifying the roles of the various federal agencies in a biological event, and developing consensus standards and guidance for high consequence response actions following a BAR.

Participating federal agencies should include Department of Homeland Security (DHS) and its Office of Health Affairs (OHA) and Federal Emergency Management Agency (FEMA); Environmental Protection Agency (EPA); Centers for Disease Control and Prevention (CDC), including the National Institute for Occupational Safety and Health (NIOSH), Laboratory Response Network (LRN), and the Division of State and Local Readiness (DSL); Federal Bureau of Investigation (FBI), and the Health and Human Services (HHS) Assistant Secretary for Preparedness and Response (ASPR). Progress and barriers should be reported back to Congress and to key stakeholders, most notably state and local government partners.

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<td>State and local public health departments are currently unable to replenish and maintain existing local caches of doxycycline due to its extremely high cost. Presumably, the SNS faces similar barriers to maintaining its supply as well.</td>
<td>The federal government should work to reduce the cost of doxycycline, including calling upon the FDA to investigate and determine ways to mitigate the cost increase.</td>
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NYC maintains a local cache of doxycycline and other medications and supplies for first responders in the event of a public health emergency. Doxycycline makes up a significant portion of this cache because of its status as a first-line prophylactic medication to prevent inhalation anthrax and other diseases caused by biological threat agents. Unfortunately, the cost of doxycycline has increased dramatically in the past several years. Prices have ranged 11 – 45 times more than in 2011, with shorter expiration dates.
As a result, the NYC Health Department and other local, state and federal agencies have not been able to purchase this critical medication. The federal government should work to reduce the cost of doxycycline, including calling upon the FDA or other appropriate agencies to investigate the issue and determine ways to mitigate the cost increase.

Aside from the immediate concern surrounding doxycycline and its exorbitant cost, all medication that is life-saving during public health emergencies must remain accessible to public health authorities not just during emergencies but in advance as well. Congress should consider all means within its power to ensure that such medications are not subject to wild fluctuations in price.

**Conclusion**

We are grateful to the Blue Ribbon Study Panel on Biodefense for giving the Directly Funded Cities an opportunity to provide feedback and participate in its process to develop recommendations concerning response and recovery from biological incidents impacting the public health. The importance of this discussion cannot be overstated, and we have taken great care to make recommendations that are actionable and critical to addressing shortcomings in our response capacity. We look forward to the forthcoming report from the Panel and future opportunities to collaborate in advancing our collective objectives.