Institute for BIOsecurity
Saint Louis University School of Public Health

The Anthrax Threat: Transitioning from Theory to Reality in Emergency Responder Practice

Spring 2007

Background

Open source intelligence material indicates that violent radical fundamentalist groups are making concerted efforts to develop anthrax as a biological weapon of terror. Cognizant of that threat analysis, members of the Haz-Mat, EMS and biosecurity communities sought and obtained support from Emergent BioSolutions to convene a two day meeting to consider pre-exposure vaccination with Anthrax Vaccine Absorbed (AVA, BioThrax™) as an alternative to the current policies of post exposure prophylaxis and treatment.

Accordingly a group of thought leaders from the emergency responder, law enforcement, public health and biosecurity community met February 9th –11th to consider the vulnerabilities of the first responder and critical infrastructure workforce should the nation again face a covert terrorist attack with *Bacillus anthracis*.

Wm. C. Patrick III reviewed the details of the cold war biological warfare research and development programs that clearly demonstrated the unique properties of anthrax that make it an ideal biological weapon and why *Bacillus anthracis* can be expected to again be the terrorist's agent of choice. In the process of discussing the biowarfare R&D programs Mr. Patrick presented data suggesting that as the inhaled dose of any agent is significantly increased over threshold for the ID 50 (Infectious Dose for 50% of exposed population), the clinical course of the disease could be markedly altered. That is, the incubation time is shortened; the clinical manifestations become relatively refractory to treatment indicted for naturally occurring disease and the mortality rates can be expected to increase significantly. Upon further elaboration Mr. Patrick educated the group about the relationship of spore size and electrostatic charge as these pertain to primary and secondary aerosolization of the agent and the difficulty of identifying the exposure zone with any degree of certainty. It became clear to the attendees that under the circumstances of an "ideal" anthrax attack the current policy of post exposure prophylaxis and treatment leaves the exposed first responder and critical infrastructure workforce vulnerable to treatment failure.

At the conclusion of the discussions of the cold war weaponization programs the meeting's focus shifted to a review of current open source threat assessments, the relative

availability of *B. Anthracis* from natural sources, the relative ease of weaponization, the lessons learned from the Bioterrorist attack of 2001, the new data on simply rendering the organism resistant to all antibiotics currently prescribed for treatment of *B. Anthracis* and the likely methods of agent deployment by terrorists. Those discussions led to the collective realization that the violent radical fundamentalists have the means, methods and apparent will to mount future attacks using anthrax as a bioweapon.

The participants then considered the question of the adequacy of current civilian EMS/Critical infrastructure workforce protection doctrine, which relies on active and passive surveillance systems combined with a program of post exposure antibiotic prophylaxis/ treatment.

Several disconcerting limitations in the contemporary "conservative" approach to civilian work force protection immediately became apparent.

- First, many potential "targets" are not protected by current mechanical monitoring systems or passive disease surveillance programs. Additionally there are significant limitations of each of those systems.
- Secondly, if the EMS/ Critical infrastructure work force were exposed to anthrax in well-planned covert terrorist attack with a disease-accelerating dose of agent, the window of opportunity for optimal treatment would have passed by the time the victims were symptomatic.
- A candid analysis of POD plans and a review of exercise outcomes reveal significant limitations and raise reasonable doubt about the public health and health system's ability to administer adequate doses of medication to the EMS/ Critical infrastructure work force in a timely fashion.
- That federal officials responsible for post event response are protected with a safe and effective anthrax vaccine while the EMS/Critical Infrastructure workforce most likely to be infected during an attack are not creates both a dangerous and inconsistent work force protection policy. That inequity in force protection has yet to be fully appreciated by most affected by the current policies.

Conference participants reviewed the DHHS FDA Final Order arising from the Implementation of Efficacy Review of AVA (Docket # 1980N-0208) as published in the Vol.70 No.242 of the Federal Register on December 19, 2005. That document clearly demonstrates that AVA represents a safe, efficacious, and proactive alternative to the existing discriminatory policies that rely on post exposure detection and treatment for the EMS and Critical Infrastructure workforce

At the conclusion of the conference the following consensus statement was developed and unanimously adopted by the participants whose signatures are attached.

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Consensus Statement (Spring 2007)

Recognizing the reality of documented attempts of radical terrorist groups to develop and deploy anthrax as a weapon of terror the undersigned are unanimous in their belief that the "civilian" Emergency Responder and Critical Infrastructure workforce should be offered the same level of prospective protection afforded to their federal counterparts.

We urge the Department of Health and Human Services, the CDC Advisory Committee on Immunization Practices, and the Department of Homeland Security to immediately clear all barriers to the funding, acquisition and delivery of AVA to Emergency Responder/Critical Infrastructure workforce on a voluntary basis.

Moreover, we believe that AVA availability should be prioritized to the Emergency Responder/Critical Infrastructure workforce in the UASI cities and any other communities known or self-assessed to be at high risk for future terrorist attacks.

Further recognizing the difficulties encountered during previous smallpox vaccination efforts we strongly recommend that a reasoned, rational, and realistic education program be developed reflective of the threat and relative risk of another bioterrorist attack using *B. Anthracis.* That education program should include a careful delineation of the efficacy and safety of AVA, the FDA approved indications, and a discussion of the relative risks and benefits of voluntary immunization with AVA vaccine versus relying on a post-exposure strategy that depends on antibiotics.

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