

An Information Paper on Anthrax Vaccination Technology

Published by the Technology Council
of the
International Association of Fire Chiefs

October 11, 2012



Overview/Problem Identification

The use of anthrax to inflict harm signifies a great potential danger to emergency responders who already risk their lives working in hazardous environments. The threat of anthrax as a weapon is a real possibility and historical precedent buttresses the reality of this threat. The Japanese cult Aum Shinrikyo sprayed aerosols containing anthrax in attacks on Tokyo in 1993. A more recent incident within the United States was the mailing of letters containing anthrax in 2001. The attacks in Japan produced zero casualties, while 5 died in the US attacks and 17 others were infected.

Anthrax is an infectious disease caused by the bacterium *Bacillus anthracis*. There are three modes of transmission for anthrax: cutaneous, gastro-intestinal, and inhalational. Cutaneous anthrax enters the body through a cut or sore on the skin. It can be recognized by a bump resembling a bug bite, which often develops into an ulcer with a black center, and which may be associated with swelling in the lymph glands. Gastro-intestinal anthrax may be contracted from eating raw or undercooked animal meat. Symptoms include nausea, fever, swollen neck, and bloody diarrhea in later stages. Inhalation anthrax is the result of breathing in anthrax spores. Early symptoms include flu-like symptoms or mild chest discomfort. Later symptoms may include the sudden development of fever, difficulty breathing, shock and coma. Death often follows. The Center for Disease Control (CDC) has designated anthrax as a Class A threat. This is the highest danger rating.

The best way to mitigate the responder's ill effect or death to anthrax while not impeding response activities is through vaccination. Currently, emergency responders do not have any mechanism to obtain the preventative vaccine to deal with the potential of exposure to anthrax. This paper will explore how anthrax vaccines are designed to work, how modern medicine incorporates this science into the vaccines that have been supplied and what steps are being taken to introduce this to the emergency response community.

A Basic Look at Immunology and Vaccination

Our immune system is an amazing protection mechanism inside our bodies. It is designed to defend us against millions of bacteria, microbes, viruses, toxins and parasites that would love to invade your body. To understand the power of the immune system, all that one has to do is to look at what happens to an organism once it expires. When a human or animal dies, its immune system (along with everything else) shuts down. In a matter of hours, the body is invaded by all sorts of bacteria, microbes, parasites and the like. Many of these pathogens are able to get into the body, but when the immune system is working the probability of infection is lower.

In order to understand how a vaccine stimulates the immune system to produce protective antibodies against Anthrax, one must understand the science and purpose behind vaccinations. A vaccine is a biological preparation that contains an agent resembling a disease-causing microorganism. This could be an attenuated (weakened) or killed microorganisms—or proteins

derived from them—which is then administered to us, mostly via an injection or by mouth, to introduce our immune system to that particular disease. Our immune system learns how to defend against such an attack. When attacked again, the system recognizes the agent as foreign and remembers how to prepare, fight and destroy the invading pathogen.

Technology Overview

In this paper, we will discuss Emergent BioSolutions' anthrax vaccine, BioThrax® (Anthrax Vaccine Adsorbed). The vaccine is prepared from a solution that develops after the filtration of culture of anthrax bacteria. BioThrax stimulates the immune system to produce protective antibodies. The antibodies help the immune system to neutralize toxins produced by anthrax bacteria. This product is administered intramuscularly (in the arm muscle) at 0, 1, and 6 months, with boosters at 12 and 18 months, and at 1-year intervals thereafter. BioThrax is the only FDA-licensed vaccine for prevention of disease caused by *Bacillus anthracis*, in persons 18 through 65 years of age at high risk of exposure. The safety and efficacy of BioThrax in a post-exposure setting have not been established.

While the immunization is meant to help individuals, as with any vaccines, there are precautions and potential side effects that must be accounted for. The most common adverse reactions at the injection site include tenderness, pain, redness, swelling and arm motion limitation. The most common systemic reactions were muscle-aches, fatigue, and headaches.

Individuals with certain medical conditions should also be wary when taking BioThrax. For example, persons who are immune-compromised including those undergoing immune-suppressive therapy may find a diminished immune response. Pregnant women should avoid vaccination to prevent harming the fetus. Subjects with a history of anaphylaxis (allergic reaction that could result in death) should be evaluated before receiving the vaccination as well. Lastly, those with allergic reactions to latex should receive the treatment cautiously due to a vial stopper used to administer the vaccine which contains dry natural rubber.

First Responder Access

Pre-incident vaccination presents an approach to shield emergency responders from the Anthrax disease while not impeding their performance. Its utilization in the first responder community could serve as a boon and protect the health and wellness of many responders in future incidents. BioThrax has been put to use by the military for this purpose for several decades.

The International Association of Fire Chiefs (IAFC), as part of the Emergency Services Coalition on Medical Preparedness, has petitioned Congress to grant first responders voluntary access to this vaccine. Progress on this front has begun to move forward at a steady pace.

Potential funding sources have been identified for the administration and distribution of the vaccine.

Two primary actions for protecting first responders and their families have been identified by the Coalition working within the Emergency Services Sector Coordinating Council (ESSCC) for infrastructure protection, and collaboratively with infrastructure protection interests within the Department of Homeland Security (DHS).

The first action is the inoculation of all first responders in conjunction with determining the optimal procedure for carrying this task out.

The second action is to provide family members of first responders with home Med Kits containing antibiotics for emergency use. These kits would only be utilized in the home if an actual outbreak were to occur in their communities. Doing so alleviates a first responder's concerns about his or her family, and thereby allows them to focus on incident response.

DHS will first launch a voluntary anthrax vaccination pilot in two U.S. states to offer the vaccine to its first responders. As of today five states have already volunteered to be pilot test states without any solicitation. Home Med Kits are already being tested in two large Midwest cities.

About the IAFC Technology Council

The IAFC Technology Council was established in 2008 as a council to provide a component within the IAFC to concentrate on emerging and existing technology and issues relating to the use of technology in the fire and emergency services fields to assist firefighters and chief officers and emergency managers in their endeavor to be a cutting edge organization. The IAFC has always considered technology an important area of concern for the emergency services. The establishment of this council is a reflection of the importance that the IAFC attaches to emerging technology to protect our most valuable resource – our personnel and to assist in delivery of services to our citizens.

Disclaimer

The IAFC Technology Council does not endorse nor recommend any commercial products or services. The views and opinions of this paper are for informational purposes only. Consult a medical doctor, immunologist or other relevant, specialized professional before taking any action regarding responder vaccines.

Bibliography

- "Anthrax." *Mayo Clinic*. Mayo Clinic, n.d. Web. Aug. 2012. <<http://www.mayoclinic.com/health/anthrax/DS00422>>.
- "Bacillus Anthracis." *Center for Bio-Security of UPMC*. N.p., 21 Sept. 2011. Web. Aug. 2012.
- "BioThrax General Product Questions." *Emergent Biosolutions*. Emergent Biosolutions, n.d. Web. Aug. 2012. <<http://www.biothrax.com/whatisbiothrax/commonquestions.aspx>>.
- "Vaccines, Blood, & Biologics." *Food and Drug Administration*. Web. June 2012. <http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm133822.htm>.
- "BioThrax – Package Insert." Food and Drug Administration. Web. Aug 2012. <<http://www.fda.gov/downloads/BiologicsBloodVaccines/BloodBloodProducts/ApprovedProducts/LicensedPrductsBLAs/UCM074923.pdf>>.

Acknowledgement

We would like to thank Eric Zamani for his research and writing of this paper. Eric Zamani is a graduate student at George Mason University currently pursuing his Masters of Public Administration degree with a focus in Emergency Management. Mr. Zamani has worked at the IAFC since January 2012 and has contributed in writing other information papers for the Technology Council. Eric is presently working on the Hydrogen Fuels Training and Education Research Project.