Deliberative Draft

Proposed Guidance for Protecting Responders' Health During the First Week Following a Wide-Area Anthrax Attack

Background

Purpose

The Department of Homeland Security requests your feedback on this document, "Proposed Guidance for Protecting Responders' Health Following a Wide-Area Anthrax Attack". Your feedback will assist us in finalizing this guidance informed by user experiences and operational feasibility. While overall comments are valued, critical feedback in the areas of defining tiers as a strategy for determining risk of exposure, the use of an activity based approach rather than occupational specialties, and feedback on options for ensuring appropriate medical countermeasures are immediately available to the responder community is sought.

This document provides policy recommendations for protection of personnel responding to a wide-area anthrax attack from exposure to Bacillis anthracis spores. A Federal interagency working group, consisting of subject matter experts in biodefense, infectious diseases, and occupational health and safety, has developed this draft consensus guidance regarding appropriate protective measures for responders in the immediate post-attack environment of an aerosolized anthrax attack. This proposed guidance statement reflects the most current understanding of the unique environment that will exist after a wide-area anthrax release. These recommendations will evolve with stakeholder input, scientific developments, and availability of new environmental monitoring techniques.

Wide-Area Anthrax Attack Scenario

This guidance applies to a particular scenario: a wide-area anthrax attack in a large U.S. city. These recommendations may not be appropriate for all biological attack scenarios, or even for all anthrax attack scenarios. 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 agents. Specifically, these recommendations apply to a scenario in which a quantity of *B. anthracis* spores in a liquid or dried preparation is disseminated as a small-particle aerosol generated by a spraying device. The spores could be released from a single point or along a dissemination line from either a ground-based (e.g., truck mounted sprayer) or an airborne (e.g., crop-duster) delivery vehicle. The scenario assumes meteorological conditions that would favor maximum plume dissemination and could result in an affected area that could encompass hundreds

of square miles and potentially expose hundred of thousands to spores. The assumptions used to address underlying uncertainties associated with this scenario are listed in Appendix 1.

The Response

In the absence of rapid and effective public health intervention, the successful execution of a wide-area anthrax attack in a major metropolitan area could have disastrous effects. A well designed, exercised and rapidly executed response is necessary to minimize catastrophic effects. Untreated, the mortality of inhalational anthrax approaches 100 percent, but the timely provision of appropriate treatment can prevent illness and death. Post-exposure prophylaxis (PEP) with antimicrobials (antibiotics and vaccine)s continues to be the mainstay of protection post-exposure, – a level of protection that is further enhanced by pre-exposure vaccination in selected populations. Human and animal data suggest that PEP administration of antibiotics taken as directed can result in a much higher level of protection when started within 48 hours after exposure and before the onset of clinical symptoms.

Distribution and administration of antibiotics to a population at risk within 48 hours of attack increases the ability to save lives, maintain social order, avoid significant economic loss, ensure continuity of government, and preserve the public's confidence in government's ability to respond to an attack. Yet, the logistical challenges to an effective response in the wake of a wide-area anthrax attack are significant. Because antibiotic PEP must be initiated prior to the onset of clinical symptoms, there is a short window of opportunity to ensure their availability to those exposed. To complicate matters, we have no mechanisms available to accurately predict the at-risk population within an adequate timeframe. Current systems do not provide for highly detailed temporal or spatial resolution around the aerosol source, nor do models allow for rapid or remote characterization of an area that is likely to be contaminated.

The Federal Government has recognized that to minimize the effects of such an attack, two critical capabilities must be in place: First, the Nation must have the capability to rapidly distribute antibiotics to the entire affected population before clinical symptoms appear. (NOTE: for planning purposes, 48 hours post-exposure is used as a delivery target). Second, civil order must be maintained both to rapidly distribute antibiotics to the entire affected population and to ensure public safety and security.

With respect to the first critical capacity, the Strategic National Stockpile (SNS) contains sufficient quantities of antibiotics for PEP following an anthrax release. BioWatch is a U. S. Government system that provides a bio-aerosol environmental monitoring and early detection of biological attacks in our Nation's largest cities. However, current BioWatch technology leaves a 12 – 36 hour lag time between agent release and recognition of a BioWatch Actionable Result (BAR) for anthrax. That leaves only 12 hours to respond to the BAR and deliver PEP to the entire at-risk population.

Recognizing that local points of dispensing (PODs) may not be able to reach the entire at-risk population within 12 hours, an additional Federal program designed to rapidly

distribute antibiotics was initiated in 2004. The program was designed to dispense to residences a short-term supply of antibiotics by U.S. Postal Service (USPS) postal carriers. Drills were conducted in 2006 and 2007 across two to three zip codes in each of three cities, Seattle, Boston, and Philadelphia. Postal carriers dispensed mock antibiotics to approximately 22,000, 36,000, and 55,000 housing units, respectively, in the three drills. In these operational drills, dispensing took only 6–9 hours. In addition to the time needed for delivery to residences, it will take time to move stocks from the SNS to the affected state(s), as well as the time needed to mobilize postal carriers and any security forces to assist in delivery to residences.

With respect to the second critical capacity, an effective response will rely on the actions of a large number of responders who will enter and work in the affected area. Mail carriers will need security escorts. Since plans for distributing PEP will likely vary across Cities Readiness Initiative (CRI) cities, the specific agencies or organizations that will provide security escorts will also vary (e.g. local police, National Guard under State active duty). As part of pre-planning strategy, entities should examine and make provisions to ensure security for those doing the distribution. Traditional first responders (law enforcement, fire, emergency medical services) will need to maintain civil order, and certain personnel working in critical capacities (power, water, telecommunications, etc.) will need to maintain critical services during the first 24 to 48 hours of the response. An effective response must address the protection of both sets of responders. Considerable planning and preparation is necessary to help ensure the appropriate safeguards are in place so responders are fully protected and confident that they are adequately protected when working in contaminated areas.

Guidance documents have already been developed for protecting responders engaged in environmental sampling and remediation, as well as for mail carriers delivering antibiotics as part of the USPS plan for residential delivery. Unified guidance for protecting other responders is now being proposed. This proposed guidance does not supersede existing guidance, but rather is intended to support ongoing efforts in planning and preparation, and expand coverage to similarly exposed responders. This proposed guidance will facilitate appropriate planning and should be refined as additional data become available.

Definition of "Responders"
Homeland Security Presidential Directive (HSPD) #8 defines first responders as

> …individuals who in the early stages of an incident are responsible for the protection and preservation of life, property, evidence, and the environment, including emergency response providers as defined in section 2 of the Homeland Security Act of 2002 (6 U.S.C. 101), as well as emergency management, public health, clinical care, public works, and other skilled support personnel (such as equipment operators) that provide immediate support services during prevention, response, and recovery operations.

This proposed guidance also defines responders broadly. "Responders" here refers to a diverse set of individuals who will be critical to mitigating the potential catastrophic effects of a wide-area anthrax attack. This includes professional and traditional first

responders (e.g., emergency medical personnel, firefighters, law enforcement, and HAZMAT personnel), public health and medical professionals, skilled support personnel, essential workers in critical infrastructure sectors, and certain Federal and private sector employees and individual volunteers assisting in activities such as distribution and dispensing of antibiotics for PEP.

Protecting Responders

Overview

While the general public (including some responders) may have been initially exposed to anthrax spores immediately following the attack, there will be many responders who as part of their duties may enter areas having increased risk of exposure. This risk can be limited through the appropriate use of personal protective equipment (PPE), decontamination and hygiene procedures, and the timely administration of antimicrobial PEP. Employers and/or organization sponsoring responders have an obligation to provide and pay for protection (e.g. PPE) and associated training to reduce responders' exposure to the hazards.[1] Pre-planning strategies need to examine what protection may be necessary and how to ensure that it is readily available to responders for immediate use in the event of a wide area aerosol anthrax attack.

Protective measures available to responders who may become exposed to anthrax spores include (1) use of personal protective equipment (PPE), (2) antimicrobial PEP, and (3) vaccination (pre- and post-exposure).[2] The primary objective for instituting these protective measures is to limit exposure and thus avert illness and death. Although PPE is usually designed to *prevent* exposure, in this setting PPE is intended to reduce the level of responder exposure (spore burden) in appropriate situations since a significant proportion of the cohort may have already been exposed. In addition, because the risk of secondary exposure is continuous and not definable, it may not be feasible to prevent responders effectively and completely from coming into contact with the hazard. Because prevention of exposure cannot be assured, even with PPE, medical prophylaxis is critically important as a foundation of protection.

Because the vaccine is not immediately effective, continuation of antimicrobial PEP until after the third dose of anthrax vaccine is administered is essential. Therefore, when employed appropriately, PEP with effective antibiotics combined with vaccination offers the best intervention for protection.

Rationale for Recommended Protections

Normally in hazardous materials response, the source or location of the hazard, contamination characteristics and locations are predictable and environmental testing can delineate areas of higher and lower concentration. In a typical setting, these data then

[1] For additional information, please see OSHA Standards 29 CFR 1910.120, 29 CFR 1910 Subpart I - Personal Protective Equipment and OSHA Document CPL 02-02-073 - Inspection Procedures for 29 CFR 1910.120 and 1926.65, Paragraph (q): Emergency Response to Hazardous Substance Releases.

[2] While performing specific activities (e.g., sampling, investigation, decontamination, etc.) that place responders at the highest risk for exposure, administrative and engineering controls can also be effective.

form the basis for risk assessments and selection of appropriate protective measures. This traditional approach is not feasible for the wide area anthrax scenario for which this guidance is designed because of current sampling limitations, the need to get antibiotics to the entire affected population within 48 hours after the attack, and the potential geographic extent of the contamination. Geography or location within the affected area alone cannot be used as the basis for assessing responder risk.

However, even though we will have limited knowledge of contaminated areas and levels of risk, it is possible to develop an activity-based approach to classifying the potential risk of exposure for responders. Responder activities that are likely to increase exposure include: environmental sampling, forensics sampling, decontamination, and extensive travel within the potentially contaminated area. Risk of exposure increases with travel frequency and duration into one or multiple contaminated areas. To address concerns that the entire responder population would be at increased risk during the first week after the attack, a tiered approach to classifying presumed increased risk of exposure is recommended based upon qualitative assessment of the probability of exposure.

Potential Exposure Level Tiers
Risk stratification among responders can be performed through identification of activities that likely present the highest potential exposure levels to *B. anthracis* spores. Given the inherent uncertainties, a balanced, prudent, and precautionary approach is necessary. It is important to note that these recommendations are activity-based rather than being based on traditional occupational duties. Activities may alter responders' tier groupings from day to day, and each responder and team leader should continuously re-assess activities to determine their activity tier. The guidance builds on internal protocols and procedures that were developed internally for USPS workers and guidance developed for those engaged in environmental sampling and remediation, and expands these protocols to other responders who are engaged in certain activities or who must travel frequently throughout the affected area immediately following the incident.

Definitions

TIER 1 – Highest Potential Exposure Levels During Responder Activities – Highest potential exposure levels should be assumed for: a) activities associated with prolonged contact with potentially contaminated surfaces (e.g., sampling, etc.); b) activities that place responders in areas that are likely to have higher spore concentration for extended periods of time; c) activities performed in areas that witnesses identify as a release site; and d) activities in areas identified as contaminated through sample measurement. Responders engaged in these activities or working in these areas are likely to be subject to higher risk of exposure from environmental contamination and secondary aerosols. All responders in this category should be considered to have elevated risk of exposure.

Examples of Tier 1 activities include, but are not limited to: environmental sampling and characterization, HAZMAT decontamination/remediation, forensics sampling, and other activities proximal to the suspected release site or area documented to be contaminated.

TIER 2[3] *– Increased Risk of Exposure, but not Highest Potential Exposure Levels During Responder Activities* – Responders in this group are assumed to a) originate from within the affected area thus assumed to have been at least potentially minimally exposed prior to work activities and b) engage in extensive and/or frequent travel throughout the affected areas. Frequent travel increases the probability of moving through contaminated areas and therefore increases the likelihood of additional exposure and increased spore burden. Responders engaged in Tier 2 activities will likely be exposed to greater levels of environmental contamination and secondary aerosols during these activities, although these exposures would be expected to be less that those engaged in Tier 1 activities. Completion of the U.S. Postal Service (USPS) delivery of antibiotics will require continuous postal carrier and security escort travel across a large at-risk area during the first 12 hours; however, unlike some Tier 1 activities, the delivery of antibiotics will not necessarily require extended exposure in highly contaminated areas. Thus, the activities of postal carriers and their security escorts are representative of activities in Tier 2.

Examples of Tier 2 activities include, but are not limited to: postal carriers and security escorts involved in antibiotic distribution, EMS, fire, rescue, police, and traffic control not otherwise supporting Tier 1 activities.

TIER 3 – Limited Risk of Exposure During Responder Activities – Responders assigned to this tier: a) originate from within the affected area; b) may be required to travel to and from their workplaces or, during the execution of their duties, may be required to make short, infrequent trips; and c) primarily work indoors. In the absence of information to the contrary, it is assumed that although any travel within the at-risk geographic area may result in the inadvertent entry into higher-risk areas, short and direct trips do not carry the same probability of exposure as do Tier 2 activities.

Examples of Tier 3 activities include, but are not limited to personnel who may be required to report to work, may be required to travel to and from their workplaces, or who, during the execution of their duties, may be required to make short, infrequent trips (e.g., essential staff maintaining critical infrastructure/key resources (CI/KR), hospital staff, mission-critical local, State, and Federal Government personnel, POD volunteers).

[3] Since contaminated spots will be noncontiguous with unknown locations, it is reasonable to suggest that for some time immediately after the primary aerosol dissipates frequent or prolonged movement outdoors is likely to increase the probability of traveling through multiple contaminated spots, thereby increasing exposure levels and spore burden. The more movement, the greater the likelihood is of increased exposure.

Recommendations for Responder Protection[4]

Summary of Recommendations:

Protection	Tier 1	Tier 2	Tier 3
Antimicrobial PEP*	√	√	√
Pre-Event Vaccination	√	√	N/A
Post-Event Vaccination	√	√	√
Respiratory Protection	√	√	NA**
Nitrile Gloves	√	√†	NA**
Protective Clothing	√	√‡	NA**
Personal Decontamination/Hygiene	√€	√€€	√€€

*Pre-event placement should be considered for Tiers 1-3 emergency services and essential CI/KR workers who will need to immediately report to and remain on duty despite or because of an ongoing emergency.
** Consider for specific situations assessed to represent increased risk.
†For responders handling multiple potentially contaminated surfaces
‡Consider uniform or clothing change policy. Consider protective garments for specific activities that may represent increased risk for contamination of garments.
€Full personal decontamination
€€As appropriate to the situation; at a minimum clothing change, laundering and personal shower (at shift end or daily)

1. **Tier 1** – Responders in this group will likely encounter higher exposure to spores, increasing the risk for inhalational or cutaneous anthrax.

   Antimicrobial post-exposure prophylaxis (PEP)
   All responders in the Tier 1 Group should begin antimicrobial PEP as early as possible and should continue for the recommended duration, depending on vaccination status (at least 60 days of antibiotics for previously unvaccinated and at least a 30 day course for those previously fully vaccinated[5] after the last exposure).

   Vaccination
   Responders likely to fall within the Tier 1 Group during an event should receive priority to receive pre-event vaccination. Post-exposure, in addition to antibiotics, all responders in the Tier 1 Group who have not been vaccinated previously, and those requiring updated boosters, should receive anthrax vaccination. Please see Recommendation 4, below.

[4] Most existing human data regarding anthrax antimicrobial prophylaxis, treatment, or vaccination were gathered in studies of occupational populations, particularly active duty uniformed service members, and most animal model studies were designed with these populations in mind. While these protective measures may be relevant to professional responders, in a large-scale attack they may not be appropriate for all responders, such as volunteers, particularly those who are younger or older than most professional responders, and those who have certain medical conditions that may affect their susceptibility to disease or the effectiveness of protective measures.
[5] The initial 6-dose vaccination series is complete and booster doses are up-to-date according to ACIP recommendations

Personal Protective Equipment (PPE)
In addition to antimicrobial PEP, responders in the Tier 1 group should adhere to existing recommendations related to the use of PPE when working in a contaminated environment. PPE includes appropriate respiratory protection (e.g., Powered Air-purifying Respirator – PAPR), protective garments, and gloves, as well as appropriate training and fit testing, and decontamination training. (Please see Appendix 6 for references containing guidance that is more detailed.)

Personal Decontamination/Hygiene
The potential for and extent of contamination for people operating in a wide-area post-attack environment are currently unknown. With Tier 1 activities, protective clothing or other exposed gear is more likely to be contaminated and may be a source of further contaminant dissemination. Appropriate decontamination procedures are necessary. Locations/facilities for proper decontamination for this higher risk group must be determined (e.g., decontamination trailers) by the Incident Command. Once decontaminated, responders in the Tier 1 Group should correctly doff and dispose of protective clothing and respiratory protection. Undergarments worn under protective clothing should be laundered or disposed of after a shift of work is completed. Responders should shower with soap or undergo some other appropriate personal decontamination after a work shift.

2. **Tiers 2 and 3** – Responders will need to act rapidly based on consistent training and preparation. As the response progresses, incident leadership may make site and activity-based decisions regarding the appropriate protective ensemble based on factors related to the specific event and additional knowledge obtained over the course of the event. It is critical that incident commanders, other incident leadership, employers, and public health authorities with jurisdiction to consider additional information (such as sampling data, witnessed release locations, etc.) when selecting protective measures for responders following an attack.

   Antimicrobial post-exposure prophylaxis (PEP)
   All people in the Tier 2 and Tier 3 Groups should begin taking antibiotics as soon as possible and should continue for the recommended duration, depending on their vaccination status (at least 60 days for those previously unvaccinated and at least 30 days for those previously fully vaccinated after the last exposure).

   Vaccination
   Responders likely to fall within the Tier 2 Group in response to an event may be offered pre-event vaccination. Post-exposure, in addition to antibiotics, all responders in the Tier 2 Group who have not been previously vaccinated, and those without updated boosters, should receive anthrax vaccination. Please see Recommendation 5, below.

   Personal Protective Equipment (PPE)
   Tier 2 – Extensive travel or remaining outdoors for extended shifts –Responders involved in Tier 2 activities (frequent and/or long-term travel throughout the affected

area) should be provided respiratory protection to reduce risk of exposure and potential inhalational burden. USPS responders (carriers participating in residential delivery of antibiotics) should adhere to existing USPS guidance regarding working in a contaminated environment. This guidance includes N95 respiratory protection, gloves, and uniform change provisions. Other Tier 2 responders (e.g., patrols, security, and rescue) should consider a uniform change provision similar to the USPS guidance. Tier 2 responders who do not wear uniforms (such as outdoor utility maintenance) should consider adding a uniform or clothing change policy; protective garments can be considered for specific activities that may represent increased contamination risk. Consistent with existing recommendations, all Tier 2 responders should use N95 (or more protective) respirators (with appropriate training and proper fit testing) while engaged in those activities as the minimum respiratory protection level to reduce the risk of inhalation of *B. anthracis* spores. Nitrile gloves should also be considered for Tier 2 responders handling potentially contaminated surfaces.

Tier 3 – **Limited travel –** Responders in this group originate from inside the affected area and will have many duties that are not likely to present risk of exposure as high as Tiers 1 and 2, but may require a specific PPE program. When specific conditions or activities indicate that there may be a significantly increased risk, responders and team leaders should consider the use of PPE (i.e., respirators, protective garments).

Personal Decontamination/Hygiene
Personal decontamination procedures are not specified for this Tier. To mitigate potential risk, personal hygiene practices should be emphasized. Undergarments worn under protective clothing should be disposed of after a shift of work is completed or removed and laundered with commercially available laundry detergent and water or dry cleaning.

3. <u>Outside responders temporarily entering the affected geographic area</u>

Responders who were not in the impacted region during an attack do not have the same baseline risk of exposure as responders who might have been in the area at the time of the attack. Furthermore, responders who do not reside in the attack area may only be exposed for a short time (e.g., some security escorts might only be at risk of exposure for the 12-24 hours that it takes to deliver the PEP). Responders who originate from outside the affected geographic area (and thus do not have prior exposure) and remain in the affected areas only briefly should be protected in a manner similar to Tier 1 or 2, depending on the activity. The recommended PPE ensemble for responders coming into the affected area includes appropriate respiratory protection (including fit-testing), uniform or clothing change (and protective garments in specific instances), gloves, appropriate training, decontamination, post-exposure antibiotics, and vaccine. Personnel and equipment should be decontaminated when exiting the affected area.

4. <u>Occupational Safety and Health Medical Surveillance and Consultation</u>

Before using a respirator, responders must undergo medical evaluation to determine the employee's ability to use a respirator and be fit-tested for the respiratory protection they will use.[6]

The employer's emergency response plan must address emergency medical treatment and first aid. In addition, responders must be provided access to medical examinations and consultations should they become injured, develop signs or symptoms of exposure to hazardous substances, or experience adverse events associated with prophylaxis (29 CFR 1910.120(f)). Medical examinations and consultations must be provided as soon as possible following the incident, and at additional times if the physician determines it is necessary. In addition, incident commanders must ensure that responders receive adequate training based on expected duties. The training shall include information regarding risk of exposure, appropriate protective measures, and potential adverse events.[7]

5. Pre- and post-event vaccination

- Pre-event vaccination – In October 2008, the Advisory Committee on Immunization Practices (ACIP) re-examined its recommendations for pre-event anthrax vaccination for responders likely to be involved in an anthrax post-attack response. The committee recognized that while the risk of exposure for first responders to anthrax is low, it may not be zero. Although emergency and other responders are not recommended for routine pre-event anthrax vaccination, ACIP determined that it is allowable for first responder organizations to choose to offer pre-event vaccination on a voluntary basis. The vaccination should be administered according to the most recent FDA guidance[8] and the vaccination program implemented under the direction of a comprehensive occupational health and safety program.
- Post-event vaccination – Post-event, post-exposure vaccination is an essential component of protection for responders exposed to *B. anthracis* spores. Previously unvaccinated responders should receive the initial vaccine dose as soon as possible and should complete a course of at least the first 3 vaccinations in the series (at 0, 2, and 4 weeks).
- Vaccine Prioritization – In the event that anthrax vaccine stocks are insufficient to meet operational requirements, the responder community must be prepared to prioritize those most at risk of exposure. Criteria for determining priorities for vaccination will be developed by the Federal government to assist local decision makers.

6. Pre-event placement of antibiotics for certain responders and critical workers

[6] For additional information, please see OSHA Standard 29 CFR 1910.134 Respiratory Protection.
[7] For additional information, please see OSHA Standard 29 CFR 1910.120 and OSHA Document CPL 02-02-073 - Inspection Procedures for 29 CFR 1910.120 and 1926.65, Paragraph (q): Emergency Response to Hazardous Substance Releases.
[8] The December 11, 2008 revision requires an intramuscular route of administration for the vaccine. Vaccine is administered in five (5) doses at 0, 4 weeks, and 6, 12, and 18 months (plus boosters).

The goals of pre-event placement of antibiotics are to ensure continuation of mission essential functions without the time lag burden of acquiring and distributing antibiotics, as well as lessening the volume of antibiotics that must be distributed post-event. As part of any planning effort, responsible parties should evaluate the feasibility of pre-event placement of antibiotics for responders (potentially including family members) who will need to immediately report to and remain on duty despite or because of an ongoing emergency.

The USPS strategy for residential delivery of antibiotics includes pre-event provision of antibiotics to postal workers and their family members. Using this as a model, local planners should consider which critical workers (and their family members) should be considered candidates for exercising this strategy. Such a strategy should include pre-event medical screening of this workforce (and their families) to ensure there are no medical contraindications to taking these antibiotics. Local planning should identify who will provide this screening (e.g. employers, public health, other). This critical workforce is represented within Tiers 2 and 3 of this document.

7. Planning guidance and responsibilities of incident commanders and public health authorities

Incident commanders, as part of a Unified Command or other incident leadership, employers, and public health authorities with jurisdiction have the ultimate responsibility for determining appropriate protective measures for responders and for the general public in the setting of an emergency. Comprehensive planning and training is essential to ensure that responders are protected while performing mission essential tasks.

One significant assumption contained within this guidance is that Federal, State, and local planners have incorporated appropriate logistical mechanisms to ensure timely availability of antimicrobial PEP and other protective measures for responders. Plans should consider local stockpiles or other mechanisms to ensure that responders will have immediate access to personal protective equipment and medical countermeasures if pre-placement in homes is not used. (See Recommendation 6, above).

Authorities should consider this guidance in formulating pre-event plans and incident-specific guidance and training, and arrange for Emergency Use Authorizations (EUAs) for the responding populations. However, they should be aware of the significant information gaps and assumptions inherent in this proposed guidance and that information available as an incident evolves may provide them with better information upon which to develop better guidance.

8. Alignment of initial antibiotic PEP dispensing strategies and deployment of responders to minimize risk of exposure to responders and population

Although recommendations regarding the preferred modalities for initial antibiotic dispensing during the first 48 hours following an attack are beyond the scope of this guidance, there are significant implications related to protecting responders. The

USPS plan for rapid distribution of antibiotics is intended to save lives of the public. Since fewer responders are needed under this plan, a secondary benefit for locations utilizing this modality is the reduced number of responders exposed. As mentioned, drills exercising the USPS plan for residential delivery of antibiotics have been conducted in Seattle, Philadelphia, and Boston. The projected staffing requirements extrapolated from these drills to deliver antibiotics to all households in a metropolitan area in 6-9 hours are significantly lower than the total staffing required to complete the same task utilizing public health PODs. In addition, the USPS plan minimizes unnecessary travel within the affected area by advising people to remain in their homes; whereas the POD model requires the entire population (or heads of household) to travel to a POD, wait in line, receive their antibiotics, and travel back home. Poor characterization of environmental contamination, risk of exposure in the first days following an attack, additional immediate travel within the affected area by the much larger number of responders, and the required travel of the affected population to come to a POD for their medication following an attack potentially increases risk of exposure.

The USPS plan for residential delivery of antibiotics decreases the overall risk to responders by significantly reducing the immediate demand for conducting initial dispensing of antibiotics using PODs. This option also reinforces guidance to "remain indoors or at-home" for the general public to assist in maintaining order which will prevent unwarranted evacuation, unnecessary travel, and help to limit further contamination by or spread of anthrax spores.

Appendix 1 – Scenario, Impact, and Response Assumptions

This proposed guidance is intended to facilitate planning for one particular scenario though parts of this guidance may be relevant to other scenarios. Building that scenario required making a variety of assumptions about the nature of the attack and the resulting environmental contamination. As specific information is gained about a given attack, these assumptions may change. Furthermore, the guidance may change based on changes in our understanding of the behavior of the contaminant, available monitoring technology, and our understanding of the efficacy of the protective measures recommended. Thus, this guidance it is not meant to supplant the judgment of incident commanders or responders on scene of an actual event, who may have access to specific data that can enable better decision making. The most important of the assumptions associated with this guidance are listed below:

Assumptions regarding attack scenario:

- The release is outdoors, to a wide area, using anthrax aerosol
- Wide-area environmental contamination is possible; this contamination will be spotty, non-contiguous, and not predicted by models
- The strain of *B. anthracis* used in the attack has not been modified or engineered to express resistance to antibiotics in the Strategic National Stockpile (SNS) Naturally occurring strains of *B. anthracis* are susceptible to ciprofloxacin and doxycycline. Contingency plans to address the threat of enhanced agents will be addressed in a different forum
- The aerosol anthrax is not military grade weaponized
- The aerosol attack is covert and initial notification will occur after environmental sensors, disease manifestation, or credible forensic intelligence provide evidence of or detect the presence of *B. anthracis*.

Assumptions regarding ability to characterize environmental distribution

- Environmental monitoring and forensic efforts is unable to provide timely information regarding the release, source strength, and scope/area of risk
- Modeling is unable to accurately predict the area of risk from primary aerosol exposure, but will be of value to incident commanders.[9,10,11]

[9] Even in the days following the attack, empirical data suggest that current plume models may only help to predict areas of highest probability of contamination and cannot accurately predict the extent and scope of contamination because of microatmospheric variability, effect of urban or other structures, lack of knowledge regarding source strength and release dynamics, and the travel of people and vehicles through areas.

[10] In an outdoor attack, levels of exposure to re-aerosolized spores in contaminated areas are likely to be orders of magnitude lower than exposure levels at the time of the attack. Potential exposure levels from undisturbed contaminated environmental surfaces would be even lower.

[11] While the literature supports a protective effect of buildings from the primary aerosol, there are very scant data regarding building effect in the setting of persistent and low level contamination. It is unclear whether an indoor environment protects against or increases potential exposure in the post-attack period.

- There will be very limited knowledge of contaminated areas and levels of risk for the first week (or more) owing to the complexity of the problem and current (and foreseeable) capacity for sampling and testing
- Travel within the geographical area could increase the likelihood of initial or additional aerosol exposure by inadvertent entry into areas of higher contamination or more prone to aerosolization

Assumptions regarding population exposure:

- By the time an attack has been detected through BioWatch, people may have been traveling in and out of affected areas for 12 – 36 hours or more
- Everyone within this area is considered at some level of risk for secondary exposure for the entire duration of their presence in the area, although the specific risk is not predictable
- Commuting and traveling of people in and out of the potentially affected area will complicate risk assessment and increase contamination
- A large number of people in a broad geographical area will inhale potentially lethal doses of *B. anthracis* spores but it will not be possible to determine specifically which people are infected. All people in that area will require antimicrobial PEP immediately.

Assumptions regarding response:

- The use of anthrax vaccine in combination with antibiotics would be authorized under an Emergency Use Authorization following specific steps by the U.S. Government to declare a public health emergency (*Nightingale SL, Emerg Infec Dis, 2007*) or under an Investigational New Drug (IND) application in the absence of those actions
- The immediate dispensing of antibiotics to the population at risk may rely on the U.S. Postal Service (USPS) plan or other "push" methods that involves postal carriers with law enforcement escorts delivering antibiotics (time to dispense ranges from 8-9 hours). Other modalities (public health PODs, retail PODS, employer PODs) will begin operation following an attack but will likely require more time to become fully operational and complete their task of dispensing antibiotics to the population at risk
- Most responders originate from inside the at-risk geographic area, and therefore will have been at risk for exposure from the primary aerosol
- All public transportation in and proximal to the aerosol release will be affected
- Responders who originate from outside the affected geographic area will be moving from a status of essentially no likely exposure into an area that places them at continuous risk for exposure to *B. anthracis* spores through secondary aerosolization
- "Remain indoors or at-home" guidance may be issued to the population to enable distribution of antibiotics, assist in maintaining order, and prevent unwarranted

evacuation and unnecessary travel; this guidance will be situation dependent and will realistically not be effective for more than 48 hours[12]

- Despite the issuance of "stay at home" orders, large numbers of the general public may self-evacuate after notification of an attack or may have to travel out of doors to obtain antibiotics or essential supplies. Others may need to travel within the geographic area in their role as responders, to maintain uninterrupted essential services, and to sustain critical infrastructure
- In addition to traditional "first responders," there are a number of other responders who will be critical during the first week following an anthrax attack including essential employees across critical infrastructure sectors who cannot abandon their responsibilities and must provide uninterrupted services immediately following an attack (e.g., hospital and nursing home staff, prison guards, airport security, border guards, and those staffing telecommunications, electrical power, water facilities)
- Most responders and essential personnel will potentially receive high enough doses to lead to development of inhalational anthrax for the entire time they remain in the region and may be at risk for developing inhalational anthrax for a period of time after they leave the potentially contaminated area, depending on the level of inhaled *B. anthracis* spores (spore burden)
- Demand for antibiotics will likely extend beyond the geographic boundaries of the affected area and could complication efforts to provide them to those requiring them.
- Epidemiological trending/mapping will be undertaken but may not be able to fully assess the potential contaminated zones

[12] Avoiding unnecessary travel within the geographic area could reduce overall public health risk by reducing the likelihood that those who unknowingly have been in a low-risk area will unknowingly travel into a high-risk area.

Appendix 2 – Protective Measures

The most effective way to protect responders is to prevent spores from initially entering the lung. Normally, this would be accomplished using primary interventions such as engineering controls (e.g., safe havens, isolation, and ventilation), proper use of personal protective equipment (PPE), work practice modifications, and limiting access and duration in the affected area. However, this scenario assumes there will be a 12-36 hour delay between the attack occurrence and recognition of the same. Therefore, primary controls for response personnel residing within the contaminated area will almost certainly not be implemented in time to prevent initial spore inhalation. For this scenario, these are adjunct measures to reduce the level of additional exposures as responders perform their duties.

Note that the ability to determine risk will be limited, and that it is likely that exposure will not be uniform for responders residing inside the affected area. It is probable that there will be significant differences in initial exposure amongst this responder group. Some local responders may not have been exposed at all during the attack (e.g., they live up wind, were indoors in a controlled environment, were out of town on the day of attack, or live in an unaffected area), and traveling into the hazard area would therefore increase in their risk. PPE and other controls for this sub group, and for the numerous unexposed responders arriving from outside the affected area, could be effective in preventing initial exposure if used according to these recommendations. However, because prevention of exposure cannot be assured, medical prophylaxis is of critical importance as a foundation of protection.

Personal Protective Equipment (PPE)
Normally, PPE is considered a primary intervention because it prevents inhalation or skin contact with *B. anthracis* spores from occurring. Depending on the circumstances (tasks, duration, specific area), N95 or higher-rated respirators can provide significant protection from inhalation of *B. anthracis* spores, if the user is properly fitted to the respirator, wears the respirator properly and for the required durations, and the respirator is appropriately removed and discarded or decontaminated. If worn properly, powered air purifying (PAPR) or supplied air respirators (SAR) can offer increased respiratory protection against inhaling *B. anthracis* spores and are recommended for certain activities, including environmental sampling, conducting remediation activities, or when there may be aerosol-generating devices or activities.

Procedural and Engineering Controls
Procedural and engineering controls can be effective when there is knowledge of what locations and activities could possibly constitute an increased hazard.

Antimicrobial Post-Exposure Prophylaxis (PEP)
When inhaled into the lungs, *B. anthracis* spores germinate into active, growing bacteria that release toxin and cause the disease manifestations of inhalational anthrax. Spores generally germinate to cause disease within a few days, but some spores can remain dormant for weeks or months before germinating. The complex series of events that

leads to germination is unclear, but antibiotics are only effective against actively growing organisms; they have no effect on dormant spores. For this reason, antibiotics are recommended for at least 60 days following the last potential exposure for previously unvaccinated individuals.

Unfortunately, compliance with taking antibiotics for extended periods can be challenging. In a study of antibiotic compliance following the 2001 attacks, completion of the full 60-day regimen ranged from 21-64 percent, depending upon location. Although a significant proportion of those who stopped taking antibiotics cited adverse events, only 0.3 percent of the 2,135 people followed after 30 days were determined to have serious adverse events associated with antibiotic use. Statistical analysis and anecdotal experience of antibiotic compliance after the 2001 attacks suggest that those who are indeed at significant risk (and those who perceive that they are at elevated risk) have significantly higher compliance rates.

Doxycycline and ciprofloxacin constitute the bulk of the oral antibiotics in the Strategic National Stockpile. Both are highly effective against *B. anthracis,* are licensed for use against anthrax, and are considered the two first-line agents of choice for anthrax. Human and animal data suggest that the use of an effective antibiotic taken as directed can result in nearly 100 percent protection when started within 48 hours after exposure and before the onset of clinical symptoms. Data from non-human primates support efficacy even after a dose > 1,500 times the 50 percent lethal dose (LD50). Modeling of exposure from spore-containing letters indicates that some people exposed to the letter in Senator Daschle's office may have been exposed to similarly high levels, and none that were promptly provided antibiotics (and later with vaccination) presented with clinical anthrax. When antibiotics are promptly initiated after exposure, failure in animal models has only been seen after cessation of antibiotic use, a phenomenon attributed to the long latency period of some spores in lung tissue.

The duration of antibiotic use is critical to effective protection. Animal data suggest that if an individual has no immune protection, antibiotics must be continued until virtually all inhaled spores have been cleared from the lungs, since only the vegetative form of the organism is affected. Currently, the number of remaining spores within the lungs cannot be accurately measured. Modeling of spore germination and clearance kinetics suggest that complete clearance may take longer than 60 days for large doses, and animal studies have found viable spores up to 90 days after exposure. Although data is lacking regarding antibiotic efficacy in the setting of repeated exposure to anthrax spores and the cumulative amount of spores inhaled, prudence and common sense support a second objective of minimizing the continued inhalational burden of anthrax spores with PPE. Recommendations for the use of PPE to ensure effective achievement of this second objective requires an understanding of potential environmental contamination and risk of exposure. In the absence of information specific to contamination levels, it is prudent to believe that some activities may increase the probability of exposure, and that responders employ recommended use of protective equipment until additional information is available to suggest otherwise.

Antimicrobial PEP and Pre and Post-Exposure Anthrax Vaccination
The currently recommended course of antibiotics post-exposure is at least 60 days following last potential exposure in previously unvaccinated individuals. Following high-level exposures, some experts recommend a longer course in the absence of post-exposure vaccination. Pre-event vaccination with anthrax vaccine provides protection from all forms of anthrax. Antibiotics may still be recommended to those who have been fully vaccinated. If large doses of spores are inhaled, it is possible that spores may germinate, producing sufficient amounts of toxin to cause disease before an adequate immune response can be achieved. In the absence of definitive data to clarify the degree of protection provided by vaccination alone, the recommended duration of antibiotic use is 30 days for exposed individuals who have previously completed the primary anthrax vaccination series and who are current with boosters.

Although antibiotics should be given for a prolonged course, studies suggest that anthrax exposure followed by administration of antibiotics post exposure generates no significant protective immune response, leaving no residual protection. Anthrax vaccine, on the other hand, has been demonstrated to impart significant protective immunity against *B. anthracis*. All available data (predominantly from non-human primate studies and one small human clinical field trial) indicate that pre-event vaccination with the licensed U.S. anthrax vaccine, BioThrax (Emergent BioSolutions, Lansing, MI formerly known as anthrax vaccine adsorbed (AVA)), is effective in protecting against development of anthrax disease. Supplementing these data with additional non-human primate data focused on post-exposure prophylaxis, a PEP regimen of anthrax vaccine and antibiotics provides protection from developing inhalation anthrax even after completion of the recommended antibiotic regimen. CDC's Advisory Committee on Immunization Practices (ACIP) and independent expert committees and advisory bodies have concluded that the optimal means to prevent illness after suspected or confirmed inhalation exposure to aerosolized *B. anthracis* spores associated with a biological attack is post-exposure prophylaxis comprising a 60-day course of antibiotics in conjunction with anthrax vaccination in a three-dose regimen (0, 2, and 4 weeks). People who are engaging in longer term (weeks to months) potential exposure may require protection beyond that provided by antibiotics and post-exposure anthrax vaccine, and would benefit from a licensed regimen of pre-exposure vaccination to confer this longer-term protection. In 2000, ACIP recommended, "pre-exposure use of anthrax vaccine should be based on a quantifiable risk for exposure." ACIP reaffirmed that recommendation in 2008, and also permitted that likely responders can be offered pre-event vaccination. Working under the assumption that access to the contaminated area could be controlled after the initial incident, responders would not be expected to have longer-term potential for exposure, and antibiotics would be adequate to protect them. The scenario of this guidance assumes wide-area contamination, which would mean that local responders would be at risk for long-term exposure.

Appendix 3 – Antibiotic Dispensing to the General Public

Multi-Layered Strategy for Dispensing Antibiotics Post Exposure
Current efforts to accelerate dispensing focus on adjunctive modalities for quick push of antibiotics into affected communities. The Cities Readiness Initiative (CRI), started in 2004, is a Federally funded effort to prepare major U.S. cities and metropolitan areas to respond effectively to a large-scale bioterrorist event by dispensing antibiotics to their entire affected population within 48 hours of the decision to do so. The CRI project started in 21 cities and has grown to include 72 CRI Metropolitan Statistical Areas that encompass 490 counties in all 50 states. To help guide State local, territorial and tribal planners, the Department of Health and Human Services (HHS) has identified several dispensing modalities:

1. Pre-event placement of medications in households. Pre-event placement of caches of antibiotics (MedKits) in households that are to be reserved for use during a declared public health emergency. A pilot study was successfully conducted in St. Louis to test the feasibility of pre-event placement of MedKits in households.[13] This study showed that the vast majority (over 95%) of those households stored their kits properly. They returned stored kits to the study team intact and unopened. However, this study did not test each person's understanding of the instructions on the package. Overall, procedures need to be developed to validate proper storage, use, and shelf life of kits. In October of 2008, a Public Health Emergency Declaration was declared by the Secretary of Health and Human Services based on the established, material threat determination and consequences of a widespread attack with *B. anthracis* spores. This declaration allowed a request for an Emergency Use Authorization for the use of home MedKits pre-event for Postal workers. This provision of MedKits is currently under discussion with the Food and Drug Administration (FDA).
2. Pre-deployment of community-based caches of medications. Pre-deployment of antibiotics in community-based caches that will function as points of dispensing (PODs) might include churches, schools, large employers, or fraternal organizations within a community. This option may include the development of retail PODs (operated by businesses to provide antibiotics to their employees and the public) or closed PODs (operated by organizations to provide antibiotics to their employees and their family members).
3. Postal Plan: Home delivery of antibiotics by the United States Postal Service (USPS). The Postal Plan was conceptualized as a way of increasing the speed of dispensing of antibiotics and reducing the population surge at PODs. With this modality, mail carriers with security escorts deliver initial doses of antibiotics directly to homes.
4. Points of Dispensing (PODs). The PODs concept was initially developed to address the smallpox threat and is the public health preferred method of providing vaccine prophylaxis at designated dispensing locations for people who are currently healthy but may have been "exposed." As it relates to anthrax, the role of the POD has been extended to dispense antibiotics to affected members of a

[13] http://emergency.cdc.gov/agent/anthrax/prep/pdf/medkit-evaluation-summary-2007.pdf

community. However, given the amount of time needed to establish and operate a fully functional POD, coupled with delay in detection mentioned earlier , the critical initial doses of antibiotics will likely not be able to be delivered to all those potentially infected within 48 hours of an attack.

The dispensing modalities outlined by HHS provide a framework for rapidly distributing antibiotics. It is apparent that any effective system will involve a mix of several modalities including traditional PODs, employer PODs, postal carrier distribution, and private sector retail chain distribution. The workload required to distribute countermeasure will include a varying mix of traditional responders and volunteers totaling, for a large metropolitan area, thousands of "responders" just for countermeasure distribution.

If the USPS Plan is used as a first strike capability for distributing and dispensing initial doses of antibiotics, then planning must include pre-event screening of USPS personnel and their families, provision of antibiotics to personnel and their families, personal protective equipment (PPE) availability, appropriate training, and proper fit-testing.

Countermeasure distribution will constitute only a fraction of the total response to a large anthrax attack. As noted earlier, responders will be involved in a variety of activities, including environmental sampling and characterization of the contaminated area, crime scene investigation and forensics, law-enforcement and security to maintain of civil order, and medical care. Furthermore, maintaining continuity of operations throughout the response will require personnel that operate and maintain critical infrastructure and key resources. Therefore, the actual number of responders in this scenario may exceed 100,000 in some large regions. It is a critical planning function for each sector to independently examine risk of exposure to their employees and plan, prepare, and stockpile accordingly.

Finally, it should be noted that the efficacy of an initial response will likely hinge upon the maintenance of calm and orderly reaction of the community. The distribution and dispensing of life-saving antibiotics relies on the smooth and effective operation of logistical and transportation systems and the throughput or flow of people (responders and the affected public) through systems that deliver antibiotics. Psychological studies of humans in crisis situations and experience in previous disasters indicate that public confidence will remain high if there is perceived (1) open flow of accurate information, (2) effective government response, and (3) rapidly accessible antibiotics for all who require it. Additional studies suggest that nontraditional responders are more likely to report to and remain on duty if they and their families are provided adequate PPE in addition to PEP. Low public confidence in these areas may lead to panic and social disorder that likely may result in cascading consequences. This creates a tenuous balance upon which may rest the success of response. It is essential to have open, honest risk communication with the general public. People will be strongly urged to stay in place for up to 48 hours to ensure the roads are clear, responders can travel to the site, and medication (e.g., antimicrobial PEP, including antibiotics and vaccine) can be dispensed to individuals in the area.

Appendix 4 - Using Anthrax Vaccine in a Post-exposure (post-event) Situation

Anthrax vaccine is approved for post-exposure use to be administered under an Investigational New Drug (IND) protocol. This program provides the use of the licensed product, BioThrax, for the unapproved indication of post-exposure prophylaxis using a shorter duration of time and fewer doses compared to the approved regimen. As outlined in the IND protocol, the post-exposure prophylaxis program is intended to provide a 3-dose regimen (0, 2 weeks, 4 weeks) of anthrax vaccine (BioThrax ™, formerly known as AVA) as an emergency public health intervention to prevent inhalation anthrax among people exposed to potentially aerosolized *Bacillus anthracis* spores.

Post-exposure prophylaxis must include BioThrax in conjunction with 60 days of selected oral antibiotics. Two of these, ciprofloxacin and doxycycline, have been approved by the Food and Drug Administration (FDA) for this indication but the other, amoxicillin, has not. Therefore, the program is made available under an Investigational New Drug (IND) application to comply with regulations concerning the use of approved products for investigational indications.

All participants must sign an informed consent form before being allowed to enroll in the program. The program, consent form, and progress reports will undergo continuing review by CDC Investigational Review Board at least annually in accordance with Title 21, Code of Federal Regulations (CFR) Part 56.109. The currently approved protocol has been approved by the CDC IRB until November 2008.

In October, 2008 the Secretary of Health and Human Services declared under section 564(b)(1)(B)(C) an emergency based on: the determination of the Secretary of Homeland Security that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a biological agent anthrax; and the determination of the Secretary of Health and Human Services of a public health emergency under section 319 of the Public Health Service Act that affects, or has the potential to affect, national security, and involves the biological agent anthrax. CDC could request use of anthrax vaccine as a part of PEP through an Emergency Use Authorization (EUA) as a medical product for use in emergencies pursuant to section 564 of the Federal Food, Drug and Cosmetic Act. This EUA allows BioThrax™ to be used in combination with antibiotics to protect civilians, emergency response personnel, and health care providers who were exposed to anthrax spores or bacteria following an intentional release due to an act of bioterrorism or as the result of a public health emergency. An EUA has facilitates the rapid implementation of anthrax vaccine administration, thereby allowing more rapid administration to the appropriate populations at risk.

Appendix 5– Knowledge Gaps

Additional study and information regarding the following items will allow for better characterization and allow for further refinement of anthrax protection guidance:

- Improved characterization of environmental hazards after wide-area release including:
  - Degree and extent of contamination (including resuspension and fate and transport)
  - Improved modeling to predict contamination
  - Risk of secondary re-aerosolization and activities to avoid to limit re-aerosolization
  - Duration and time kinetics of contamination
  - Impact of rain or other dilution factors on outdoor contamination
  - Indoor versus outdoor contamination characterization
  - Effects and determinants of cross-contamination via vehicle or human activity. Assessment of magnitude and evaluation of interventions to minimize cross-contamination.

- Required duration of antibiotic PEP including:
  - Variation with exposure dose
  - Variation with addition of anthrax vaccine

- Protective efficacy of vaccine in preventing inhalation anthrax including:
  - Contingencies not covered in current ACIP recommendations, e.g., when initial 6-dose series in incomplete, booster doses are not up to date
  - Post-exposure vaccine recipients who are eligible for pre-exposure vaccine by their activities
  - Local responders whose exposure potential may not be related to activities as much as by their living in a contaminated area
  - Multiple exposure levels and prolonged exposure
  - Using abbreviated or truncated vaccination regimens

- Safety and efficacy of alternative routes of anthrax vaccine administration to reduce adverse side effects

- The prioritization of vaccine either for logistical or inadequate supply needs

- Correlation of immune protection to enable research and predict risk

- Safety and efficacy of vaccine and antibiotic PEP in special populations

- Emergency Use Authorization application process for responder populations

- Efficacy, feasibility and technical requirements of improvised collective protection areas for responders coming from outside the hazard area and therefore not exposed to the primary dispersal (e.g., expedient isolation, safe havens)

- Method development for rapid human decontamination using low or no water techniques. Methods and guidance for determining the efficacy of decontamination.

- Development of rapid, effective decontamination capacity and capabilities necessary after a wide area release

Finally, this guidance should be reviewed in 18 months to assess the status of existing knowledge and decide whether updated guidance on protecting responders after a wide-area anthrax attack can be generated.

Appendix 6 – Additional References

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