Anthrax Immunization
Questions and Answers

The Department of Defense is implementing a vaccination program, against the biological warfare agent anthrax, which will be administered to all active duty and reserve personnel.

The vaccination program will consist of a series of six inoculations over an 18 month period, with initial emphasis on those service members deployed to high biological warfare threat areas in Southwest and Northeast Asia and service members within 35 days of deployment to those areas. The vaccine is FDA-licensed and exhibits few side-effects.

POLICY/AUTHORITY

Q1. Why vaccinate now?

A1. Since the Gulf War, the Department of Defense has increased the level of attention given to biological warfare defense and other force protection measures. The current world threat environment and the unpredictable nature of terrorism make it prudent to include biological warfare defense as part of our force protection planning. Anthrax is 99 percent lethal to unprotected individuals exposed to battlefield concentrations of the agent.

Q2. Who approved this vaccination program? On what authority?

A2. The final decision to vaccinate will be made by the Secretary of Defense in accordance with the procedures prescribed in DODD 6205.3. The vaccine implementation plan was developed with the full cooperation of the Services and the Joint Chiefs of Staff and coordinated with the Armed Forces Epidemiological Board and appropriate medical agencies.

Q3. How is the policy applied?

A3. In November 1993, DoD established the policy, responsibilities and procedures for stockpiling biological agent vaccines and determined which personnel should be immunized and when the vaccines should be administered. The policy, Department of Defense Directive 6205.3, specifically states that personnel assigned to high threat areas and those pre-designated for immediate contingency deployment to these areas (such as personnel in units with deployment dates up to 30 days after mobilization) should be vaccinated in sufficient time to develop immunity prior to deployment.
THE THREAT

Q4. What is anthrax?

A4. Anthrax is an infectious disease that normally afflicts animals, especially cattle and sheep. Anthrax spores can be produced in a dry form which may be stored and ground into particles. When inhaled by humans, these particles cause respiratory failure and death within a week.

Q5. Has any country ever used it as a weapon?

A5. No, but several countries are believed to have weaponized anthrax as a biological warfare agent.

Q6. Has the threat of biological warfare changed?

A6. The threat of biological warfare presents a constant risk to U.S. forces. DoD analysts maintain an updated evaluation of the level of threat, adjusting the information as necessary to reflect the risk to U.S. operations.

Q7. How real is the threat?

A7. Very real. Our assessments of the potential offensive biological threat facing American service men and women indicates it is necessary to have a robust biological defense program today.

THE VACCINE

Q8. When will vaccinations begin?

A8. If approved by the Secretary of Defense, inoculations of personnel in high threat areas will begin as soon as possible with general vaccination of the force to follow. Michigan Biologic Products Institute (MBPI), under contract to the Department of the Army, has produced and stockpiled the vaccine to support inoculation of the force.

Q9. Who is the executive agent for the biological immunization effort?

A9. DODD 6205.3 designates the Secretary of the Army as the Executive Agent for the DOD Immunization Program for Biological Warfare Defense.

Q10. How will the program be implemented?
A10. Each Service participated in the development of the Armed Forces Immunization Plan. The vaccine will be centrally procured but the task of immunizing will be decentralized.

Q11. How many military members will be vaccinated?

A11. The total depends on the scope of the final decision. Could total 2.4 million.

Q12. What vaccine will military members be given?

A12. If this decision is taken, military members will receive “Anthrax Vaccine Adsorbed (injected).” It is a sterile commercial product manufactured by the Michigan Department of Public Health, Lansing, Michigan. It is fully licensed (U.S. License No. 99, 1970) by the U.S. Food and Drug Administration (FDA) for human use and has had an excellent safety record.

Q13. How does the vaccine work?

A13. The vaccine promotes increased resistance to Anthrax by active immunization. The recipient develops protection by means of antibodies and other immune mechanisms to the bacterium following immunization.

Q14. What is the protocol for this vaccine? How many shots does it take?

A14. Immunization consists of three subcutaneous injections, 0.5mL each, given 2 weeks apart followed by three additional subcutaneous injections, 0.5mL each, given at 6, 12, and 18 months.

Q15. How long does it take after the first shot before protection is achieved?

A15. Functional protection is achieved in most individuals after the first three doses. (If asked: Based on research at U.S. Army Research Institute for Infectious Diseases, Ft. Detrick, MD)

Q16. How long does the vaccine remain effective, once administered? Does it require a booster of any kind?

A16. If immunity is to be maintained, subsequent booster injections of the vaccine at one year intervals are recommended.

Q17. Who developed the vaccine?
A17. The product was developed and is manufactured by the Michigan Department of Public Health, Lansing, Michigan. It is fully licensed (U.S. License No. 99, 1970) by the U.S. Food and Drug Administration (FDA) for human use.

Q18. Who is producing the vaccine for DoD?


Q19. Is the vaccine available outside of DoD?

A19. The Michigan Department of Public Health produces the Anthrax vaccine commercially, and the product is therefore available to the general medical community for appropriate use. The Department of Defense has recently contracted with the MDPH to fulfill requirements for a stockpile, however, a supply is available for continued support of routine use for at-risk personnel (Veterinarians, State Health Offices, Animal Product Processing, etc.).

Q20. Has this vaccine been used in the past? How many times? By the military?

A20. Yes, the vaccine has been routinely administered to populations at risk (veterinarian’s, laboratory works, civilians working with live stock) for several years. The Michigan Department of Public Health estimates private sector usage at between 400 to 500 doses per year. This vaccine has been purchased by the Army since 1970 for use by at-risk laboratory workers (estimated at between 500 to 1000 total recipients), and it was used during the Gulf War (approximately 150,000 recipients) to immunize U.S. forces against Iraq’s weaponization of B. anthracis.

Q21. Was it FDA-licensed at the time it was given?

A21. Yes. It was licensed by the FDA in 1970.

Q22. What other countries are developing Anthrax vaccines?

A22. Two other countries, Great Britain and Russia, are known to have a vaccine to Anthrax. The vaccine developed by the British is similar in production methods to that used by the United States, although it is not exactly the same vaccine. The Russian vaccine was based on a live, attenuated strain of the bacteria that causes the disease. Other countries may also be developing such vaccines.

SAFETY

Q23. Why immunize at all? Why not treat with antibiotics after exposure?
A23. Immunization is the safest, most effective way to provide protection against Anthrax.

Q24. Is this vaccine FDA approved?

A24. Yes. It is fully licensed (U.S. License No. 99, 1970) by the U.S. Food and Drug Administration (FDA) for human use.

Q25. How safe is the vaccine?

A25. The vaccine is safe. There is no evidence from records at the Michigan Department of Public Health that Anthrax Vaccine Absorbed (injected) is associated with chronic or permanent local or systemic effects. Since it was first licensed in 1970, very few reports of adverse events have been received.

Q26. What are some of the side effects from taking this vaccine?

A26. Reported side effects to the vaccine are mostly limited to local reactions. Minimal local reactions, such as redness and swelling, are seen in up to 30% of recipients. Moderate reactions are seen in up to 4% of recipients. Severe local reactions, which include edema that may extend to the elbow or forearm, are very rare (less than 1%). Some recipients may develop a non-tender, subcutaneous nodule that can last up to 2 months, but which resolves without treatment. Systemic reactions, such as fever, malaise and headache, are extremely rare (less than 0.2% or less than 2 per 1,000) with this vaccine. There have been no long term side effects from the vaccine.

Q27. Can the vaccine be taken by military members who are pregnant?

A27. Anthrax vaccine, like all other vaccines in the U.S., is classified as “pregnancy category C,” which means that animal reproduction studies have not been conducted with anthrax vaccine. Therefore, prudent medical practice dictates that all vaccinations, including anthrax, should be routinely deferred during pregnancy unless clearly needed. Every woman will be questioned about the possibility of pregnancy. Pregnant women will not receive the anthrax vaccine unless anthrax exposure occurs or is imminent. If a woman becomes pregnant after beginning the vaccine series, the series will be suspended until she is no longer pregnant. When she is no longer pregnant, the vaccine series will continue.

Q28. Is there a requirement for long-term follow-up after this vaccine is administered?
A28. No. This is an FDA-licensed product and does not require patient monitoring beyond the normal patient care immediately following the injection.

**COST**

Q29. How much does each dose of the vaccine cost? What is the cost of the program?

A29. The current cost of a single dose at the manufacturer level is approximately $3.50. A Troop equivalent dose (TED), consisting of the full six dose regimen, costs approximately $21.00. When all associated costs (transportation, storage, administration, etc.) are included, the cost to immunize an estimated 2.4 million personnel (over a six-year period) is approximately $130 million.

**THREAT/RISK FACTORS**

Q30. What about the threat of agents other than anthrax? Are vaccines being developed for other biological agents?

A30. As potential biological warfare threats are identified, we are working with the FDA to determine appropriate protection mechanisms. Vaccines are being developed, whenever appropriate, for all validated biological threat agents. Certain biological agents, such as physiologically active compounds, may not be effectively contravened using a vaccine.

Q31. What about Botulinum Toxoid? Will a similar program be developed for protection of U.S. forces against that threat?

A31. A Botulinum vaccine is available for use as an Investigational New Drug or IND. That means it is not yet FDA-licensed and must be administered only under informed consent. DoD is working with the FDA to license a Botulinum vaccine for use as a force protection measure.


A32. Anthrax in a weaponized form has the potential to cover significant areas of a battlefield. It’s difficult to determine who would be at greatest risk from a biological threat. What is clear is that biological weapons, in particular anthrax, have the potential to be devastating to an unprotected force.

**LEGAL/MORAL ISSUES**

Q33. Will service members have a choice in receiving the vaccine?
A33. No. All service members will be required to take the vaccination in accordance with the DOD directive for the purpose of protecting our forces.

Q34. Will those refusing to be vaccinated be court-martialed? Discharged?

A34. Each case will have to be determined on its own merits but in general, persons refusing to comply will face disciplinary action.

Q35. Will military members be asked to sign a consent form before being given the vaccine?

A35. The vaccine is fully licensed by the FDA, and does not require signed consent. Vaccine recipients will be provided with appropriate information on the vaccine at the time of immunization, or upon request at any other period.

Q36. Will the military members receive any kind of education about the vaccine?

A36. Yes, Service members will be educated as a matter of routine prior to immunization.

Q37. In overseas areas where family members are present, will family members be vaccinated also? If not, should U.S. reconsider having family members overseas with military members?

A37. The issue of vaccinating other than U.S. forces, to include civilians, is currently under review.

Q38. What about DoD civilians, contractor employees and coalition forces located in high threat areas?

A38. The current DoD Vaccination Plan includes immunization of mission essential non-military DoD employees in the Southwest Asia area. For questions on other categories of U.S. citizens, refer to the State Department.

PERSIAN GULF ILLNESS

Q39. Were soldiers given any biological vaccines during the Gulf War?

A39. Yes. During the Gulf War approximately 150,000 Service members received at least one dose to immunize U.S. forces against Iraq’s weaponization of *B. anthracis*. Approximately 8,000 doses of Botulinus Toxin were also administered during the Gulf War.
Q40. Have the biological agent vaccines administered during the Gulf War been linked to Gulf War illness?

A40. No. Several scientific bodies have addressed this issue and to date, there is no scientific information to that affect.

BIOLOGICAL AGENTS

Q41. What are biological agents?

A41. Viruses, bacteria, and toxins that can be used against U.S. interests.

Q42. How are biological agents deployed?

A42. Biological agents can be deployed in numerous ways from simple spray devices to ballistic missiles. The agents are often difficult to detect, symptoms are delayed, and without preventive medical efforts such a vaccination, the results can be devastating and wide spread.

Q43. Are Biological agents detected differently from chemical agents?

A43. It’s important to clearly distinguish the difference between the biological and chemical agents. The science and technology required to detect biological versus chemical agents is vastly different.

BIOLOGICAL DEFENSE PROGRAM HISTORY

Q44. What was the U.S. biological offensive program?

A44. The Biological Research and Development Program was a classified program conducted from 1942-1969. It was responsible for large-scale research and development programs in biological warfare agents (BW), BW intelligence, and BW defense. It was ended by Executive Order on November 25, 1969. Since then, the Department of Defense has engaged only in research and development of defense materials to protect U.S. Forces from the threat of biological warfare.

Q45. Why was the Biological Research and Development Program developed?
A45. In 1941, a National Academy of Sciences committee surveyed the world's BW situation. This committee concluded that BW weapons were feasible and urged President Roosevelt to take steps to reduce U.S. vulnerability to BW attack.

Q46. Where was the Biological Research and Development Program located?

A46. Camp Detrick, Maryland (now Fort Detrick) was the home of the Biological Research and Development Program from 1943 to 1969. Since 1969, the Medical Biological Defense Program has operated at Fort Detrick.

Q47. Why was the program continued after WWII?

A47. The program continued in response to concerns about the continued vulnerability of the United States to covert biological weapons attack.

Q48. What was U.S. policy regarding the use of biological weapons during the Cold War?

A48. The U.S. policy regarding biological warfare between 1941 and 1969 was to first deter its use against the U.S. and its forces, and secondly to retaliate if deterrence failed.

Q49. Does the U.S. still have an offensive biological program?

A49. No. In an Executive Order issued on November 25, 1969, President Nixon discontinued all U.S. activities that supported the offensive focus of the Biological Research and Development Program. The Army continued a defensive biological research program to include vaccine research. U.S. BW weapon stocks were destroyed by 1973.

Q50. Did the U.S. ever produce infectious biological agents for retaliatory use?

A50. During WWII, a plant was constructed in Indiana to provide retaliatory BW capability using aerial bombs; however, it ceased operation before infectious BW agent production began. From the end of WWII until 1950, no production was carried out for purpose of operational readiness, and no facilities were available. The first limited BW retaliatory capability was achieved in 1951 when an anti-crop bomb was developed. By 1954, a BW antipersonnel agent was being produced. Production of BW anti-crop and antipersonnel agents continued throughout the 1960s. In August 1969, President Nixon directed an immediate end to all BW production. DoD antipersonnel BW stocks and munitions were destroyed between May 1971 and May 1972. Anti-crop agents were destroyed between April 1971 and February 1973.

Q51. Does the U.S. have a biological research program today?
A51. Yes. Since the inception of the Biological Research and Development Program in 1942, the U.S. has conducted research and development into defensive measures against biological warfare. That defensive program, known today as the Biological Defense Research Program, continues in accordance with the 1969 Presidential policy statement. The Biological Defense Research Program seeks to develop effective warning and detection devices, protective clothing and equipment, and continues to assess the vulnerability of the U.S. and its forces to enemy BW attack.

Q52. Does the U.S. still have an offensive BW capability, or conduct offensive biological tests?

A52. No. United States BW weapon stocks were destroyed by 1973. Today, the Army only has a Biological Defense Research Program. No open air testing for offensive biological warfare has been conducted by this nation since 1969.

Q53. Does the U.S. still have live biological agents?

A53. Yes, U.S. military laboratories maintain limited archives of the microorganisms and toxins associated with BW efforts in order to develop vaccines, drugs and other therapeutics needed to protect our personnel. It does not maintain agents for any offensive biological weapons purposes.

Q54. When was the U.S. biological warfare program first made public?

A54. The Congress and American public were initially made aware of tests conducted as part of the Biological Research and Development Program in 1977 when the report, "U.S. Army Activity in the U.S. Biological Warfare Programs," was released.