

2019-2024 Public Health Emergency Preparedness (PHEP) Notice of Funding Opportunity – Supplemental Guidance and Resources

Domain 4: Key Components of Anthrax Operational Readiness

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Overview

CDC has classified anthrax as a Category A biological warfare agent because of its great potential to adversely affect public health. Anthrax is considered one of the most serious biowarfare or bioterrorism agents because of the ability of the aerosolized spores to readily cause infection via respiratory (inhalation) exposure and the high mortality resulting from inhaling anthrax. Failure to anticipate this threat – or the lack of capability to respond effectively – could result in substantial illness and death.

Since the 2001 anthrax attacks, federal, state, and local agencies have worked to strengthen their abilities to effectively respond to an anthrax event. The capability to respond to anthrax events will continue to be a major focus of the PHEP program, especially in designated metropolitan jurisdictions where the threat of an anthrax event is determined to be extremely high.

Purpose

State and local jurisdictions must effectively plan and be ready to respond to an anthrax incident, implementing measures to mitigate the adverse health, social, and economic consequences. Coordination among law enforcement, public health, homeland security, and health care sectors is essential. Operational readiness depends on the coordination of multiple capabilities and agencies with expertise in laboratory testing, environmental and occupational exposure measures, and the quick and effective distribution of antimicrobials, vaccines, and other medical countermeasures (MCMs).

Programmatic Requirements

Per the 2019-2024 PHEP notice of funding opportunity (NOFO), CDC expects PHEP recipients to work with relevant subject matter experts, law enforcement, and health care entities and organizations to build operational readiness for an anthrax event. Following are strategies and activities that, taken together, constitute operational readiness, according to CDC subject matter experts.

A jurisdiction is likely to be operationally ready for an anthrax event when it can demonstrate the following activities.

1. A **comprehensive pre-event planning process** that results in an anthrax plan developed with input from relevant subject matter experts and community partners including people with access and functional needs. Such a planning group would include representation from diverse sectors such as epidemiology and laboratory science, emergency management, law enforcement, communication experts, health care providers and organizations, hospitals, and community organizations. Following the recognition of an anthrax event, this planning group will continue to provide input on decisions relating to antimicrobial and vaccine allocation, communication and community mitigation efforts, and other prevention and treatment efforts.
2. Assurance that **response roles of all participating agencies** are clearly delineated and practiced so that they are ready to respond. This consists of a comprehensive outline of roles and responsibilities of federal, state, and local agencies; nongovernmental entities; hospitals; transportation; education; and law enforcement agencies.
3. Ability to **standup an incident command structure**. Jurisdictions must work with anthrax subject matter experts to analyze the threat; guide incident action planning and response; make response decisions; provide guidance on mitigation measures; gain and maintain situational awareness; request and track resources;

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engage relevant partners to provide needed services such as antimicrobials; collect, manage, and share information; and safely sustain operations during a defined response period.

4. Meet the response needs of the incident by having **adequate numbers of appropriately trained staff** and processes and procedures in place to effectively integrate surge staffing into response operations.
5. Planning that addresses **legal and regulatory measures** encompassing
 - Federal legal authorities that will enable distribution and dispensing of MCMs including liability protections under the Public Readiness and Emergency Preparedness Act (PREP Act), emergency dispensing orders (EDOs), emergency use authorizations (EUAs), investigational new drugs (INDs), and emergency use instructions (EUIs).
 - The jurisdiction's legal authorities that will enable distribution and dispensing of MCMs including the legal status of individual and entity volunteers, liability and immunity, expanding scopes of practice, workers' compensation, licensure reciprocity, data collection and privacy, use of memoranda of understanding, and other relevant issues.
6. Operational capability **to distribute required MCMs** including vaccines, antimicrobials, antitoxins, and ancillary medical supplies to distribution sites, treatment centers, and hospitals.
7. Operational capability **to dispense or administer required MCMs** to the impacted population for as long as 60 days, starting within 48 hours of a federal deployment decision. Operational capability is characterized by the ability to do the following.
 - Provide prophylaxis to public health responders and critical workforce personnel.
 - Dispense antimicrobials to 100% of the target population within 48 hours of a federal deployment decision and ensure appropriate follow-up, which may include ability to identify those individuals receiving MCMs and ability to recall them for distribution of additional antimicrobial courses.
 - Administer vaccine to the potentially exposed population in accordance with respective regulatory mechanism(s) and requirements for use in adults (EUI or EUA) and children (IND), and determine the optimal operational strategies for the jurisdiction to reach the vaccine target population.
 - Understand the anthrax vaccine post-exposure prophylaxis (PEP) dosing strategies, including dose-sparing regimens, in combination with appropriate antimicrobials.
 - Distribute and apply relevant clinical guidance to treatment facilities.
 - Monitor, track, and report on needs for antimicrobials, antitoxins, vaccines, ancillary medical supplies.
 - Monitor recipients of vaccines, antimicrobials, and antitoxins for adverse events and report to stakeholders according to regulatory requirements, such as IND, EUA, and FDA MedWatch.
 - Demonstrate knowledge of decontamination procedures for an individual and infection control precautions for anthrax.
8. Ability to **coordinate with health care partners** to perform the following activities.
 - Plan for evaluation and medical care needs of persons presenting to health care facilities with documented or suspected anthrax infection.
 - Ensure agreements are in place to share personally identifiable information (PII) during a public health emergency.
 - Confirm mechanisms are in place for health care systems to request antimicrobials, antitoxins, and ancillary medical supplies from the Strategic National Stockpile (SNS).
 - Demonstrate knowledge of decontamination procedures for an individual and infection control precautions for anthrax with the ability to rapidly respond to inquiries from the health care community.

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9. **Public health laboratory capability** to collect specimens and test for *Bacillus anthracis* characterized by the ability to perform the following activities.
 - Rule in or rule out *Bacillus anthracis* at clinical, public health, or hospital laboratories.
 - Package and ship specimens to a qualified *Bacillus anthracis* testing laboratory, using specimen-specific shipping and handling procedures.
 - Demonstrate competency and proficiency at performing all diagnostic tests in the *Bacillus anthracis* algorithm at Laboratory Response Network (LRN) laboratories.
 - Plan for potential surge testing following recognition of an event and work with anthrax subject matter experts to develop algorithms to assist clinicians in determining optimal testing and treatment strategies.
10. Ability to ensure effective **rapid information sharing to inform response actions** with key partners regarding significant results from epidemiologic investigations, laboratory collection information, MCM availability, and information to and from the health care system.
11. Ability to ensure timely and **effective communication to all stakeholders and the public** regarding disease presentation, risk factors, and role of and access to prophylaxis and treatment.
12. **Epidemiologic and surveillance capability** to perform the following activities.
 - Collect and transmit exposure risk data within 24 hours of case notification.
 - Collect information on adverse events related to anthrax MCM use and share information.
 - Conduct active surveillance in both affected and adjacent areas.
13. Operational capability to provide **environmental and occupational exposure prevention and response** characterized by the ability to do the following activities.
 - Develop clearance goals for contaminated areas based on guidance from a committee of subject matter experts.
 - Standup trained and properly equipped environmental sampling teams to collect environmental samples according to CDC-recommended methods.
 - Ensure at-risk responders with access and functional needs are offered appropriate MCMs, such as antimicrobial prophylaxis and vaccination, which requires potential pre-event identification of populations with access and functional needs that would be part of this critical infrastructure workforce.
14. Ability to **collaborate with key partners to recommend and implement nonpharmaceutical intervention strategies** that allow for the following activities.
 - Plan for necessary community mitigation measures. For example, how to use local, state, or federal quarantine authorities (if needed) to limit access into or out of the impacted and surrounding areas that are deemed a public health risk because of contamination.
 - Determine need to evacuate affected population from contaminated areas and evaluate and implement early containment of suspected contamination area as needed.
15. Ability to develop and execute a plan to **maintain continuity of operations** during an anthrax mass casualty incident to implement the following activities.
 - Communicate with staff to provide emergency notifications, updates on situational awareness, instructions for reporting to work, and guidance on protective measures they can take for themselves and their families.
 - Cross-train staff to ensure redundancy in skills and capability to maintain critical functions.
 - Allow some staff to telework (if appropriate) and capacity to support off-site communications and computer access.
 - Monitor worker health.

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- Maintain security of facilities, supplies, and staff.
16. Planning, execution, and evaluation of **a series of progressive exercises** designed to assess, validate, and improve on operational readiness for declaration of an anthrax mass casualty incident, as defined by the these key components and with documentation of improvement actions. Exercises should follow a progressively complex approach using Homeland Security Exercise and Evaluation Program (HSEEP) standards that include various stakeholders and various anthrax scenarios.

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Resources for Strengthening Anthrax Operational Readiness

Title	Location
Clinical Framework and Medical Countermeasure Use during an Anthrax Mass-Casualty Incident: CDC Recommendations	https://www.cdc.gov/mmwr/pdf/rr/rr6404.pdf
Emergency Use Instructions (EUI) for Doxycycline and Ciprofloxacin for Post-exposure Prophylaxis (PEP) of Anthrax	https://www.cdc.gov/anthrax/medical-care/emergency-use-doxycycline-ciprofloxacin.html
Use of Anthrax Vaccine in the United States: Recommendations of the Advisory Committee on Immunization Practices (ACIP), 2009	https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5906a1.htm
Receiving 60-day Anthrax Medical Countermeasures from CDC's Strategic National Stockpile: Planning Considerations for State, Local, Tribal, and Territorial Partners	https://cdcpartners.sharepoint.com/sites/OPHPRDSLRLPS/On-TRAC/AssistanceCenter/ResourceCenter/Pages/60-Day-Anthrax-Plan.aspx
Receiving, Distributing, and Dispensing Strategic National Stockpile Assets: A Guide for Preparedness, Version 11, February 2014	https://www.hsdl.org/?abstract&did=799144
Anthrax Case Investigation System (AIS): Purpose and Use of System	https://www.cdc.gov/anthrax/pdf/anthrax-case-investigation-system-H.pdf
Biological Incident Annex, National Response Framework	http://www.fema.gov/pdf/emergency/nrf/nrf_BiologicalIncidentAnnex.pdf
Recommended Specimens for Microbiology and Pathology for Diagnosis of Anthrax	https://www.cdc.gov/anthrax/specificgroups/lab-professionals/recommended-specimen.html
Anthrax: Collecting, Preparing, and Shipping Serum Specimens to CDC for Serology Testing	https://www.cdc.gov/anthrax/specificgroups/lab-professionals/cdcspecimens.html
Guidance for Protecting Responders' Health During the First Week Following A Wide-Area Aerosol Anthrax Attack (2012)	https://www.dhs.gov/sites/default/files/publications/Guidance%20for%20Protecting%20Responders%27%20Health%20-%20October%202012_0.pdf
Interim Clearance Strategy for Environments Contaminated with <i>Bacillus anthracis</i> (2012)	https://www.epa.gov/sites/production/files/documents/cdc-epa-interim-clearance-strategy.pdf
Notice to Readers: Protecting Building Environments from Airborne Chemical, Biologic, or Radiologic Attack	https://www.cdc.gov/mmwr/preview/mmwrhtml/mm5135a4.htm
NIOSH: Recommendations for the Selection and Use of Respirators and Protective Clothing for Protection Against Biological Agents	https://www.cdc.gov/niosh/docs/2009-132/default.html
Guideline for Isolation Precautions (2007): Preventing Transmission of Infectious Agents in Healthcare Settings	https://www.cdc.gov/anthrax/pdf/infection-control-guidelines-for-healthcare-setting-2007.pdf
CDC MMWR: Occupational Health Guidelines for Remediation Workers at Anthrax Contaminated Sites	https://www.cdc.gov/mmwr/preview/mmwrhtml/mm5135a3.htm
Model Health Safety Plan (HASP) for Clean-up of Facilities Contaminated with Anthrax Spores	https://www.osha.gov/dep/anthrax/hasp/index.html

