

Anthrax Vaccine – Waste Not! Want Not!

- **According to the U.S. GAO¹**, every year since 2009 an estimated 1.5-2 million vaccine doses of the FDA-licensed anthrax vaccine stored in the Strategic National Stockpile (SNS) go to waste. Some estimates put the waste at 600,000 doses a month. These doses could be offered to Americans at high risk to anthrax bioterrorism.
- **Who should be considered for the vaccine?** Because the anthrax weapon is invisible, odorless, tasteless, and easily re-aerosolized personal protective equipment is not fool-proof since identifying the hot zone is nearly impossible.² As a result the vaccine must be considered for all who routinely respond to “white powder scares”.³ This group includes but is not limited to: police/security officers, fire fighters, paramedics/EMTs, public health officials, public works personnel, utilities employees, HAZMAT, SWAT, and health care professionals who serve as first receivers in emergency rooms.
- Lessons from the two-wave, multi-site, deadly attack via the US Postal Service, suggest that the vaccine is also appropriate for all Americans from groups victimized by the 2001 anthrax attacks.⁴ This includes mail/shipping carriers, media personalities, government officials and their staff.
- To bolster business continuity, the US Department of Labor has a tool on its website <http://www.osha.gov/SLTC/etools/anthrax> to help determine the credible risk of anthrax exposure/attack. A workplace in the Yellow or Red zone of this matrix ought to consider a pre-attack vaccination program for its employees, as well.
- **Why not rely on antibiotics after an attack?** Pre-attack vaccination is the best strategy for preparedness to anthrax bioterrorism since the resultant immunity protects against anthrax disease inflicted by both antibiotic-sensitive and antibiotic-resistant organisms.⁵
- Experts agree future biological attacks could use anthrax that is resistant to all currently-stockpiled, pertinent antibiotics.^{6,7} In an attack with antibiotic-resistant strains of anthrax of sufficient dosage, antibiotics fail and the infection could quickly progress to a toxic death well before the vaccine mechanism of action could be expected to confer immunity to the victims.⁸
- Since the likely and worse-case attack scenario is with antibiotic-resistant anthrax⁹, the prudent plan is voluntary, pre-attack, vaccination for any person who self-assesses a high risk of exposure due to occupation, location of home/business, commute, or choice of recreation.
- **There is very little risk in this strategy.** Anthrax vaccine adsorbed (AVA) is FDA-licensed as safe and effective.¹⁰ To date, over 11.6 million doses of AVA have been administered to more than 2.9 million individuals. The Institute of Medicine has found that the rate of adverse events for this vaccine is similar to rates with other adult vaccines (flu, HAV, Tetanus).^{6,11} Niu et al. (2009) found that out of the 6 million doses administered from 1998 to 2007, there were 79 adverse events per 100,000 doses, or less than 0.1% of all administered doses.^{12,13}
- **What is the demand for the vaccine or support for this?** Presently emergency responders (and many civilians) are expressing a wish to receive the vaccine according to the current FDA approved label.¹⁴ In one qualitative survey sponsored by Missouri State Emergency Management Agency 63% of emergency responders queried want the anthrax vaccine. The CDC Advisory Committee on Immunization Practices (ACIP) supports the use of the anthrax vaccine for emergency responders.¹⁵ Vaccinating local emergency responders would bring their level of preparedness up to the federal standard of protection enjoyed by the National Guard Weapons of Mass Destruction Civilian Support Teams.¹⁶
- **Conclusion:** The anthrax bioterrorism risk to Americans could be significantly mitigated by distributing and administering SNS anthrax vaccine through a voluntary, pre-exposure immunization program.

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- ¹ GAO, Project Bioshield: Actions Needed to Avoid Repeating Past Problems with Procuring New Anthrax Vaccine and Managing the Stockpile of Licensed Vaccine. GAO-08-88 (Washington, D.C.: October 2006) pp. 24-25.
 - ² 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.
 - ³ Webb GF. A silent bomb: the risk of anthrax as a weapon of mass destruction. *Proc Natl Acad Sci USA.* 2003 Apr 15; 100(8):4355-6.
 - ⁴ NOVA Online. Interviews with Biowarriors: William Patrick III. PBS. Nov 2001.
 - ⁵ 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
 - ⁶ NOVA Online. Interviews with Biowarriors: William Patrick III, Ken Alibek, Sergei Popov. PBS Nov 2001
 - ⁷ 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.
 - ⁸ NOVA Online. Interviews with Biowarriors: Sergei Popov. PBS Nov 2001
 - ⁹ Wein L.M, Craft DL, Kaplan EH. (2003) *Proc. Natl. Acad. Sci. USA* **100**, 4346–4351.
 - ¹⁰ 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.
 - ¹¹ Grabenstein JD. Vaccines: countering anthrax – vaccines & immunoglobulins. *Clin Infect Dis.* 2008 Jan 1;46(1):129-36.
 - ¹² Niu M, Ball R. Adverse events after anthrax vaccination reported to the Vaccine Adverse Event Reporting System (VAERS), 1990-2007. *Vaccine* (2009), doi: 10.1016/j.vaccine.2009.08.027
 - ¹³ Sever JL, Brenner AI, Gale AD, Lyle JM, Moulton LH, Ward BJ, et al. Safety of anthrax vaccine: an expanded review and evaluation of adverse events reported to the Vaccine Adverse Event Reporting System (VAERS). *Pharmacoepidemiol Drug Saf* 2004;13:825–40
 - ¹⁴ Stanhope, W. Emergency Responder Consensus Statement for Pre-attack Anthrax Vaccination. Saint Louis University Institute for Biosecurity. August 2007.
 - ¹⁵ Centers for Disease Control and Prevention. Use of Anthrax Vaccine in the United States: Recommendations of the Advisory Committee on Immunization Practices (ACIP), 2009. *MMWR* 2010;59(No. RR-6):[19-20].
 - ¹⁶ MILVAX. Information About the Anthrax Vaccine and the Anthrax Vaccine Immunization Program (AVIP)