

12-02

## STATEMENT OF POLICY

### Anthrax Vaccine Response

#### Policy

The National Association of County and City Health Officials (NACCHO) recommends that the federal government, through the Centers for Disease Control and Prevention (CDC) and Office of the Assistant Secretary for Preparedness and Response (ASPR), provide local health departments with technical and financial assistance to enhance current plans to prepare for and respond to the threat of an anthrax attack.

To assist local health departments with responding to such an event, NACCHO makes the following policy recommendations:

- The CDC should support local public health agencies in preparing for this type of response. The CDC's Anthrax Prevention webpage states, "During an emergency the only people who should not get the anthrax vaccine after possible exposure are those who have had a serious allergic reaction to a previous dose of anthrax vaccine."<sup>1</sup> In light of this statement, the 2013 guidance from CDC on Anthrax Vaccine Adsorbed (AVA) Post-Exposure Prioritization,<sup>2</sup> and reductions to local preparedness funding, the CDC should provide local public health agencies with assistance (both technical and financial) in developing the capabilities to address this threat. Additionally, ASPR should establish a mechanism, either through stockpiling or vendor agreements, for providing the needed vaccination ancillary supplies (including syringes for subcutaneous injection and needles for administration, bandages, cotton balls, and alcohol swabs) to local public health agencies to support the rapid establishment of operational capacity to administer vaccine to large populations.
- The ASPR's Strategic National Stockpile (SNS) program should build the capacity to support anthrax vaccine response full scale exercises by providing simulated vaccine, ancillary supplies, and cold chain shipping and management supplies that are not already included in the 'Eagle Package' exercise materials.
- The CDC has developed specific guidance on the prevention and treatment of anthrax. For persons not included in the Food and Drug Administration-approved indication for post-exposure prophylaxis (PEP) with AVA, AVA will be available for PEP use for children, pregnant women, nursing mothers and older adults (i.e.,  $\geq 66$  years) under appropriate emergency use regulatory provisions. The CDC should clarify the process by



which the emergency use regulatory provisions will be obtained as well as the length of time needed to for this process. The CDC and ASPR should also further clarify the definition of a “true exposure” and provide more guidance on storage and handling of vaccine (cold chain management), administration, planning for concurrent administration of vaccine and dispensing of antibiotics, the management of adverse events associated with the anthrax vaccine, and on Investigational New Drug (IND) requirements for the vaccine. Federal agencies should also incorporate efficiencies into the current IND requirements for a large-scale anthrax vaccination response to make those requirements practical for the rapid administration to large populations.

- Additionally, it is critical that local public health agencies continue to receive financial support for these federal programs and efforts required to enhance local abilities/capacity. Without continued financial support to maintain a minimum level of preparedness capabilities, retain licensed and professional staff, and recruit medical volunteers that can help administer this vaccine, operational readiness for an anthrax event will be greatly diminished.

### **Justification**

The CDC Advisory Committee on Immunization Practices (ACIP) “recommends AVA for use in adults aged 18-65 years to be given in conjunction with a course of antimicrobials to prevent infection after suspected or known exposure to aerosolized *B. anthracis* spores [...] The vaccine is given at a dose of 0.5 mL SC (subcutaneous) at 0, 2, and 4 weeks postexposure, unless the emergency response requires a change to the IM (intramuscular) route or use of dose-sparing regimens.”<sup>3</sup>

According to ACIP, “In the event of a large-scale release of *B. anthracis* spores, the Strategic National Stockpile will distribute medical countermeasures to affected states, and state and local public health agencies will then dispense antimicrobials to and vaccinate numerous at-risk persons.”<sup>3</sup>

The intentional release of anthrax over a large area will require a swift response to mitigate loss of life due to the short window in which PEP is effective to treat the affected population. Current planning for PEP relies on the dispensing of a 60-day course of antibiotics combined with three doses of vaccine for persons exposed to inhalational anthrax.<sup>2,4</sup> Concurrent dispensing of antibiotics and administration of anthrax vaccine in response to an intentional release of aerosolized anthrax will pose significant operational and logistical challenges for local public health agencies. Preplanning and assuring an adequate level of trained and qualified staff are currently foundational mitigating activities available to local health departments to address the issues involved in this type of response. CDC guidance will help local health departments to plan for anthrax vaccinations concurrent with antibiotics dispensing since vaccination supplies are not included in the Strategic National Stockpile for an anthrax response.

NACCHO is concerned that local public health agencies are not adequately prepared or funded to mount a vaccination campaign concurrent with an antibiotic dispensing campaign in the aftermath of an aerosolized anthrax attack, due to the challenges local health departments face in

how to implement the ACIP and CDC guidance related to anthrax vaccine and lack of support (both technical and financial) dedicated to this area of preparedness.

General guidance from the federal government suggests that vaccine, in addition to antibiotics, is the best response to an intentional release of anthrax. There is now an official statement from the CDC with regard to local preparedness efforts for prioritization of vaccination.<sup>3</sup> Previous preparedness planning has focused on dispersing an initial 10-day dose of antibiotics into an exposed population within 48 hours of the decision to do so. As recommended in the ACIP guidance, local public health agencies need the technical and financial support to begin preparing for a response that will include providing three doses of vaccine concurrent with a regimen of antibiotics.<sup>3</sup> A response will be substantially more effective if the logistical and operational issues can be adequately addressed prior to an actual event. In addition, without the financial support to maintain an adequate level of licensed and professional staff, public health agencies will find it difficult to deliver these federal medical countermeasures to the public in an emergency, resulting in increased illness and mortality.

### **References**

1. CDC. Anthrax Prevention webpage. Retrieved January 22, 2020, from <http://www.cdc.gov/anthrax/medical-care/prevention.html>.
2. CDC. Considerations for Anthrax Vaccine Adsorbed (AVA) Post-Exposure Prioritization, 2013. Retrieved January 22, 2020, from <https://www.cdc.gov/anthrax/pdf/ava-post-event-prioritization-guidance.pdf>.
3. CDC. (2019). [Use of Anthrax Vaccine in the United States: Recommendations of the Advisory Committee on Immunization Practices, 2019](#). *Morbidity and Mortality Weekly Report*, 68 (RR-4).
4. CDC. Administering the Anthrax Vaccine webpage. Retrieved January 22, 2020, from <https://www.cdc.gov/vaccines/vpd/anthrax/hcp/administering-vaccine.html>.

### **Record of Action**

*Proposed by NACCHO Medical Countermeasures Workgroup*

*Approved by NACCHO Board of Directors March 2012*

*Updated July 2017*

*Updated April 2020*