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# An Incomplete Picture

**Despite promises that hospitalizations after anthrax vaccinations would be reported, the Pentagon withheld data on more than 20,000 cases.**

[BY BOB EVANS](#)

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The Pentagon never told Congress about more than 20,000 hospitalizations involving troops who'd taken the anthrax vaccine, despite repeated promises that such cases would be publicly disclosed.

Instead, a parade of generals and Defense Department officials told Congress and the public that fewer than 100 people were hospitalized or became seriously ill after receiving the shot from 1998 through 2000.

They also showed Congress written policies that required public reports to be filed for hospitalizations, serious illnesses and cases where someone missed 24 hours or more of duty.

But only a sliver of those cases were reported, while the rest were withheld from Congress and the public, records obtained by the Daily Press show.

Critics of the vaccine, veterans' advocates and congressional staffers say the Pentagon's deliberate low-balling of hospitalizations helped persuade Congress and the public that the vaccine was safe.

Keeping the actual number of illnesses secret contributed to a shorter list of government-recognized side effects for the drug, giving patients and physicians a false idea of what might constitute a vaccine-related illness or problem. Doctors are expected to know the full list of side effects and alert federal drug safety officials whenever they see a repeat of those symptoms.

Repeated evidence of the same adverse side effect after a vaccination is one of the most telling signs of a systematic problem with a drug or vaccine, as opposed to a coincidental relationship, vaccine safety experts say.

During the Daily Press' investigation of the vaccine and its effects, the newspaper found three cases of amyotrophic lateral sclerosis - ALS, or Lou Gehrig's disease - that the military hadn't reported. The disease destroys muscles and nerves, is always fatal and rarely hits people younger than 45.

One of the three cases involves Navy Capt. Denis Army of Virginia Beach. Army died in 2000, after developing symptoms less than a week after his first anthrax vaccination - and a few days before his 45th birthday. His widow filed the first public acknowledgement of his death and its temporal connection to the vaccine this year. That occurred after she talked to a Daily Press reporter and learned that she could file a report with the federal Vaccine Adverse Event Reporting System, or VAERS.

## SAILOR'S DEATH NOT REPORTED BY MILITARY

Navy Petty Officer 2nd Class Kristin SHEMELEY died of ALS in 2001, at 29. Her symptoms began about two months after her third shot, a sworn legal document detailing her illness says.

Before SHEMELEY died, she spent 14 months in Walter Reed Army Medical Center in Washington, where she was regularly visited by high-ranking military officers, said her mother, Ginger SHEMELEY of Quakertown, Pa. She says her daughter repeatedly told those generals and admirals that she was suffering because of the vaccine and even pleaded with one of them to stop giving it to troops. Several of those generals and admirals had promised Congress that such cases would be publicly reported to VAERS.

The military never filed a VAERS report on Kristin SHEMELEY. Ginger SHEMELEY filed one after her daughter died.

Col. John Grabenstein, director of the military's vaccine agency, said no one from the military intentionally misled Congress or the public. He said the 20,765 hospitalizations merely followed vaccinations in time, without documented proof of a cause-and-effect relationship.

He said a statistical analysis showed that those who'd been vaccinated weren't more likely to be hospitalized or likely to seek medical treatment than those in the military who hadn't been vaccinated from 1998 through 2000.

Some medical experts say this approach doesn't adequately address the problems of many people who report illnesses after anthrax vaccination. That's because the approach is limited to comparing rates of illness involving one symptom or disease - instead of the complex combination of symptoms and illnesses that many veterans report after getting their shots.

The data that the Daily Press used to document the underreporting of hospitalizations came from a report that Grabenstein supplied in response to the newspaper's request. It's never been made public until today.

It covers 1998 through 2000, when the Pentagon did detailed evaluations every three months to compare hospitalizations, clinic visits and medical treatment data for those who'd been vaccinated, compared with troops who hadn't. This quarterly analysis stopped and hasn't been done since, Grabenstein said.

The practice of not reporting all hospitalizations continues.

Quarterly analysis of the vaccine's effects ended just as the nation's only manufacturing site for the drug

regained its license. That was in 2002, after federal inspections found many safety and other problems that prompted a shutdown and renovation that began in early 1998.

The company's current manufacturing techniques provide greater potency compared with earlier versions of the drug, said the Government Accountability Office, Congress' investigative arm. The manufacturer, BioPort Inc., says there's no difference in the drug made since 2002 that might cause health problems.

## TOP GENERAL NOT TOLD MONITORING TO END

The decision to discontinue the quarterly health monitoring program means that the biggest gap in research about the vaccine remains: There are no systematic long-term studies of the health of those who've taken the drug. Most studies that the Pentagon cites as support for the vaccine's safety involve monitoring that lasted days to a few months.

None lasted as long as five years, the minimum length of time recommended by a nationally recognized panel of scientists assembled by the Institute of Medicine in 2002. The institute is a nonprofit organization that provides expert advice to Congress and other government agencies.

After the quarterly reviews of the vaccine's effects stopped, more than a million troops were forced to take the vaccine - until a federal judge ruled last year that the drug had never been adequately licensed for protection against anthrax use in warfare.

He ordered the military to make vaccination voluntary. The Pentagon is appealing that ruling. Lawyers argued the case Thursday, and a decision is expected by February.

## VACCINE MONITORING STILL IMPORTANT

Grabenstein said he decided to halt the quarterly studies after consulting the chairman of the Institute of Medicine panel and its staff, and with doctors affiliated with the military. He acknowledged that he didn't consult the general who ultimately was responsible for the anthrax program.

The chairman of the institute panel, Brian Strom, said he didn't recall what was discussed at the time about the quarterly reports. But he said, "I think they should continue to be using it," in case there's a problem.

Another panel member, Linda Cowan, said she's sure the committee expected quarterly reviews to continue and pointed to a number of the panel's recommendations and findings that she said clearly contradicted Grabenstein's interpretation of its report.

Strom and Cowan emphasized that they thought the vaccine was still safe.

Beth Clay isn't so sure. She directed the staff of Congress' House Government Reform Committee investigation into the anthrax vaccine from 1998 to 2001. She continued working on the subject as a congressional staff member through 2003, after her Republican boss was no longer chairman of the

committee.

Clay said the military's decision not to report all the hospitalizations gave the public and Congress a rosier picture of the vaccine than it deserved.

"We were never given this data," she said. "Had we seen this, the committee would have had significant questions" and would have demanded more information about the program.

After reviewing the report obtained by the Daily Press, Clay said it raised several questions about the vaccine's safety. She said Congress was never told about the detailed level of data in the report but was assured regular monitoring of the vaccine and its health effects would continue.

Terminating the quarterly reviews would seem to break those promises, she said. "It's just appalling that they didn't keep up with this," she said.

## LINK BETWEEN VACCINE, HOSPITALIZATIONS?

Steve Robinson is executive director of the National Gulf War Resource Center, a lobbying and advocacy group for veterans. He said he was stunned when he learned that the reviews had stopped: "They track the flu vaccine and not the anthrax vaccine, which is totally crazy to me."

He said discovery of the hospitalization data showed that the Pentagon couldn't be trusted to monitor the vaccine's safety.

"You can't let Enron investigate Enron, and you can't let DOD (the Department of Defense) investigate DOD," he said. "We work with the people who have been hurt by this vaccine every day."

No one knows how many, or how few, of the 20,765 hospitalizations are directly attributable to the vaccine. Ruling out certain illnesses, such as broken bones or injuries from falls or other accidents, might appear a safe bet. But military doctors have documented cases where broken bones and other injuries from falling were the result of vaccine-induced loss of consciousness affecting the nervous system - sometimes beginning months after vaccination.

The difficulty of figuring out what's related and what isn't is why safety officials encourage people to file reports even if they're not sure.

## WHY PENTAGON DIDN'T FILE HOSPITAL REPORTS

Still, medical experts consulted by the Daily Press said it's unlikely that the vast majority of the 20,765 hospitalizations resulted from the vaccine. They said that if all hospitalizations had been filed with VAERS, it would have overloaded the system and caused problems for experts trying to analyze the data.

Grabenstein said those were among the reasons that the full number of hospitalizations was not reported. Another reason, he said, was that examinations of the data showed that if there were adverse effects from the vaccine, they were so infrequent, they weren't detectable by statistical analysis. Doing this type

of analysis - instead of simply reporting the incidents to VAERS - provided a more definitive look at the health effects of the vaccine, he said. As a result, "we decided not to file" public reports about all hospitalizations, he said.

Those considerations weren't relayed to Congress or the public.

During the years covered by the hospitalization report obtained by the Daily Press, dozens of sick veterans who'd received the shot went to Capitol Hill, complaining of various health problems. Some got the shot for the 1991 Persian Gulf War, in which the vaccine had its first widespread use. Others were members of the military forced to take the shots under a mandatory program that began in 1998.

Their complaints had common themes: Fatigue. Chronic pain in joints and other symptoms of arthritis. Tingling in their feet, arms and hands. Mental lapses. Often, more than one of the symptoms were present, making diagnoses difficult.

Sympathetic doctors testified that these complaints were indicative of autoimmune problems, in which the body's natural protective mechanisms go haywire and start attacking healthy cells and tissue. The doctors said that could result if the vaccine overstimulated the vets' immune systems. The vaccine primes the system to develop protection against anthrax.

Bewildered and sometimes-angry members of Congress asked how many vets were affected. Pentagon doctors and generals used the cases reported to VAERS - fewer than 100 hospitalizations or other "serious events" from 1998 to 2000 - or said the number was so small, it couldn't be detected.

## VACCINE REPORTS ARE FIRST LINE OF DEFENSE

The two sets of numbers for how many hospitalizations followed the shot come from a comparison of two sets of data kept by three federal agencies.

The Food and Drug Administration and the Centers for Disease Control and Prevention maintain the only database open to public inspection, VAERS. VAERS is the nation's first line of defense in identifying possible problems with vaccines after they've been licensed, said Susan Ellenberg, who led the FDA's efforts to monitor vaccine safety from 1993 to 2004.

During congressional testimony before the House Government Reform Committee's Subcommittee on National Security, Veterans Affairs and International Relations in July 1999, Ellenberg explained how and why the system worked.

VAERS was established to help identify and head off problems once a vaccine is licensed and more people are taking it, she said. The few hundred people typically involved in vaccine or drug testing and licensing trials can't mimic the diversity of age, race, gender and other biologic variables encountered once the vaccine gets widespread public use, she explained.

Reports to VAERS by civilian doctors and hospitals are mostly voluntary, based on suspicion of a connection between an illness or injury and a vaccination, Ellenberg told Congress.

Doctors and others are encouraged to file a report, known as a VAERS-1, even when they aren't sure there's a cause and effect, she said. That's because VAERS requires as many reports of problems as possible, so experts can identify possible patterns and investigate further, she said.

## GENERALS' TESTIMONY PROMISED REPORTS

During the same congressional hearing, Lt. Gen. G. Robert Claypool - then the deputy assistant secretary of defense for health operations policy - assured Congress that military doctors, hospitals and medical officials were filing VAERS-1 forms, too.

And, he said, they were expected to report even more cases than civilians - including all hospitalizations.

"The duty to report adverse medication events has been codified for many years," Claypool testified. "The joint regulation requires submission of a form VAERS-1 for all adverse events resulting in more than 24 hours of lost duty time or any period of hospitalization. These requirements represent a higher standard than in comparable civilian community health care settings."

There was no mention that the word "all" didn't mean all hospitalizations.

Two months later, Lt. Gen. Ronald R. Blanck, then the Army's surgeon general and the top Pentagon official responsible for the anthrax vaccine program from 1998 to 2000, gave similar assurances to Congress.

He said, "We have a reporting system that when either of those two criteria are met, that is, either a patient is hospitalized following an anthrax immunization or misses duty because of it for greater than 24 hours, we have an active reporting system. That must be reported to us. We, in turn, report it to the Food and Drug Administration, and they have a group that reviews those reactions."

Clay and other congressional aides say these assurances came in private, too. "We had lengthy conversations that they were supposed to report," she said.

But the numbers reported were very low. And the Pentagon stuck with them for years to persuade the public that the shot was safe.

In December 2003, Pentagon officials conducted a news conference to rebut a judge's ruling that the shots had been given illegally and that troops had been used as "guinea pigs." Grabenstein was asked whether he had "any data on the numbers of people who have had bad adverse reactions to the vaccine and would have required hospitalization."

He said that only 69 hospitalizations had been reported to VAERS for the anthrax vaccine from 1998 through 2000. A panel of civilian experts had analyzed each, he said, and decided that 11 were results of the shot. The 69 cases were "a complete, exhaustive list of what was reported," Grabenstein said.

Grabenstein told the Daily Press that his statement wasn't misleading. He said no one should expect all

hospitalizations after vaccination to be reported to VAERS - despite the Pentagon's written policies - because the number included cases unrelated to the vaccine, sometimes years after vaccination.

He said, "The simple answer is it's so obvious, it's never appeared in the memo."

## NO EXCEPTIONS NOTED IN POLICY MEMOS

The memo, "Policy for Reporting Adverse Events Associated With the Anthrax Vaccine," serves as the standing order for all military personnel. It reads: "For the purposes of reporting anthrax vaccine adverse events, a Form VAERS-1 must be completed and submitted using service reporting procedures for those events resulting in a hospital admission or time lost from duty for greater than 24 hours or for those events suspected to have resulted from contamination of a vaccine lot."

The memo lists additional circumstances requiring a report, but nothing that would permit excluding hospitalizations after vaccination. It refers to the Pentagon's formal regulations, which don't include the exclusions that Grabenstein cited.

The data on all hospitalizations after anthrax vaccination comes from the Pentagon's Defense Medical Surveillance System, or DMSS. This computerized tracking system pulls medical records for every shot, clinic visit, hospitalization or other instance of medical treatment for active-duty military personnel.

Experts in health care and statistics say it's one of the most important medical databases in the world. That's because of its precision, its millions of patients, and the diversity of drugs and vaccines used by the armed forces. By design, it's more complete and accurate than VAERS. Unlike VAERS, its data isn't open to the public.

## EXPERTS: NO EXCUSE FOR SECRET DATA

The Institute of Medicine report that Grabenstein cited as supporting the vaccine's safety and his decision to end the quarterly monitoring program also says the DMSS database should be open to researchers outside the government, with precautions to protect the privacy of individuals' health records.

This hasn't been done. Grabenstein said the military had not been able to figure out how to protect individuals' health records and make it work.

Strom of the institute panel and other experts say it should not be that difficult. "There's no excuse," he said. "We use these kinds of data sets in Medicaid and Medicare data all the time. There are technological solutions."

Cowan, another member of the panel, said the institute's recommendation was based, in part, on the military saying it couldn't afford all the analysis that the data was good for: "That way, you get the most of what the American people have invested in."

Strom said keeping the data from the public only bolstered the perception that the military was hiding the truth about the vaccine.

Walter Schumm is a professor of family studies and an expert on statistical methods at Kansas State University. He said he and other researchers would love to get the DMSS data. He's a retired Army colonel who's spent more than a decade using statistical analysis to examine the vaccine's safety - after friends and others in uniform began complaining about health problems after the shots.

Schumm has used other data made public on the anthrax vaccine to publish several scientific papers that poke holes in the safety assertions made by Pentagon doctors and researchers.

Good science involves people with different approaches to the same problem having a chance to test their theories, Schumm and others say. Their findings might cement the safety assertions, he said, but no one knows for sure until the military loosens its hold on the facts and data.

He said, "If you let independent people have the data, you risk losing control. In combat, letting things get out of control gets people killed, so loss of control is a very sensitive issue. I'm just sure they're trying to protect their program."

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