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The Centers for
Disease Control and
Prevention

FINAL

CONSIDERATIONS FOR ANTHRAX VACCINE ADSORBED (AVA) POST-EXPOSURE PRIORITIZATION FINAL

DISCLAIMER:

This document considers prioritization of Anthrax Vaccine Adsorbed (AVA) in a post-event setting. This document does not include implementation considerations for post-event vaccination. This document does not include policy or implementation considerations for pre-event vaccination. This document does not include policy considerations for reserving vaccine in a post-event setting (e.g., holding back vaccine because of high risk of subsequent event). This document does not address vaccination for long-term exposure risks to *Bacillus anthracis* spores (> 6 months). The principles in this document apply regardless of the number of doses available.

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PRELUDE

This document reflects the current understanding of the unique situation that will exist after a wide-area aerosol anthrax attack and outlines a prioritization scheme for post-event use of AVA. Supplies of AVA may be insufficient to protect the entire exposed population in a large scale release. Producing new lots of AVA can take months, so production may not be rapidly increased in a surge fashion when an event occurs.

These guidelines are a risk-based approach to handling prioritization of AVA following an intentional release of *Bacillus anthracis* spores. The initial focus is on individuals present in the primary area of release (affected area) because they are at the highest risk of exposure to primary aerosols of *B. anthracis* spores. Risk based on exposure to secondary aerosols of *B. anthracis* spores will determine subsequent groups. The document describes the risk-based approach to prioritization of AVA on page 9. Please note, early in the wake of a release of *B. anthracis* spore aerosols, the ability to precisely identify boundaries of the affected area will be difficult. As more illness surveillance data and analyses from environmental sampling emerge, our understanding of the event and risk of illness will evolve and improve over time.

As stated in the disclaimer, this document considers prioritization of AVA in a post-event wide-area *B. anthracis* spore aerosol attack and not policy considerations for pre-event vaccination or for reserving vaccine post-event. All persons with potential exposure to *B. anthracis* spores will be offered a 60-day course of antibiotics post-event. Thus, there are no prioritizations for antibiotics,[1] since adequate supplies of antibiotics are available. In addition, this guidance is focused on considerations for vaccine only and will not consider specific worker safety requirements, such as personal protective equipment (PPE).[2] This document offers guidelines for operational planning. Ultimately, decisions about vaccine administration, program monitoring, and implementation of these guidelines will be made by federal, state, and local health and emergency management officials who are responsible for administration of vaccine. Protection of responders in the first week after a wide-area aerosol anthrax attack is addressed in a separate document (The "*Guidance for Protecting Responders Health during the First Week Following a Wide-Area Aerosol Anthrax Attack*").[3]

KEY POINTS

- Vaccine supplies may be insufficient to immunize the entire potentially exposed population in a wide-area *B. anthracis* spore aerosol attack
- CDC recommends 60 days of post-exposure antibiotics for everyone potentially exposed to *B. anthracis* spores. There are sufficient antibiotics in the U.S. stockpile for all potentially exposed persons to protect against illness
- CDC recommends anthrax vaccine as part of post-exposure prophylaxis because vaccine offers protection for a longer duration of time, i.e., after persons stop taking antibiotics
- These considerations for post-exposure AVA for a wide-area anthrax aerosol attack are subject to change at any time when/or if new information becomes available

[1] Information regarding antibiotics for an anthrax event can be found in:
Use of anthrax vaccine in the United States: recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR 2009; 59(No. RR-6). Access at: www.cdc.gov/mmwr/PDF/rr/rr5906.pdf

[2] Information regarding PPE for an anthrax event can be found in:
DHHS (NIOSH) Publication Number 2009-137. Access at: http://www.cdc.gov/niosh/docs/2009-132/default.html; and,
OSHA Anthrax e-Tool. Access at: http://www.osha.gov/SLTC/etools/anthrax/ppe.html

[3] Federal *"Guidance for Protecting Responders' Health during the First Week Following a Wide-Area Aerosol Anthrax Attack"* dated September 2012. Access at: http://www.phe.gov/Preparedness/responders/Pages/anthraxguidance.aspx

1. BACKGROUND ON ANTHRAX AND AVA[4]

Anthrax is a zoonotic disease caused by the spore-forming bacterium *B. anthracis*. The spores can tolerate dry conditions and remain viable for long periods of time. The precise infectious dose of *B. anthracis* in humans for the various routes of exposure is not known; yet, anthrax may develop after exposure to a relatively small number of spores.

Human anthrax cases worldwide occur almost exclusively from natural exposures (i.e., not a result of bioterrorism). Human anthrax is categorized into four forms according to the route of exposure to *B. anthracis* spores: inhalation, cutaneous, gastrointestinal, and injections[5]. During a wide-area aerosol anthrax release, inhalation, gastrointestinal, and cutaneous infections may occur. Inhalation anthrax is a systemic infection caused by inhalation of *B. anthracis* spores that are deposited at the alveolar epithelial surface where they can germinate. Inhalation anthrax is not transmitted person-to-person (i.e., person-to-person spread of inhalation anthrax disease has not been documented).

Reported incubation periods for inhalation anthrax in humans range from 1 to 43 days. Studies in non-human primates suggest viable spores can persist in the body up to 100 days. Antimicrobial agents are effective against germinating and vegetative *B. anthracis*, but dormant spores are not affected by antimicrobials. Even with antibiotics and aggressive case management, the case fatality ratio for patients with inhalation anthrax remains high (i.e., 45% in 2001).

Studies have not identified consistent risk factors for inhalation anthrax once exposed; therefore, risk cannot be categorized based on health status or age.

1.1 INFORMATION ABOUT ANTHRAX VACCINE ADSORBED (AVA)

Evidence for the efficacy of AVA comes from several studies in animals (including in non-human primates), and from a controlled vaccine trial in humans, observational data in humans, and immunogenicity data for humans and other mammals. Multiple studies and review panels examining the data have concluded that it is acceptably safe.[4]

AVA is the only licensed human anthrax vaccine in the United States and is marketed as BioThrax (Emergent BioSolutions in Lansing, Michigan). AVA is a sterile, milky-white suspension prepared from cell-free filtrate of microaerophilic cultures of a toxigenic, but avirulent non-encapsulated strain of *B. anthracis*. AVA is currently licensed for pre-exposure use in persons aged 18–65 years who are at high risk for exposure. The current licensed schedule [as of May 17th 2012[6]] consists of 3 doses of 0.5-mL intramuscular (IM) injections (at 0, 1, and 6 months) and 0.5-mL IM boosters at 12 and 18 months after the primary injections and at 1-year intervals thereafter, if needed. AVA is not licensed for use in children (i.e., persons aged <18 years), pregnant women, or persons >65 years of age. AVA is also not licensed for post-exposure use. CDC's Advisory Committee on Immunization Practices (ACIP) recommends a post-exposure prophylaxis (PEP) regimen of 60 days of appropriate antimicrobial prophylaxis combined with 3 subcutaneous (SC) doses of AVA (administered at 0, 2, and 4 weeks post exposure) as the most effective protection against inhalation anthrax for persons exposed to aerosolized *B. anthracis* spores.

Although AVA is not licensed for post-exposure prophylaxis use, the vaccine will be offered to **all** age groups (including those 0-17 years of age and those 66 and older). AVA will likely be made available to

[4] All background information on anthrax and on AVA safety and efficacy was drawn from:
CDC. Use of anthrax vaccine in the United States: recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR 2010; 59(No. RR-6). Access at: http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5906a1.htm
[5] Price EP, et al. Molecular epidemiologic investigation of an anthrax outbreak among heroin users, Europe. Emerg Infect Dis [serial on the Internet]. 2012 Aug [*8/24/12]*. http://dx.doi.org/10.3201/eid1808.11134
[6] Please see: http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm304758.htm

all adults (those 18 and up) under an Emergency Use Authorization EUA)[7] during a public health emergency. Because there are no data on AVA in children, vaccine would be offered to children 0-17 years under an Investigational New Drug (IND) protocol. [8]

1.2 ANTHRAX AS A PUBLIC HEALTH CONCERN

Anthrax is a health concern because of its potential use as a biological weapon. *B. anthracis* is one of the biologic agents most likely to be used as a weapon because: 1) its spores are highly stable; 2) the spores can infect through the respiratory route; and, 3) the resulting inhalation disease has a high case-fatality rate.

In 1979, an unintentional release of *B. anthracis* spores from a military microbiology facility in the former Soviet Union resulted in at least 69 deaths. The anthrax outbreak after *B. anthracis* spores were intentionally distributed through the U.S. mail system in 2001 further underscored the dangers of this organism as a terrorist threat and its ability to create atypical pathways of transmission.

[7] Please see: http://www.fda.gov/RegulatoryInformation/Guidances/ucm125127.htm and http://www.fda.gov/downloads/EmergencyPreparedness/Counterterrorism/UCM217253.pdf
[8] Please see: http://www.fda.gov/RegulatoryInformation/Guidances/ucm126491.htm

2. AVA PRIORITIZATION GUIDANCE BACKGROUND AND METHODS

At the request of National Security Staff (NSS), CDC convened the Federal Anthrax Vaccine Post-Event Prioritization Steering Committee (Federal SC), consisting of representatives from several agencies[9].

- Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (DHHS)
- Food and Drug Administration (FDA), DHHS
- National Vaccine Program Office (NVPO), DHHS
- National Institutes of Health (NIH), DHHS
- Office of the Assistant Secretary for Preparedness and Response (ASPR), DHHS
- Department of Defense (DoD)
- Department of Homeland Security (DHS)
- Environmental Protection Agency (EPA)
- Department of Labor (DOL)

The Federal SC met in a series of 2 in-person meetings and 4 teleconferences over 12 months to review and discuss scientific data and policy implications around AVA prioritization. The Federal SC has reviewed comments from technical experts in biodefense, infectious diseases, respiratory diseases and occupational health and safety. The Federal SC also reviewed feedback from focus groups[10] with members of the public, as well as professional groups.

Nineteen focus groups (FGs) of the general public, healthcare, public health, public safety/emergency management, and first responders were held in Seattle and Phoenix in May and June 2012. These populations were in the FGs because they either will be directly affected by the guidance, and/or have to implement it. Focus groups explored whether the explanation of priorities, as laid out in this document, were sufficient and justifiable.[10] Participants generally agreed that risk of exposure and job activities (for responders and critical infrastructure) were key elements to prioritization; similar to the guidance document.

On June 21st, 2012, CDC's Advisory Committee on Immunization Practices (ACIP) reviewed the draft guidance. The ACIP concurred the prioritization criteria were reasonable, and the prioritization tiers aligned well with the criteria.

On August 20th-21st 2012, the Federal SC held a 2-day meeting to review the prioritization process, focus group data, and a guidance draft. The first day was a public meeting with invited stakeholders.[11] The second day was a closed meeting, in which the Federal SC addressed modifications to this draft document.

The meeting on August 20th was attended by representatives from:

- Healthcare agencies
- Occupational health
- Technical experts
- Critical Infrastructure (CI) sector (e.g., information technology, communications, transportation, water and energy)
- Emergency response
- State and local health departments
- Federal SC members

[9] Please see **Appendix D**: Federal Steering Committee Members for information on the members [pg. 16]
[10] Please see **Appendix B**: Focus Group Summary Results for key findings from the 19 focus groups [pgs. 12-13]
[11] Please see **Appendix C**: August 20th Stakeholder Meeting Invitees/Attendees for information on the meeting attendees [pgs. 14-15]

Overall, stakeholders [on August 20th] concluded the criteria laid out for prioritization of AVA post-event were reasonable and that the proposed tiers aligned appropriately with the criteria.

3. DEFINITIONS AND MAJOR CONCEPTS

WIDE-AREA AEROSOL ANTHRAX ATTACK

This document applies to a wide-area aerosol anthrax attack, such as in a larger U.S. city. A wide-area, outdoor aerosol attack employing *B. anthracis* spores would present different challenges than a smaller scale or indoor anthrax attack or attacks involving other biological agents. The scenario assumes meteorological conditions favoring maximum plume dissemination, affecting an area encompassing hundreds of square miles and potentially exposing hundreds of thousands of people to spores.

PRIMARY VS. SECONDARY AEROSOLIZATION

After a terrorist attack, respiratory or inhalation exposure to *B. anthracis* spores can occur through primary and secondary aerosols. Primary aerosols are particles dispersed in air resulting from the initial release, whether by a disseminating device or by handling of an agent-containing package (e.g., in processing of mail). Individuals exposed in this initial release would be at highest risk of subsequent disease. Secondary aerosols result from disturbance and re-suspension of settled particles. Through accumulation (to other spores or debris) or other changes, these settled particles might not retain the characteristics of the original material; consequently, re-aerosolization may result in larger diameter particle aerosols and lower airborne concentrations, both of which may decrease the risk for inhalational exposure when compared with primary aerosols.[12] Although the relative level of risk of exposure to anthrax from a primary versus secondary aerosolization is difficult to quantify, expert opinions suggest that primary aerosolization poses a higher risk than secondary aerosolization.[12,13] The risk of spore inhalation is better understood in relation to primary aerosolization, compared to re-aerosolization (where the data are more limited and more likely to be understood from experimental settings). Nevertheless, there is scientific evidence demonstrating *B. anthracis* spores, like any other small particles, can re-suspend off surfaces due to natural forces and human activity. It is assumed the rate of re-aerosolization will decrease by several orders of magnitude, as time after initial particle deposition increases and spores are bound by particles resulting in non-respirable size.[14,15,16,17,18,19,20] Re-aerosolization would likely be a lesser risk over all, but still remains a sufficient concern to be factored into policy making.

RESPONDERS

"Responders" refers to a diverse set of individuals who are critical to mitigating the potential catastrophic effects of a wide-area anthrax aerosol attack. This definition includes professional and traditional first responders (e.g., emergency medical services practitioners, firefighters, and HAZMAT personnel); the emergency management community; public health and medical professionals; skilled support personnel; emergency service and critical infrastructure personnel[21]; certain federal and private sector employees; and, individual volunteers assisting in response activities.

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[12] Los Alamos National Laboratories. (2011). Bacillus anthracis outdoor secondary aerosolization (re-aerosolization): annotated bibliography. Washington, DC. Government Printing Office.

[13] Federal *"Guidance for Protecting Responders' Health during the First Week Following a Wide-Area Aerosol Anthrax Attack"* dated September 2012. Access at: http://www.phe.gov/Preparedness/responders/Pages/anthraxguidance.aspx

[14] Birenzvige A. Inhalation Hazard from Re-aerosolized Biological Agents: A Review. CRDEC-TR-413. Aberdeen Proving Ground, MD: US Army Armament Munitions Chemical Command; 1992.

[15] Chinn K. Technical Assessment of Re-aerosolization Hazard from Biological Field Trails. WDTC/JCP-00/008. Dugway Proving Ground, UT: US Army Dugway Proving Ground; 2000.

[16] Davids D, Lejuene AR. Secondary Aerosol Hazard in the Field 321, Project 18. Suffield, Alberta, Canada: Defense Research Establishment Suffield; 1981.

[17] Jensen JG, Fagan MW. Analysis of Dugway Biological Agent Re-aerosolization Demonstration Trials. ARFL-HE-WP-TR-2000-0120. Wright-Patterson Air Force Base, OH: Air Force Research Laboratory; 2000.

[18] Peck R, Wagner FW, Buchanan LM. Field Tests of Protective Clothing Exposed to BW Aerosols. Report 112. Camp Detrick, Frederick, MD: US Army, Biological Department, Chemical Corps Division; 1949.

[19] Resnick IG, Marten DD, Larsen LD. Evaluation of the Need for Detection of Surface Biological Agent Contamination. Dugway Proving Ground, UT: Dugway Proving Ground, Department of the Army; 1990.

[20] Turnbull PCB, Lindeque P, Le Roux J, Bennett AM, Parks SR. Airborne movement of anthrax spores from carcass sites in the Etosha National Park, Namibia. J Appl Microbiol 1998; 84(4):667-676.

[21] See **Attachment A**: NIPP Sectors and Sector Components [pgs. 10-11] to view Critical Infrastructure (CI) sectors. NOTES: (1) Not all CI sector personnel are prioritized to receive AVA after a wide-area aerosol anthrax attack. (2) The four disciplines and six specialized capabilities that define the Emergency Services sector are identified under "Emergency Services" on pg. 10.

THE HIGHEST RISK FOR RESPONDERS

A small group of selected responders performing Category 1 activities[22] (the highest risk of exposure during responder activities) in support of Unified Command's[23] environmental and criminal response will likely encounter the highest potential exposure to earlier-released spores, increasing the risk for inhalation anthrax. Highest potential exposure levels should be assumed for the selected responders performing activities in areas that are identified as the point of initial release (affected area). These activities may involve prolonged contact with potentially contaminated surfaces, contaminant sampling, environmental remediation, and forensic investigations. It is estimated there will be between 100-200 selected responders performing the highest risk activities.

LAYERING CONTROLS OF PROTECTION FOR RESPONDERS

The most effective way to protect the health of persons who enter an affected area post-event (e.g., volunteers and responders) immediately following wide-area anthrax aerosol attack is to minimize their exposure to *B. anthracis* spores. For most common hazards and usual exposure scenarios this protection would be accomplished using primary interventions such as engineering controls and administrative controls. These types of controls can be effective when there is knowledge of what locations and activities could possibly constitute an increased hazard. Engineering controls are used to remove a hazard or place a barrier between the worker and the hazard. Well-designed engineering controls can be highly effective in protecting workers. Examples include physical barriers between responders and contaminated items using Plexiglas or other impermeable materials. Administrative controls are frequently used with existing processes where hazards are not particularly well-controlled, including limiting tour of duties to reduce the duration a responder is potentially exposed. Proper use of personal protective equipment (PPE) is also an important measure to prevent exposure to biohazards such as *B. anthracis*.

In case of a wide-area aerosol anthrax attack of *B. anthracis* spores, it will likely be necessary to dispatch responders or volunteers before it is possible to delineate specific areas contaminated with *B. anthracis* spores. Such a scenario is premised on an assumed delay (12-36 hours or longer) between the time of the attack and recognition that an attack has occurred. Therefore, primary controls for response personnel residing within the contaminated area will almost certainly not be implemented in time to prevent initial spore inhalation among some responders. For such people, there are adjunct measures (including antibiotics and PPE) to minimize the level of additional exposure for responders. When possible, entry into the potentially contaminated area early in a response should be limited for personnel who were not residing or working in the affected area at the time of the original attack.

The ability to determine exposure risk will be limited in the immediate aftermath of a wide-area aerosol anthrax attack, and exposure will likely not be uniform for responders, even among those residing inside the affected area. Some local responders may not have been exposed during the attack (e.g., if they live upwind of the aerosol release, were indoors in a controlled environment at the time of attack, were out of town on the day of attack, or live in an unaffected area). This document will not outline the specifics on the usage of PPE or antibiotics for responders. For more information on antibiotics (to prevent anthrax infection), and PPE, please see the references in footnotes 1 and 2.

KEY POINTS

- Data and expert opinion concur that primary aerosolization is a higher risk than re-aerosolization
- Primary interventions, such as engineering and administrative controls, when available, can be effective ways to protect the health of responders by limiting exposure

[22] As defined in the Federal *"Guidance for Protecting Responders' Health during the First Week Following a Wide-Area Aerosol Anthrax Attack"* dated September 2012. Access at: http://www.phe.gov/Preparedness/responders/Pages/anthraxguidance.aspx

[23] As defined in the draft "*Planning Guidance for Recovery Following Biologic Incidents*" dated May 2009. Please go to the following website and click under "Supporting and Related Materials." Relevant pages: 35-46. http://www.regulations.gov/#!docketDetail;dct=FR%252BPR%252BN%252BO%252BSR;rpp=25;po=0;D=EPA-HQ-ORD-2009-0331

4. SUMMARY OF POST-EXPOSURE PROPHYLAXIS (PEP) PRIORITIZATION RATIONALE

Below are summary points, some previously discussed in the document, on the major principles and rationale for post-event AVA prioritization.

- ACIP recommends that PEP should include 3 doses of anthrax vaccine combined with a 60-day course of antibiotics:
    - It should provide the optimal degree of protection.
    - We anticipate sub-optimal adherence to the recommended full 60 day course of antibiotics.
    - We are not certain the anthrax strain will be sensitive to available antibiotics.
    - Vaccine should provide longer duration of protection even after people stop taking antibiotics.
        - If residents continue to occupy the affected area, and because it will be impossible to achieve complete decontamination of an outdoor environment, risk of exposure will continue after 60 days.
    - The vaccine prioritization tiers are meant to convey priority for starting a 3-dose vaccine regimen with the intent that all persons starting a regimen should finish it.

- The degree of exposure to *B. anthracis* spores will influence the prioritization of AVA vaccine:
    - The risk for inhalation anthrax following exposure to *B. anthracis* spores, particularly for periods extending beyond the duration of antimicrobial prophylaxis coverage, is best estimated by the degree of exposure, and not by health status or age. Therefore, decisions about AVA prioritization should be made based on estimated degree of exposure.[24]
    - Highest priority should be given to any individual who was potentially exposed to primary aerosolization and therefore is at highest risk of inhalation anthrax.
    - Secondary priority should be given to those with greatest risk for re-aerosolization (secondary aerosolization)
    - Exposure risks for children and adults in the general population are indistinguishable based on present knowledge.
    - In the initial days and weeks after an event, determination of the exposure risk for the population will be difficult. As more data become available, considerations of risk and prioritization will likely be refined.

The prioritization scheme is based on risk of inhalation anthrax. The risk of spore inhalation is better understood in relation to primary aerosolization, compared to re-aerosolization (where the data are more limited and more likely to be understood from experimental settings). Re-aerosolization would likely be a lesser risk over all, but remains a sufficient concern to be factored into policy making. Supplies of AVA may be insufficient to immunize the entire potentially exposed population in a large scale *B. anthracis* release. Production of additional lots of AVA will not be rapid enough to provide doses when an event occurs. Communications regarding limitations of vaccine supply should be provided to the general population and to responders. Medical monitoring and surveillance should continue to identify disease secondary to breakthrough infection, exposure to secondary aerosolization of spores, or late incubation past 60 days. There will be demand for vaccine in border areas, as well as areas further away from the affected area. We must clearly communicate the "border" will be a probabilistic one that will be defined in part by availability of medical countermeasures.

4.1 ACTIVITY-BASED APPROACH

Classifying the potential risk of exposure for responders for secondary aerosolization is determined by an activity-based approach. Selected responders will be performing the highest risk activities in support of

[24] As stated in the "prelude" of this document (p.1), there are sufficient amount of antibiotics to offer all exposed people a 60-day course of antibiotics post-event. AVA supply, however, may be insufficient for all potentially exposed persons.

Unified Command's[25] environmental and criminal response that likely present the highest potential exposure levels to *B. anthracis* spores (e.g., environmental assessment and decontamination activities as defined in the Federal "Guidance for Protecting Responders' Health during the First Week Following a Wide-Area Aerosol Anthrax Attack").

4.2 Considerations for Critical Infrastructure Personnel (Workers in Essential Operations)

Emergency managers and health authorities, in collaboration with community partners, should, in advance, identify individuals they deem essential to the functioning of the community (workers in certain essential operations such as water, energy, communications, information technology, transportation, and personnel within the emergency services sector).[26] After an event, these managers and authorities may choose to prioritize vaccination programs targeted to these individuals to facilitate their return to their essential duties.

4.3 Considerations for Responders

The current anthrax vaccine prioritization outlined on page 9 characterizes responders who were in the area at the time of the initial release (and thus during the primary aerosolization) as having a higher risk of exposure than responders who were not in the affected area. As with the general public, responders who reside in the impacted area also have potential for long-term exposure.

The following are methods for reducing responders' risk to secondary exposure to *B. anthracis*:

- As vaccine (AVA) may not be available to all responders and personnel entering the impacted area, tours of duty for such responders should be limited to 30 days, to be followed by an additional 60 days of PEP after last known exposure.
- Responders or other personnel who have received anthrax vaccine as part of a pre-event program and have maintained annual booster doses could be identified and assessed for early deployment to help minimize the need for vaccine for the personnel entering the area. This could include those in the military or those having received AVA as part of their military or emergency response duties.
- The overall risks to responders' safety and health can also be reduced by limiting the number of responders entering the affected area. This restriction may be a particularly prudent step when vaccine supplies are limited.

[25] As defined in the draft "*Planning Guidance for Recovery Following Biologic Incidents*" dated May 2009. Please go to the following website and click under "Supporting and Related Materials." Relevant pages: 35-46. http://www.regulations.gov/#!docketDetail;dct=FR%252BPR%252BN%252BO%252BSR;rpp=25;po=0;D=EPA-HQ-ORD-2009-0331

[26] See **Appendix A**: NIPP Sectors and Sector Components (pgs. 10-11). NOTES: (1) Not all CI sector personnel are prioritized to receive AVA after a wide-area aerosol anthrax attack. (2) The four disciplines and six specialized capabilities that define the Emergency Services sector are identified under "Emergency Services" on pg. 10.

5. VACCINE PRIORITIZATION TIERS

The following tiers[27] are based on risks associated from primary exposure, work or activities that pose the potential for high risk of exposure from primary aerosolization and prolonged or repeated exposures from secondary aerosolization. This document offers guidelines for operational planning. Decisions will ultimately be made by federal, state, and local health and emergency management officials who are responsible for administration of vaccine.

TIER 1: HIGHEST RISK OF EXPOSURE

- **Individuals in the affected area who were present during the initial release of *B. anthracis* spores have the highest risk of exposure.**

- **Selected responders involved in highest risk activities in support of Unified Command's environmental and criminal response**
  - Individuals not in the affected area (i.e., not present during the initial release of *B. anthracis* aerosols) BUT at the highest potential risk for exposure because of occupational exposure to secondary aerosols. This refers to a small group of highly specialized responders ["selected responders"] who will be in the initial area of release in the early phase of a response and will be involved in tasks that will pose the highest risk of exposure to high concentrations of secondary aerosols. These selected responders number approximately 100-200 and are those with prolonged contact with potentially contaminated surfaces through contaminant sampling, environmental remediation, and forensic investigations.

TIER 2: MEDIUM RISK OF EXPOSURE

- **Individuals without exposure to primary aerosols of *B. anthracis* BUT at potential risk for exposure to secondary aerosols of *B. anthracis***
  - Occupational risk groups, such as: responders, laboratorians, and workers in certain essential operations (such as water, energy, communications, information technology, transportation, and personnel within the emergency services sector[28]) who were not in the affected area during the initial attack. Their risk stratification based on activities performed is not likely to result in highest potential for exposure. Examples include: volunteers involved in dispensing antibiotics; laboratorians handling contaminated samples; Points of Dispensing (PODs) support staff; and medical support staff.
  - Persons who were away from the affected area during the initial attack and have returned to the affected area because they reside or commute routinely to the affected area.

TIER 3: LOWER RISK OF EXPOSURE

- **Individuals living in border areas, and progressively distant from affected areas**
  - Once the area of contamination is established, persons living in the areas bordering the affected area will be considered as having a low risk of exposure because they were not present in the known affected area during the primary exposure, are not involved in activities that may cause re-aerosolization, and do not reside within the affected area.

[27] **The bullets below each tier are not in rank order**

[28] See **Appendix A**: NIPP Sectors and Sector Components (pgs. 10-11). NOTES: (1) Not all CI sector personnel are prioritized to receive AVA after a wide-area aerosol anthrax attack. (2) The four disciplines and six specialized capabilities that define the Emergency Services sector are identified under "Emergency Services" on pg. 10.

APPENDIX A: NATIONAL INFRASTRUCTURE PROTECTION PLAN (NIPP) SECTORS AND SECTOR COMPONENTS[29]

After September 11th 2001, the Federal government, in cooperation with State, local, tribal, and territorial officials, as well as the widest possible range of private sector entities, developed an agreed-on national plan for infrastructure protection (NIPP) and taxonomy for use when planning for or responding to all hazard events. The NIPP contains a total of 18 infrastructure sectors and this guidance document suggests that the 6 most critical sectors [not all of the 18 sectors] be considered for AVA prioritization. In the case of a wide-area anthrax aerosol attack, the 6 sectors deemed most critical (in no particular order) are: water, energy, communications, information technology, transportation, and personnel within the emergency services sector.

Note: This is NOT a prioritized list

Note: (Department / Agency) denotes which Federal entity has lead or co-lead for coordinating activities within each respective sector

AGRICULTURE AND FOOD (USDA AND HHS)
- Food & Agriculture industry owners & operators; Food & Agriculture industry trade associations

BANKING AND FINANCE (TREASURY)
- Clearinghouses; Commercial banks; Credit rating agencies; Exchanges/electronic communication networks; Financial advisory services; Insurance companies; Financial utilities; Government & industry regulators; Government subsidized entities; Investment banks; Merchants; Retail banks; and Electronic payment firms

CHEMICAL (DHS)
- Chemical industry owners & operators; Chemical industry trade associations

COMMERCIAL FACILITIES (DHS)
- Public assembly; Sports leagues, gaming; Lodging; Outdoor events; Entertainment & media; Real estate; and Retail

COMMUNICATIONS (DHS)
- Wirelines; Wireless; Satellite, and Cable & Broadcasting transport networks

CRITICAL MANUFACTURING (DHS)
- Primary metal manufacturing; Machinery manufacturing; Electrical equipment, appliance, and component manufacturing; and Transportation equipment manufacturing

DEFENSE INDUSTRIAL BASE (DOD)
- Industry owners & operators that; Enable R & D; and Design, produce, deliver, and maintain military weapons systems, subsystems, and components or parts to meet US military requirements

DAMS (DHS)
- Dam projects; Navigation locks; Levees; Hurricane barriers; Mine tailing impoundments; and Other water retention/control facilities

[29] **Source:** *Critical Infrastructure Partnership Advisory Council (CIPAC) Annual Report – 2011*. Access at: http://www.dhs.gov/xlibrary/assets/cipac/cipac-annual-2011.pdf

APPENDIX A: NATIONAL INFRASTRUCTURE PROTECTION PLAN (NIPP) SECTORS AND SECTOR COMPONENTS[30]

EMERGENCY SERVICES (DHS)
- Disciplines: Law enforcement; Fire and Emergency services; Emergency management; and Emergency medical services
- Specialized Capabilities: HAZMAT; SAR; EOD; SWAT; Aviation units; and Public Safety answering points

ENERGY (DOE)
- Electricity; Oil; and Natural gas assets

GOVERNMENT FACILITIES (DHS)
- Facilities owned or leased by Federal, State, local, tribal or territorial governments both in the US and overseas

HEALTHCARE AND PUBLIC HEALTH (HHS)
- Direct patient care (providers, hospitals, etc.); Medical materials (medical devices, supply); Pharmacy, labs, & blood; Mass fatality; Health plans and payors (insurance companies); and Health information & technology

INFORMATION TECHNOLOGY (DHS)
- High assurance IT products and services to all sectors

NATIONAL MONUMENTS AND ICONS (DHS AND DOI)
- Assets on either the National Register of Historic Places or the List of National Historic Landmarks

NUCLEAR REACTORS, MATERIALS AND WASTE (DHS)
- Commercial power plants; Non-power reactors used for research, training, and radioisotope production; nuclear fuel-cycles facilities; nuclear /radioactive materials used in medical, industrial and academic settings; and the Transportation, storage and disposal of nuclear/radioactive waste

POSTAL AND SHIPPING (DHS)
- Mailing & shipping industry

TRANSPORTATION SYSTEMS (DHS)
- Aviation; Mass transit & passenger rail; Highway & motor carrier; Freight rail; and Pipelines

WATER (EPA)
- Public drinking; and Waste water treatment facilities

[30] **Source:** *Critical Infrastructure Partnership Advisory Council (CIPAC) Annual Report – 2011*. Access at: http://www.dhs.gov/xlibrary/assets/cipac/cipac-annual-2011.pdf

APPENDIX B: SUMMARY of FOCUS GROUP RESULTS

The purpose of this summary report is to provide stakeholder feedback and recommendations regarding AVA prioritization as part of ongoing preparedness planning.

METHODS

Nineteen focus groups (FGs) were conducted in two US cities in the Spring of 2012 with two primary stakeholder groups: 1) professional groups: such as public health, healthcare, public safety/emergency management, and first responders and 2) the general public. Focus group participants were not told that risk from primary anthrax aerosol exposure is greater than that from secondary aerosol exposure. FGs were asked to provide criteria and rationale for prioritization as if they were "decision-makers."

The findings below are presented in accordance with the core questions posed during the focus group sessions. These populations were recommended to be in the FGs because they either will be directly affected by the guidance, and/or have to implement it.

WHAT DO PARTICIPANTS KNOW ABOUT ANTHRAX? …ABOUT THE ANTHRAX VACCINE (AVA)?

- All participants in the professional FGs had substantial knowledge about anthrax.
    - Almost all emergency management, public health, public safety and fire/EMS participants in both cities were aware of the anthrax vaccine. A handful of health care and law enforcement participants were unaware of the anthrax vaccine.
- In contrast, the general public was largely unaware of the existence of a vaccine.

In all groups, other knowledge about the vaccine, beyond its existence, was varied.

WHAT CRITERIA WOULD YOU USE TO DECIDE HOW TO ALLOCATE VACCINE THAT IS AVAILABLE?

- Participants in the professional FGs listed three key criteria for determining prioritization:
    - Risk of direct exposure (either at the time of the event, or directly affected area post-event)
    - Risk of continual/repeated exposure
    - Need to maintain critical infrastructure/continuity of operations
- Participants in the general public FGs consistently listed two key criteria for determining prioritization:
    - Repeated exposure
    - Initial risk of exposure

GIVEN THAT ANTIBIOTICS PLUS VACCINE PROVIDE THE BEST PROTECTION FROM ANTHRAX INFECTION, BUT INITIALLY THE SUPPLY OF VACCINE MAY BE LIMITED, WHO SHOULD BE VACCINATED FIRST?

- Participants in the professional FGs determined as highest priority anyone who was:
    - Directly exposed at the time of the event
    - Involved in the response
    - Needed to support critical infrastructure
    - First "receivers" including hospital and health care personnel

- Participants in the general public FGs determined as highest priority anyone who was likely to experience repeated exposure or initial risk of exposure.
    - Additionally, repeated exposure was often prioritized above initial risk of exposure because participants believed the antibiotic would be sufficient for a single exposure.
    - The general public participants were less able to articulate the concept of critical infrastructure but a few individuals tried to express the importance of this group as a priority.

Opinions from professional and general public participants differed on which groups comprised the lower priority groups.

APPENDIX B: SUMMARY of FOCUS GROUP RESULTS

- Participants of the professional groups generally prioritized (as follows) based on the perceived necessity of the individual's return to the area:
    1) Returning residents to the affected area
    2) Workers/commuters into the affected area
    3) Bordering residents/workers
    4) Travelers through the area

- Participants of the general public groups prioritized (as follows) based on the individual's perceived level of choice to return to the area:
    1) People living in bordering areas (presuming these individuals had not evacuated)
    2) Returning residents/workers into the already affected area
    3) Travelers through the area

IN WHAT WAYS IS YOUR PRIORITIZATION SIMILAR TO OR DIFFERENT FROM "A PREVIOUS GROUP'S" PRIORITIZATION?

- Participants in the professional groups felt strongly that "job function" needed to be a consideration.
    - Participants in the professional FGs placed individuals involved in critical infrastructure into the highest priority group.
    - Individuals involved in the response or in public safety were also placed in the highest priority group.

- Participants in the general public FGs mostly agreed that primary exposure to *B. anthracis* spores guided prioritization, as did the potential for repeated exposure(s). However, safety and "choice" also guided prioritization.
    - They placed lab workers, who they assumed were well equipped with personal protective equipment and trained in the handling of agents such as anthrax, to be a lower priority.
    - They also considered residents and those who worked in the affected area as a lower priority because these individuals were perceived to have a choice to return and would almost certainly be choosing to put themselves in harm's way needlessly.

WHAT KINDS OF THINGS SHOULD GOVERNMENT OFFICIALS DO OR SAY THAT WOULD MAKE YOU FEEL CONFIDENT IN THEIR DECISIONS AND ACTIONS ABOUT HOW TO ALLOCATE THE AVAILABLE VACCINE?

- Both stakeholder groups were similar in their opinions when communicating about anthrax or an anthrax-related terrorist event to the public. Their top three recommendations were:

1. Communicators should develop one unified message from all messengers.
    - Participants thought it was important to consider the distinctions between the roles of local government vs. federal government in communicating an event but that the content of the messages should remain consistent.
    - Key spokespeople need to be perceived as credible for the message to be believable. Each jurisdiction varied in which spokespeople would be considered most credible. In some jurisdictions, it was a public health figure and, in other jurisdictions, it was a well-received political figure.

2. In terms of process for prioritization, "transparency is key."
    - Participants expressly mentioned that transparency included, "how the decision about distribution was made, who made it and the science behind it."

3. In terms of content, participants wanted to know very specific facts about anthrax and exactly what they could do to minimize exposure. Other information was deemed secondary.

APPENDIX C: AUGUST 20th STAKEHOLDER MEETING INVITEES/ATTENDEES

Agency/ Dept.	First Name	Last Name	E-mail	Present
ACP	Sandra	Adamson Fryhofer	sandra@drsandrafryhofer.com	*
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ASTHO	Jim	Blumenstock	jblumenstock@astho.org	*
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WOHA	Ken	Chase	kchase@woha.com	*
NVPO	Bruce	Gellin	bruce.gellin@hhs.gov	
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RxResponse	Erin	Mullen	emullen@rxresponse.org	*
ODPH	Jean	O'Connor	jean.c.oconnor@state.or.us	*
AAP	Erica	Pan	Erica.Pan@acgov.org	*
NBSB	John	Parker	JOHN.S.PARKER@saic.com	*
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DHS	Sally	Phillips	Sally.Phillips@hhs.gov	*
LADPH	Alonzo L.	Plough	aplough@ph.lacounty.gov	*
EPA	Shawn	Ryan	Ryan.Shawn@epamail.epa.gov	

Agency/ Dept.	First Name	Last Name	E-mail	Present
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DHS	Stephen	York	stephen.york@dhs.gov	*
CCHD	Bob	Zehentbauer	bobz@columbiana-health.org	*

APPENDIX D: FEDERAL STEERING COMMITTEE MEMBERS

- **The Centers for Disease Control and Prevention (CDC), DHHS**
  - Nancy Messonnier
  - Raymond Strikas
  - Nicki Pesik (up to June 2012)
  - Tracee Treadwell
  - Zunera Mirza

- **Food and Drug Administration (FDA), DHHS**
  - Lewis Schrager
  - Cynthia Kelley
  - David Rouse (as of January 2012)

- **National Vaccine Program Office (NVPO), DHHS**
  - Bruce Gellin

- **National Institutes of Health (NIH), NIAID,DHHS**
  - Richard Gorman

- **Office of the Assistant Secretary for Preparedness and Response (ASPR), DHHS**
  - George Korch
  - Lisa Kaplowitz

- **Department of Defense (DoD)**
  - Patrick Garman (up to March 2012)
  - Scott Stanek (as of March 2012)

- **Department of Homeland Security (DHS)**
  - David Adams
  - Sally Phillips
  - Stephen York (as of May 2012)

- **Environmental Protection Agency (EPA)**
  - Cayce Parrish

- **Department of Labor (DOL)**
  - Jack Longmire
  - Ted Yee (as of August 2012)