The Anthrax Vaccine and Gulf War Illness

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STORY HIGHLIGHTS

- In anticipation of biological warfare, military personnel were given the anthrax vaccine during the 1990s Gulf War.
- After their service, Gulf War veterans suffered a wide range of debilitating symptoms that became known as the Gulf War illness or "Gulf War Syndrome."
- There were numerous concerns regarding the safety of the anthrax vaccine, which is considered by many to have been a

In the early nineties, the United States speculated that Iraq's Saddam Hussein had the capability of using biological weapons against military coalition forces in the Gulf War.[1] In response to this potential threat, military personnel from the U.S. and other countries were given several non-traditional vaccines, including anthrax vaccine, in addition to yellow fever, typhoid, hepatitis B, pertussis and other vaccinations routinely given to soldiers.[2]

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U.S. Department of Defense (DoD) officials considered anthrax to be a likely organism that could be weaponized and a licensed anthrax vaccine had been stockpiled for emergency use since 1987.[3] Military personnel from the United Kingdom also were given vaccines for anthrax, the plague and pertussis and Canadian military personnel received similar combinations.

U.S forces received experimental drugs, such as pyridostigmine bromide, and a different battery of vaccines, including anthrax vaccine and botulinum toxoid vaccine.[1] No previous deployment in U.S. history had involved vaccination of large numbers of soldiers against biological agents.[1]

Gulf War Illness

Shortly after their service in the Gulf War in 1990-1991, returning American soldiers and civilian workers reported that they were suffering from debilitating symptoms such as severe fatigue, joint and nerve pain, headaches, memory loss, gastrointestinal issues, insomnia and respiratory and neurological disorders.[4] This cluster of acute and chronic multi-symptom illness affecting veterans of the Gulf War became known as the Gulf War illness or “Gulf War Syndrome.”[4]

A 2014 report by the U.S Department of Veterans Affairs concluded that Gulf War illness has been consistently reported in all studies of the health of Gulf War veterans. The syndrome has been documented to affect about 25-30 percent of Gulf War veterans, which is approximately 175,000 to 250,000 of the 700,000 U.S. troops deployed in the war.[5] According to the report:

Studies published since 2008 continue to document poorer general health status and greater disability among Gulf War veterans than in contemporary veterans who did not deploy to the Gulf. Despite the extensive number of studies conducted with Gulf War veterans in the 23 years since Desert Storm, medical surveillance in this population remains seriously inadequate.[5]

The initial argument by government health officials seeking to explain the pattern of symptoms associated with Gulf War illness was that the symptoms were a result of stress psychological trauma suffered by the troops. However, more convincing evidence pointed to a combination of pharmaceutical, chemical and environmental exposures[5] and the safety of the anthrax vaccine was prominently questioned because of continuing reports of a high number of serious reactions among those given the six dose series of anthrax shots. A GAO report in 2002 found that 85 percent of the troops given the mandatory anthrax shot reported reactions and that 16 percent had either left the military or changed their status in part because of the mandatory anthrax vaccination program.[6]

Off-Label Use of Anthrax Vaccine by U.S. Soldiers

Anthrax is a serious bacterial infection but is not contagious. It is usually contracted through direct exposure to an infected animal or animal waste products in contaminated soil when the bacteria enter the bloodstream of a person through a skin wound or by swallowing or inhaling anthrax spores. If left untreated with antibiotics, lethal toxins from the anthrax bacteria multiply in the body and can kill up to 20 percent of those infected.[7]

At the time of the Gulf War, BioPort Corporation, now Emergent Biosolutions, was the exclusive manufacturer of anthrax vaccine (BioThrax) supplied to soldiers[8] and the U.S. Food and Drug Administration (FDA) had licensed BioThrax vaccine as effective based on evidence against cutaneous anthrax (acquired through the skin).[9] However, there was no evidence for effectiveness against aerosol (inhaled) exposure, which is the weaponized form

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of anthrax that military personnel would be exposed to in a bioterrorism attack, and so the FDA had not licensed BioThrax as effective against inhalation anthrax.[3]

Therefore, when the DoD ordered that anthrax vaccine be given to soldiers heading to the Gulf War, as well as other military personnel during the 1990's and early 2000s, it was an "off-label" (experimental) use of the vaccine.[10] It violated the licensed use authorized by the FDA and published in the approved vaccine manufacturer's package insert.[3]

This licensing issue was specifically highlighted in 1995 in a letter written to the vaccine's first manufacturer, the Michigan Department of Health,[11] from the director of the army's Medical Chemical and Biological Defense Research Program stating that...

> *This vaccine is not licensed for aerosol exposure expected in a biological warfare environment."[3] Moreover, another report released by the Department of Defense's anthrax project manager noted that, "protecting service members from aerosol exposure to anthrax can only legally be done if the FDA licenses the vaccine for that specific schedule and indication.[3]*

Although individual physicians may legally use licensed vaccines for off-label uses in some circumstances, the physician is responsible for assessing presumed "off-label" benefits against potential risks for each individual given the vaccine.[3] However, with mandatory vaccination programs, the risk-benefit decisions that should typically be made by the physician is eliminated. Therefore, under U.S. law mandatory vaccination programs are not supposed to use experimental (investigational) vaccines but only those vaccines that have been licensed by the FDA for approved indications.[3]

Questions About Squalene in the Anthrax Vaccine

There were several reports in the 1990s that some experimental anthrax vaccines given to American soldiers during the Gulf War contained squalene—an oil based adjuvant that hyper-stimulates

an immune response. Squalene adjuvants were not licensed for use in the U.S. at that time, and there was evidence that squalene-containing vaccines used in other parts of the world had been linked to severe brain and immune system dysfunction.[12]

Although the FDA states that aluminum hydroxide was the adjuvant used in the anthrax vaccine and not squalene, the FDA has confirmed that lab testsmay reveal the presence of squalene.[13]

Interestingly, a study published in *Experimental and Molecular Pathology* in 2002 demonstrated that that the production of anti-squalene antibodies in patients with Gulf War illness is linked to the presence of squalene in certain lots of anthrax vaccine.[14]

A document on the FDA's website notes:

> *Because of the difficulty of removing squalene-containing fingerprint oils from laboratory glassware, it is hard to know whether the squalene is truly present in some lots of the vaccine or is introduced by the testing process itself. DOD, FDA, and several civilian advisory committees agree that squalene at such low levels has no adverse health consequences.[12]*

The National Vaccine Information Center (NVIC) has argued that squalene adjuvants have not been tested in comparison to placebos in large trials published in scientific journals. Moreover, there are no studies specifically evaluating cellular, molecular and DNA changes in the body after squalene-adjuvant vaccines have been administered.[12]

The inclusion of squalene adjuvants in some lots of anthrax vaccine may have been authorized under section 564 of the Federal Food, Drug, and Cosmetic Act, which allows the FDA Commissioner to approve unapproved medical products or unapproved uses of approved medical products to be used in "an emergency" to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by chemical, biological, radiological and nuclear threat agents when there are no adequate, approved, and available alternatives.[15]

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DoD Mandated Anthrax Vaccine for All Military Personnel Despite Safety and Effectiveness Questions

Questions about the safety of BioThrax vaccine, as well as its effectiveness against weaponized inhalation anthrax, were growing long before the DoD decided to not only continue giving anthrax vaccine to soldiers fighting in Iraq and Afghanistan, but also to expand the vaccination program to all U.S. military personnel and DoD civilian contractors. In 1996, in anticipation of mandating the widespread use of the anthrax vaccine in the military, BioPort Corporation submitted an investigational new drug application (IND) to the FDA to expand the approved indications for the vaccine to include (1) aerosol exposure to the insert; (2) switching to intramuscular injection and (3) reducing the number of doses.[3]

On Dec. 15 1997, the Clinton administration decided to initiate the Anthrax Vaccine Immunization Program (AVIP), which made the anthrax vaccine mandatory for all 2.5 million active duty U.S. service personnel.[3] A few weeks prior to the launch of the AVIP, Secretary of Defense William Cohen held up a five-pound bag of sugar on national television warning the public that if the bag did indeed contain anthrax, it could kill half of the population of Washington, DC.[3]

In March 1998, Secretary Cohen was publicly given the anthrax vaccine after which mandatory anthrax vaccinations began for all military personnel and DoD civilian contractors.[3]

This decision for mass vaccination was made despite the fact that the FDA had not yet approved any changes to the vaccine manufacturer's package insert.[3] In a report published in the *American Journal for Public Health*, the author Meryl Nass MD wrote:

The Vaccine Reaction
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Six months after the IND was filed, but before any supporting data to amend the original license was submitted to the FDA, the assistant secretary of defense for health affairs, Dr. Stephen Joseph, asked the acting deputy commissioner of the FDA, Dr. Michael Friedman, for a go-ahead to use the vaccine, thus skirting the FDA's normal regulatory procedures for amending a vaccine license. Less than 2 weeks into his new position, Friedman wrote back, "While there is a paucity of data regarding the effectiveness of Anthrax Vaccine for prevention of inhalation anthrax, the current package insert does not preclude this use." However, Friedman's words merely expressed his personal opinion and did not comply with the requirements of the Code of Federal Regulations for amending the vaccine's label; therefore, they provided no legally acceptable justification for the vaccine's off-label use.[3]

In June 2001, there was an announcement made that there would be a "slow down" of the AVIP. Interestingly, the FDA had not released any more anthrax vaccine supplies in over a year. DoD announced that the only groups scheduled to receive the anthrax vaccine were the same two groups originally receiving the vaccine before DoD broadened the program in 1998: research laboratory personnel at high risk for anthrax exposure and active Special Forces troops.[3]

After Sept. 11, 2001 and Anthrax Letter Bombs: Calls for Expanded Military and Civilian Anthrax Vaccinations

When the terrorist attacks on New York City and Washington, DC occurred on Sept. 11, 2001, they were almost immediately followed by the release of anthrax-contaminated mail in the U.S. postal system, and there were calls for expanded use of anthrax vaccine not only in the military but also some suggested the vaccine also should be given to the civilian population.[16]

NVIC was among the groups and individuals that questioned the use of the reactive anthrax vaccine by large numbers of American civilians, pointing out there were logistical problems for anyone attempting to launch a successful bioterrorism attack using weaponized anthrax (or smallpox) on the U.S. population, which would require the failure of both extra internal and external homeland security measures put in place after 9/11.[17]

Judge Issues Temporary Ban on Mandatory Anthrax Vaccination of U.S. Troops

In March 2003, a lawsuit was filed in U.S. District Court in Washington, DC on behalf of U.S. military personnel and DoD civilian contractors forced to get BioThrax vaccinations, asking the Court to declare the vaccine "experimental."[18] In October 2004, U.S. District Court Judge Emmet G. Sullivan ruled that it was "illegal" for the federal government to mandate anthrax vaccinations, which by then had been given to more than 1.2 million troops since 1998.[19]

Judge Sullivan issued an injunction banning the Pentagon from forcing military personnel serving in Iraq, Afghanistan, South Korea and parts of Asia and Africa from being required to get anthrax shots without their informed consent until the FDA adequately reviewed and licensed the vaccine.

> *Congress has prohibited the administration of investigational drugs to service members without their consent," Sullivan said. "This Court will not permit the government to circumvent this requirement." Sullivan wrote, "The men and women of our armed forces deserve the assurance that the vaccines our government compels them to take into their bodies have been tested by the greatest scrutiny of all—public scrutiny. This is the process the FDA in its expert judgment has outlined, and this is the course this court shall compel FDA to follow.*[19]

Proposed Pediatric Anthrax Vaccine Trial

In 2006, the Pentagon resumed mandatory anthrax vaccinations of troops after the FDA pronounced BioThrax vaccine as "safe and effective," including against inhalation anthrax.[20]

In March 2013, BioThrax manufacturer, Emergent Biosolutions, and the U.S. Department of Health and Human Services (HHS) proposed to conduct clinical trials of anthrax vaccine on American infants and children. According to an article in *Nature*, "Interest in a vaccination campaign was spurred by a 2011 modelling exercise, 'Dark Zephyr', which found that a release of anthrax spores in a city the size of San Francisco, California, would compel officials to vaccinate 7.6 million people—including 1.7 million individuals under age 18."

The Alliance for Human Protection, along with NVIC and other health safety groups, opposed the trials, citing the vaccine's poor safety record, including many documented cases of brain and immune system damage suffering by military personnel in the Gulf War.[21]

Within a week, bioethicists with the US President's Commission for the Study of Bioethical Issues, also advised against proceeding with the proposed pediatric clinical trials, stating that until a bioterror attack occurs, tests of anthrax vaccine or other anti-bioterrorism "countermeasures" should not pose risks greater than those that a child might encounter in daily life or during a routine pediatric checkup.

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