



Regionalization of Bioterrorism Preparedness and Response

Summary

Introduction

The anthrax attacks of 2001, the outbreak of severe acute respiratory syndrome (SARS), and weapons of mass destruction tabletop exercises have made it clear that no single community can prepare fully, nor respond completely, to a large-scale bioterrorism event. Policymakers recognize the need to forge relationships and coordinate preparedness planning efforts at the local, state, national, and international levels.¹ However, there is little consensus about the optimal level of localization or regionalization for each of the resources and services that must be operationalized during a bioterrorism response.

We sought to evaluate the evidence regarding the effectiveness of existing regional systems that facilitate a response to bioterrorism. We sought evidence regarding the tasks that would need to be performed during a bioterrorism response (such as triage, provision of emergency medical care, transportation, and surveillance) and regionalized organizations that would likely contribute personnel, material, and information required to perform these bioterrorism response tasks.

Methods

Key Questions

The Key Questions addressed in this Report are:

1. What are the key tasks of local responders—such as local public health officials, clinicians, and emergency medical personnel—during a bioterrorism event?
2. What resources do local responders require to perform the tasks identified in Key Question 1?

3. Which existing regional systems for delivery of goods and services could be relevant to supplying the resources identified in Key Question 2?
4. Can regionalization of bioterrorism preparedness planning facilitate supplying needed resources to local responders during a bioterrorism event?
5. How do geographic variations in the affected population (e.g., urban as opposed to rural), special populations, and the interplay of private and public sector players affect regionalized systems?

Literature Searches

We sought relevant articles in four primary literature sources: the medical, emergency management, and supply chain management literatures, and government documents. We sought articles describing bioterrorism preparedness plans, vaccination strategies, evaluations of regionalized health care delivery systems, case studies of emergency responses, disaster preparedness plans, evaluations of responses to disasters, case studies about regional practices to increase the efficiency of manufacturing and distribution services, descriptions and evaluations of government programs responding to the 2001 anthrax cases, and bioterrorism-relevant events (e.g., naturally occurring outbreaks and disasters).

We developed separate search strategies for each of our four primary literature sources. In general, for each literature source we searched databases such as MEDLINE[®], indices of key journals and conference proceedings, and the Web sites of relevant organizations. At least one investigator screened titles, abstracts, and articles, as necessary, to determine if they met inclusion



criteria. From each included article, we abstracted the following data: information describing the regional system, methods and results of evaluations of the system, information about the quality of the study, as well as references in the bibliography that might meet inclusion criteria.

Methodologies for Evaluating Relevant Regional Systems

From each of the four literature sources, we sought evaluative information about:

- Clinical outcomes: morbidity and mortality
- Financial outcomes: costs associated with the event or responses to it
- Process outcomes: timeliness of the response; adherence to clinical protocols; measures of cooperation, coordination, and communication among responders; information about the incident command structure that was used and how it affected the regionalized response; and iterative application of lessons learned from prior bioterrorism-relevant responses
- Outcomes associated with the efficiency of the bioterrorism response supply chain including considerations of: the design of the supply chain network, inventory management, postponement (which refers to the concept of customizing a product late in the supply chain), modularization (which refers to the use of standard parts that can be used in multiple end products), supply chain coordination, management of incentives, and management of information.

Supplemental Analyses

Because we found no evidence about regionalization of two key bioterrorism response tasks—bioterrorism surveillance and the stockpiling of medical supplies required for a bioterrorism response—we performed simulations of regionalization of these tasks, using estimates derived from the published literature. In our surveillance simulation, we explored the tradeoffs in sensitivity and specificity caused by analyzing surveillance data locally versus regionally. In our simulation of regionalization of inventories of bioterrorism-relevant medical supplies, we evaluated the costs and benefits of differing strategies for pre-attack stockpiling and post-attack distribution of antibiotics.

Results

We reviewed 8536 citations, more than 500 websites, 1006 government reports, and numerous texts for potential inclusion in this Evidence Report. Of these, 396 articles, 61 government reports, and 75 Web sites met our inclusion criteria.

Synthesis of the Literature Describing the Existing Infrastructure for Bioterrorism Response

We included 22 articles, 25 government reports, and 14 Web sites on systems and organizations with existing infrastructures likely to contribute to a regionalized bioterrorism response. This literature describes numerous systems including, but not limited to, public health departments at local, state, national, and international levels (e.g., CDC, World Health Organization); the National Disaster Medical System (a federally coordinated program that provides medical and mental health assistance including the evaluation of patients and provision of hospital care when local capabilities are overwhelmed); Disaster Medical Assistance Teams (voluntary specialty medical teams that can be deployed to provide a wide range of disaster medical services and resources); the Metropolitan Medical Response System (which expands municipal bioterrorism preparedness through grants that provide pharmaceuticals and other supplies and requires detailed preparedness planning by recipient cities); and the Department of Homeland Security (which has oversight responsibilities for many of the key bioterrorism response agencies and programs such as the Federal Emergency Management Agency and the Strategic National Stockpile). This literature suggests that numerous response agencies with regional organizations could contribute to a bioterrorism response. However, most of these agencies were designed either independently or for purposes besides bioterrorism response, and efforts to coordinate them for bioterrorism preparedness are only now emerging or under development.

Synthesis of Supply Chain Case Studies Relevant to the Bioterrorism Response Supply Chain

A traditional supply chain is the integrated network of entities involved in all aspects of the manufacture of goods, including the procurement of raw materials, their assembly into the manufactured product, transportation of the product to distributors, and distribution to final customers.² The bioterrorism response supply chain has several related components: suppliers of raw materials, manufacturers of goods (e.g., product manufacturers such as drug and device manufacturers), purchasers, providers who distribute the products, customers/payors (e.g., the government, employers, and individuals), and the transportation systems that connect these components.³ Supply chain management concepts are directly relevant to those elements of a bioterrorism response that require the purchase, inventorying, distribution, and rapid dispensing of supplies. We included 22 articles and one Web site describing innovations relevant to the bioterrorism supply chain. From this literature we synthesized four key lessons:

1. Strategies to improve supply chain network designs, including regionalization of some elements of the supply chain (such as pooling of inventories at regional warehouses), can reduce inventories, improve the capacity to serve target populations, and save money. Some bioterrorism response supplies have limited shelf lives, so minimizing inventory may be important from economic and logistics perspectives.
2. Several supply chain case studies demonstrated that redesigning final products to be assembled from a limited number of common component parts, even if those component parts are costly, can result in overall cost savings for the supply chain (modularization). Similarly, postponing final customization of end products can reduce total inventories and costs. For bioterrorism, this supports the practice used by the Strategic National Stockpile of pre-packaging antibiotics and medical supplies for use in multiple localities, for a variety of bioterrorism events, and for use by a variety of patient populations.
3. Coordination of activities of heterogeneous bioterrorism response supply chain members, with specific consideration of the incentives of all stakeholders in the supply chain, can increase efficiency and reduce costs.
4. For the bioterrorism response supply chain, information systems that can accurately characterize the available supply of goods and personnel and the ongoing needs of the community affected may benefit the response.

Synthesis of the Literature Describing Responses to the 2001 Anthrax Attacks

We included 30 articles, 14 government reports, and 22 Web sites describing regionalized aspects of the response to the anthrax bioterrorism of 2001. None of these were evaluations; rather, most described particular aspects of the response to the anthrax attacks. From these articles, we synthesized five key lessons.

1. Cooperative agreements and regionalized response plans are needed for effective response to bioterrorism events. Pre-event regionalized planning and asset sharing agreements among local public health agencies and hospitals may facilitate enhanced surge capacity and coordinate responses during a bioterrorism event.
2. Incident command must be well defined and accepted by all relevant responders.
3. Information systems for communication among responders and with the public must be implemented and tested prior to an event.
4. The costs and benefits of acquiring, storing, and maintaining local inventories of medical supplies have not been established.

5. The Laboratory Response Network significantly enhanced regional laboratory surge capacity. Whether the surge capacity provided by the Laboratory Response Network will be adequate for a bioterrorism event of larger magnitude remains untested.

Synthesis of the Literature Describing Responses to Naturally-Occurring Outbreaks

We included 177 articles, 10 government reports, and 33 Web sites about responses to natural outbreaks including SARS, pandemic influenza, meningococcal meningitis, smallpox, and West Nile virus. From our review of this largely descriptive literature, we synthesized three main lessons regarding a regional response to outbreaks resulting from bioterrorism.

1. Communication and cooperation between health authorities of neighboring regions are needed for adequate and rapid responses. Rapid communication can be difficult to achieve through interim agreements. Thus, cooperation during a bioterrorism response may benefit from pre-event development and routine use of shared communication systems.
2. In the event of a bioterrorism attack, international cooperation to detect, report, and respond may reduce associated morbidity or mortality, as it did during the SARS outbreak.
3. During a bioterrorism event, strategies to protect responders and their families may be an essential component of maintaining a robust work force.

Synthesis of the Literature Describing Disaster Responses

We included 41 articles, 21 government reports, and 12 Web sites that described regionalized responses to natural or manmade disasters or described regionalization of disaster response systems. From these articles, we synthesized three key lessons, though evaluative evidence is limited.

1. Information management is essential for assessing the needs of the local community and the resources available to them, and for coordinating responses from regional agencies.
2. A key component of effective regional responses to disasters includes mutually agreed upon pre-event protocols that establish chain of command structures, including plans for how the chain of command changes as regional and federal response agencies become involved.
3. Mutual aid agreements (such as the Master Mutual Aid agreement in California and the Emergency Management Assistance Compact in the rest of the United States)^{4,5} are key components in providing surge capacity for regional response to disasters. These agreements ensure that every locale does not have to be staffed and prepared for a

maximal intensity event. They enable risk to be spread among several locales, and provide cost-sharing of disaster preparedness. Mutual aid agreements for bioterrorism are likely to benefit from careful pre-event consideration of liability issues, remuneration, and licensing.

Synthesis of the Literature Describing Regionalization of Trauma Care

We included 80 articles and government reports that described regionalization of trauma care; 40 of these reported the results of evaluations of regionalization of trauma care. From these, we synthesized four key lessons, based on the evaluative evidence.

1. Pre-event hospital designation contributes to lower costs and improved patient outcomes. The evidence from trauma care regionalization suggests that a key component of high quality, cost-effective care is limiting high-cost specialty care to specifically designated hospitals with increased experience in treating severely injured patients. A bioterrorism response system may benefit from the pre-event designation of hospitals.
2. Formalized protocols for pre-hospital and hospital care contribute to improved patient outcomes. A regionalized bioterrorism response may benefit from similar protocols so that first responders know where and how to rapidly transport exposed patients.
3. An established communication network is essential to the coordinated regionalization of trauma care. Such a system could play an important role during a bioterrorism response.
4. Correctly aligned incentives, particularly sufficient funding, are critical to maintaining the participation of designated trauma hospitals. The included articles suggest that regionalized trauma care systems do not provide sufficient incentives for some hospitals to remain in the system. A bioterrorism response system is likely to benefit from incentives for hospital participation.

Synthesis of the Literature Describing Regionalization of Surveillance for Bioterrorism

Our search identified 36 articles, two government reports, and one Web site describing regionalization of surveillance systems for bioterrorism. From these, we draw four key lessons.

1. Evaluations of regionalization of surveillance data collection and analysis are needed. Although numerous syndromic surveillance efforts in local areas are promising, no study has evaluated the tradeoffs in terms of costs and benefits of regionalizing bioterrorism surveillance.

2. If a regionalized surveillance system uses local data collection with regional analysis, considerations of means to reduce costs of data collection and to share relevant analyses with local data collectors may enhance local participation.
3. A common technology platform may facilitate the collection and analysis of surveillance data.
4. Privacy issues are a key concern: collection and analysis of surveillance data need to protect individual privacy while containing sufficient detail to detect new outbreaks.

Simulation Model Results

The results of our surveillance model suggest that whereas large outbreaks can be relatively easy to detect using either unpooled (i.e., local) or pooled (i.e., regionalized) data analysis methods, small outbreaks can be difficult to detect by either method. Additionally, we found that pooling strategies may improve detection capabilities, but the circumstances under which pooling strategies are consistently more effective or cost effective than using unpooled data remain poorly characterized.

Our inventory logistics simulation model yielded three results. First, the mortality associated with anthrax bioterrorism may be highly sensitive to the number of people seeking prophylactic antibiotics. This is a critical finding given that for many types of bioterrorism responses it will be difficult to determine whether an individual has been exposed to the biothreat agent. Second, strategies that deliver multiple Push Packs to the site of the attack, until the regional Vendor Managed Inventory has been delivered to these areas, may reduce mortality. Finally, increasing the availability of local inventories may be cost effective only if the annual probability of attack is high.

Summary of Answers to Key Questions

Key Question 1: What are the key tasks of local responders during a bioterrorism event? The literature describes nine main bioterrorism response task categories: preparedness planning, field assessment and triage, diagnosis, management of the acutely ill, prevention of the spread of disease, surveillance, outbreak investigation, communication, and emergency management. For each of these main tasks, we considered the subtasks that responders are required to perform. For example, subtasks of surveillance include collection, analysis, and reporting of surveillance data.

Key Question 2: What resources do local responders require to perform the tasks identified in Key Question 1? For each task described above, we abstracted information about four broad categories of resources required for that task: personnel, material, information, and financial. For example, for the key task of “prevention of the spread of disease,” numerous personnel, material and information resources are required, including: clinicians, public health officials, logisticians and

pharmacists (personnel); pharmaceuticals, isolation facilities, sites for mass vaccination, and supplies for mass care (material); prevention guidelines, home-care instructions for patients, and information regarding characteristics of the infectious agent to aid decisionmaking about quarantine, isolation, and evacuation (information); and the financial support for each of these.

Key Question 3: Which existing regional systems of delivery of goods and services could be relevant to supplying the resources identified in Key Question 2? We found numerous systems and organizations with regionalized infrastructures engaged in the timely delivery of bioterrorism-relevant material, personnel, and information. Specifically, we found systems and organizations responsible for each of the response tasks described in our answer to Key Question 1: for preparedness planning (e.g., the Joint Commission on the Accreditation of Healthcare Organizations), field assessment and triage (e.g., US trauma care system), diagnosis (e.g., Laboratory Response Network), management of the acutely ill (e.g. Medicins Sans Frontieres), prevention of the spread of disease (e.g., Strategic National Stockpile), surveillance (e.g., Electronic Surveillance System for the Early Notification of Community-based Epidemics), outbreak investigation (e.g., Epidemic Intelligence Service), communication (e.g., ProMed), and emergency management (e.g., Emergency Management Assistance Compacts).

Thus, we conclude that numerous existing systems and organizations could contribute to a regionalized bioterrorism response. Many of these have long histories of successful participation in bioterrorism-related events such as infectious disease outbreaks and natural disasters. However, most of these systems were designed independently, typically to facilitate particular response tasks. Ongoing efforts to coordinate such systems have not been evaluated.

Key Question 4. Can regionalization of bioterrorism preparedness planning facilitate supplying needed resources to local responders during a bioterrorism event?

Our evidence synthesis produced six main results about regionalization of services for bioterrorism preparedness and response.

1. There have been few evaluations of whether regionalization has benefited a particular response organization or task. Efforts to develop a regionalized infrastructure for bioterrorism responses will likely benefit from careful evaluations of the numerous tasks involved in a bioterrorism response and the alternative strategies for providing the necessary resources to perform these tasks.
2. Regionalization has benefited response capability in disaster situations. Our review of the responses to natural and manmade disasters found that during large-scale disasters, local response capacity can be quickly overwhelmed. The key method of organizing regionalized disaster responses is by mutual aid agreements. The elements of successful mutual aid agreements include pre-event ratification of legislation by all signatories to resolve issues of

compensation, liability, and insurance, and uniform information systems to track needs and resources. Bioterrorism responses are likely to benefit from mutual aid agreements in all states (including agreements with neighboring regions of Mexico and Canada), which will provide surge capacity for public health services.

3. Regionalization efforts have successfully expanded surge capacity for laboratory services. During the anthrax attacks, the Laboratory Response Network successfully provided laboratory surge capacity. Whether there is sufficient transportation infrastructure to facilitate the delivery of laboratory specimens from a bioterrorism attack location to Laboratory Response Network facilities during a larger bioterrorism event has not been evaluated.
4. Information technologies facilitate accurate determination of response needs and available resources, effective application of the chain of command, communication among responders and with the public, and surveillance. Our review of evaluations of supply chains emphasized the importance of accurate information for coordination of all elements of the supply chain. Additionally, the evaluations demonstrated that investments in information technologies often resulted in net cost savings for the supply chain while improving service. The disaster response literature provided examples of how inadequate information infrastructures led to delays in responses. Regionalization of bioterrorism preparedness and response efforts will likely benefit from careful consideration of the information technologies that can facilitate sharing of information by different response organizations and by responders at local and regional levels.
5. The disaster and outbreak response literatures emphasize that local responders are often at risk of personal injury during a response. Because local responders will be the first on a scene during an emergency, bioterrorism responses may benefit from careful consideration of the incentives of local personnel to participate in a response and from first responder training that emphasizes personal safety, triage, diagnosis, and outbreak management tasks.
6. Few included articles specifically articulated lessons learned from their bioterrorism-related preparedness or response experiences. Our review of government documents, particularly responses of military personnel, found that organizational commitment is a key factor in implementing a 'lessons learned' approach to ensuring that knowledge gained from both good and bad experiences is maintained in institutional memory. Plans to regionalize services for a response to a large-scale bioterrorism event could benefit from the experiences of responses to small bioterrorism events and relevant naturally occurring outbreaks if the lessons learned from these experiences were documented and used to improve planning efforts. Given the complexity of a bioterrorism response, the iterative

application of lessons learned from one experience to the next requires commitment from all relevant response organizations to institutionalize a 'lessons learned' approach.

Key Question 5: How do geographic variations in the affected population, special populations, and the interplay of private and public sector players affect regionalized systems? In the United States, special populations including children, the elderly, the disabled, and pregnant women account for about 134 million people.^{6,9} Thus, bioterrorism preparedness planning requires consideration of these special populations. However, we found little evidence that specifically addressed variations in regionalized responses on the basis of geography, population, or public-private cooperation.

Discussion

Given the complexity and cost of training, staffing, equipping, and mobilizing an adequate bioterrorism response infrastructure, no single community can be expected to develop and maintain the necessary capacity for a large-scale bioterrorism response. Instead, regionalization may benefit some bioterrorism preparedness and response capabilities. Our extensive search of four literature sources relevant to bioterrorism responses found that the response infrastructure for a bioterrorism event includes numerous agencies with regionalized organizational structures. However, most of these agencies have been developed independently or for purposes other than bioterrorism response, and efforts to coordinate them for bioterrorism preparedness are underway but not yet widespread. Specifically, the Department of Homeland Security, which has oversight and coordination responsibilities for many of the agencies that would contribute to regionalized bioterrorism responses, is currently reorganizing its regional structure.

We conclude that regionalization is likely to benefit elements of a bioterrorism response including the provision of surge capacity in essential response services such as triage, the provision of medical care, distribution and dispensing of prophylactic therapies, outbreak investigation, security management, and emergency management. Additionally, regionalization may be a cost effective strategy for developing teams of trained response personnel and maintaining inventories of response equipment. Numerous response organizations with regionalized infrastructures will serve key functions during a large-scale bioterrorism response. Coordination of these organizations may benefit from implementation of information management strategies and pre-empt agreements that specify response roles, remuneration, and chain of command.

Future Research

Despite the large number of studies and articles we reviewed, we found very few evaluations of systems relevant to bioterrorism preparedness, and even fewer evaluations of the regionalization of a system relevant to bioterrorism preparedness. Future research is needed to fill this gap in the literature. Specifically, evaluations are needed for a better understanding of the costs and benefits of regionalization of surveillance, inventory management and distribution systems, and information management.

Availability of the Full Report

The full Evidence Report from which this summary was taken was prepared for the Agency for Healthcare Research and Quality (AHRQ) by the Stanford–UCSF Evidence-based Practice Center under Contract No. 290-02-0017. Printed copies may be obtained free of charge from the AHRQ Publications Clearinghouse by calling 800-358-9295. Requesters should ask for Evidence Report/Technology Assessment No. 96, *Regionalization of Bioterrorism Preparedness and Response*. Additionally, the report and this summary will be available online through AHRQ's Web site at www.ahrq.gov.

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