



Pre-Attack Anthrax Vaccination – A Risk-Based Review

- Security Risk is defined as a function of three variables:
 - the probability that there is a threat
 - the probability that there is vulnerability
 - the potential impact(As any of these variables approaches zero, the overall risk approaches zero.)

- Probability there is a threat of an anthrax attack:
 - Those with access to classified intelligence data are routinely administering the anthrax vaccine to US-deployed National Guard Civil Support Teams.^{1,2}
 - Declassified information has confirmed that known enemies of the United States including Al Qaeda have anthrax weaponization expertise.³
 - Per Department of Homeland Security officials, the threat of an aerosolized anthrax attack is the number one bioterrorism concern.⁴

- Probability that there is vulnerability
 - The U.S. has already suffered a covert, multi-wave, multi-site, lethal anthrax attack.⁴
 - Anthrax can and has been made resistant to all currently-stockpiled, pertinent antibiotics.^{5,6}
 - The anthrax weapon is invisible, odorless, tasteless, and easily re-aerosolized.⁷
 - Identifying the safe zone from the attack zone and preventing cross contamination from exposed to those not exposed is difficult and not fail-safe.⁸
 - Continuous sampling detectors currently in use in the US Postal Service still allow nearly 28 million parcels in any given hour through before sounding the alarm.
 - Antibiotics have no affect on anthrax spores or the toxins produced by the organism.⁹
 - Adherence to long term antibiotic regiments, as seen in the 2001 anthrax attacks, is poor.¹⁰
 - In an attack with antibiotic-resistant strains of anthrax of sufficient dose, post-exposure antibiotics afford no protection and the vaccine mechanism of action cannot be expected to confer immunity to the victims in time to prevent disease.¹¹

- Potential Impact
 - The destructive capability of weaponized anthrax is equivalent to that of a nuclear bomb.¹²

- Other Facts
 - Adverse events associated with antimicrobial prophylaxis in victims of the 2001 anthrax attacks were commonly reported; 57% (n=3,032/5343) reported adverse events during the first 60 days of the prescribed regiment.¹³
 - The anthrax vaccine is FDA-licensed as safe and effective.¹⁴
 - Over 2 million military personnel have received more than 8 million doses.
 - The Institute of Medicine has stated that the rate of adverse events for this vaccine is similar to rates with other adult vaccines (flu, HAV, Tetanus).^{15, 16}
 - The Department of Homeland Security has certified the vaccine as a "qualified anti-terrorism technology" under the "Support Anti-Terrorism by Fostering Effective Technology Act" (SAFETY Act).
 - The anthrax vaccine is included as a covered countermeasure under the Public Readiness and Emergency Preparedness Act (PREP Act). This is pursuant to a declaration issued by the U.S. Department of Health and Human Services (HHS) that the threat of exposure to anthrax and the resulting disease constitutes a public health emergency.

- Regarding a covert attack with a non-contagious biological weapon, the key to community preparedness and resilience is to immunize before the attack. This is especially true if the biological agent is likely to be engineered to be resistant to post-attack countermeasures.

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- ¹ Army Anthrax Vaccine Immunization Program Plan.
<http://www.vaccines.mil/documents/481ARMYresumptionplan.pdf>. 2002 Sep 24.
- ² Emergency Use Authorization (EUA) for Anthrax Immunizations Extended.
[http://www.vaccines.mil/documents/782Anthrax EUA Extension.pdf](http://www.vaccines.mil/documents/782Anthrax_EUA_Extension.pdf). 2005 Aug 5.
- ³ Jeffrey W. Runge, MD, Assistant Secretary for Health Affairs, Department of Homeland Security, written testimony before the House Committee on Homeland Security, July 22, 2008
- ⁴ Doolan DL, Freilich DA, Brice GT, et al. The US capitol bioterrorism anthrax exposures: clinical epidemiological and immunological characteristics. *J Infect Dis*. 2007 Jan 15;195(2):174-84.
- ⁵ NOVA Online. Interviews with Biowarriors: William Patrick III, Ken Alibek, Sergei Popov. PBS Nov 2001
- ⁶ Athamna A, Athamna M, Abu-Rashed N, Medlej B, Bast DJ, Rubinstein E. Selection of *Bacillus anthracis* isolates resistant to antibiotics. *J Antimicrob Chemother*. 2004 Aug;54(2):424-8.
- ⁷ Weis CP, Intrepido AJ, Miller AK, Cowin PG, Durno MA, Gebhardt JS, Bull R. Secondary aerosolization of viable *Bacillus anthracis* spores in a contaminated US Senate Office. *JAMA* 2002 Dec 11; 288(22): 2853-8.
- ⁸ Doolan DL, Freilich DA, Brice GT, et al. The US capitol bioterrorism anthrax exposures: clinical epidemiological and immunological characteristics. *J Infect Dis*. 2007 Jan 15;195(2):174-84.
- ⁹ Spencer R. C., *Bacillus anthracis*. *J Clin Pathol* 2003;56:182-197
- ¹⁰ Shepard CW, Soriano-Gabarro M, Zell ER, et al. Antimicrobial postexposure prophylaxis for anthrax: adverse events and adherence. *Emerg Infect Dis* 2002;10: 1124-1132.
- ¹¹ NOVA Online. Interviews with Biowarriors: Sergei Popov. PBS Nov 2001
- ¹² Wein, L. M., Craft, D. L. & Kaplan, E. H. (2003) *Proc. Natl. Acad. Sci. USA* **100**, 4346–4351.
- ¹³ Shepard CW, Soriano-Gabarro M, Zell ER, et al. Antimicrobial postexposure prophylaxis for anthrax: adverse events and adherence. *Emerg Infect Dis* 2002;10: 1124-1132.
- ¹⁴ Federal Register: Biological Products; Bacterial Vaccines and Toxoids; Implementation of Efficacy Review; Anthrax Vaccine Adsorbed; Final Order. December 19, 2005 (Volume 70, Number 242) p75180-75198.
- ¹⁵ Institute of Medicine, “The Anthrax Vaccine, Is It Safe? Does It Work?” Committee to Assess the Safety and Efficacy of the Anthrax Vaccine, Medical Follow-Up Agency, Washington, DC: National Academy Press, 2002
- ¹⁶ Grabenstein JD. Vaccines: countering anthrax: vaccines and immunoglobulins. *Clin Infect Dis*. 2008 Jan 1;46(1):129-36.

Thomas K. Zink, MD
Adjunct Professor
Senior Advisor to the Director
tkzinkmd@comcast.net
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SAINT LOUIS
UNIVERSITY