Ambulatory Medical Visits among Anthrax-Vaccinated and Unvaccinated Personnel after Return from Southwest Asia

Guarantor: Lt Col Paul A. Rehme, USAF BSC
Contributors: Lt Col Paul A. Rehme, USAF BSC*§; Col Robert Williams, USAF BSC (Ret.)†; LTC John Grabenstein, USA‡

The Department of Defense launched a mandatory anthrax immunization program for military personnel in December 1997. This program has been criticized for many reasons, including concern over side effects. This study was designed to give a quick answer to the question of whether vaccinated persons who deployed to southwest Asia were more likely to seek medical care upon their return than their unvaccinated counterparts. The results demonstrated that there was no greater risk for vaccinated persons to have a diagnosis recorded in the Ambulatory Data System (0.96 RR) than unvaccinated persons. In addition, there was no significant increased risk for a recorded diagnosis in any 1 of the 17 International Classification of Diseases, Ninth Revision, categories or for 16 specific adverse health conditions.

Introduction

The health of military personnel returning from overseas deployments has long been the subject of special attention. Specific concerns about whether anthrax vaccination has any effect on the health of vaccinated individuals provides additional need to assess the health care utilization patterns of returning personnel.

The purpose of the study was to determine whether persons deployed to southwest Asia who were immunized against anthrax were at a different risk for needing ambulatory medical care upon returning home than deployed persons who were not immunized. Using a cohort design that used data already available in large, linked databases, we evaluated the possible confounding effects of age, gender, race, and rank.

Background

Anthrax is an ancient disease affecting livestock with occasional human cases.[1] In the past several decades, it has emerged as a significant biological warfare threat as a result of its high lethality, stability, and relative ease of dispersal.[2] The anthrax vaccine currently in use in the United States was licensed in 1970 by the Food and Drug Administration and is manufactured by BioPort Corporation (formerly the Michigan Department of Public Health and Michigan Biologic Products Institute). Anthrax vaccine consists principally of protective antigen adsorbed onto aluminum hydroxide. Until 1991, anthrax vaccine was used primarily by persons in animal-related industries at risk for occupational exposure.[3,4] In January 1991, the U.S. military used anthrax vaccine to counter the possibility that Iraq would use weaponized anthrax against American troops. Approximately 150,000 American troops received at least one anthrax immunization in 1991.[5] Despite the findings of numerous review panels to the contrary,[6–9] some people still consider the anthrax vaccine to be a possible cause of the array of symptoms commonly referred to as Persian Gulf War illnesses.

In December 1997, the Secretary of Defense announced the Department of Defense plan to immunize all military personnel against anthrax. The program began in March 1998 with an accelerated anthrax immunization program for U.S. personnel deployed in southwest Asia. Since that time, more than 140,000 U.S. Air Force personnel (and more than 508,000 Department of Defense personnel overall) have started the anthrax immunization series.[10] Some people have raised questions regarding the safety of the vaccine, citing cases of unusual adverse events.

The purpose of this study was to use the information in readily available databases to determine whether individuals who received the anthrax vaccine were more likely to seek outpatient care than those who were not immunized.

Materials and Methods

All Air Force medical treatment facility (MTF) visits in the southwest Asia (SWA) theater of operations have been tracked since 1995 using database tracking tools developed by Air Combat Command, such as the Medical Surveillance–Theater and Desert Care 2 programs. A master database of all SWA outpatient encounters is located at Air Combat Command headquarters at Langley Air Force Base, Virginia. We extracted a table from that database containing all medical encounters involving personnel still on active duty in May 1999 (data set 1). The table included all encounters from January 1998 through March 1999. This table represents the study population, all users of outpatient care during deployment to SWA. This approach was intended to avoid the influence of any "healthy deployer" effect that might bias or confound measures of health status. We used information from the medical encounter database rather than a personnel database because the personnel database has a reputation for being unreliable and we could be confident that personnel had deployed if they had a documented SWA medical encounter.

All U.S. Air Force personnel included in data set 1 were matched by Social Security number to the master Ambulatory Data Systems (ADS) file maintained on the Defense Medical Surveillance System computer in Bethesda, Maryland. ADS is

*Air National Guard, Office of the Air Surgeon, 3500 Fetchet Avenue, Andrews Air Force Base, MD 20762.
†Air Combat Command, Surgeon General, 162 Dodd Boulevard, Suite 100, Langley Air Force Base, VA 23665.
‡Anthrax Vaccine Immunization Program Agency, Office of the Surgeon General, 5111 Leesburg Pike (Skyline 5, Suite 401), Falls Church, VA 22041-3258.
§Current address: Headquarters Pacific Air Forces, Office of the Command Surgeon, 25 E Street, Suite D-1, Hickman Air Force Base, HI 96853.
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used to document outpatient medical encounters at all U.S. Air Force medical treatment facilities. A separate International Classification of Diseases, Ninth Revision (ICD-9), diagnosis code is entered for all appropriate diagnoses at each encounter.

All ADS encounters at U.S. Air Force MTFs around the world between January 1, 1998, and March 10, 1999, for the study population were extracted, including the date of the encounter and the ICD-9 code (data set 2). A third table was extracted from the Defense Eligibility Enrollment Registry System (DEERS), in which the master immunization records are maintained for the Air Force. This table matched individuals within data set 1 by Social Security number and included all anthrax immunizations recorded as of March 10, 1999 (data set 3). Finally, a fourth data set was derived from the Air Force Personnel Center database maintained at Randolph Air Force Base, Texas, to gather demographic information on the study population: date of birth, gender, race, and military rank.

We examined the U.S. Air Force MTF ADS data table (data set 2) and excluded all encounters that did not include an ICD-9 code. We excluded all visits for routine examinations or procedures not associated with an adverse health condition (e.g., routine blood testing, normal Papanicolaou smears, vaccinations). We also excluded all repeat occurrences of the same diagnosis code for each individual. We excluded all encounters that occurred before the SWA medical encounter because these would be irrelevant with regard to anthrax immunization given in the SWA theater. The ICD-9 diagnoses were all matched to a description and then grouped according to standard ICD-9 categories.[11] These categories correspond roughly to the physiological systems involved in the disease process (Table I).

We used the anthrax immunization table (data set 3) to code all personnel as either vaccinated or not vaccinated depending on whether individuals had received at least one anthrax immunization. This was our exposure variable. In early 1998, all anthrax immunizations were given in the SWA theater, and only those persons who were going to be in the theater for more than 30 days after immunization were immunized; therefore, not all persons deployed to SWA were immunized. We elected to use a 6-month follow-up period after the first recorded anthrax vaccination to attempt to capture any vaccine-related encounters while not substantially limiting the number of personnel in the study. We did not want to include persons who could contribute less than the 6 person-months of follow-up. Therefore, we included those ADS patient encounters that occurred within the 6-month follow-up period after the SWA encounter.

TABLE I

ICD-9 CATEGORIES WITH NUMERICAL CODES AND REPRESENTATIVE DIAGNOSES WITHIN EACH CATEGORY

Infectious and Parasitic Diseases (001–139): candidiasis, dermatophytosis, herpes simplex, helminthosis, infectious mononucleosis, molluscom contagiosum, pityriasis, scabies, sexually transmitted diseases, streptococcal sore throat, viral exanthemata, varicella, viral disease unspecified, viral enteritis, viral warts
Neoplasms (140–239): benign neoplasms, bone/skin neoplasms, hemangioma, Hodgkin's disease, leiomyoma, lipoma, lymphoma, melanoma, sarcoidosis
Endocrine, Nutritional, and Metabolic Diseases and Immunity Disorders (240–279): diabetic disorder (D/O), electrolyte imbalance, gout, hypercholesterolemia, hyperlipidemia, hypovolemia, obesity, pituitary D/O, thyroid D/O
Diseases of the Blood and Blood-Forming Organs (280–289): anemia, lymphadenitis, thrombocytopenia
Mental Health (290–319): adjustment reaction, alcohol D/O, anxiety D/O, depression, neurotic D/O, psychogenic pain, relationship problems, stress reaction, tension headache, tobacco use D/O
Diseases of the Nervous System and Sense Organs (320–389): astigmatism, carpal tunnel syndrome, conjunctivitis, eustachian tube D/O, eye pain, glaucoma, hearing loss, hematoma, hordeolum, hypermetropia, iridocyclitis, keratitis, migraine, multiple sclerosis, myopia, otitis, retinal D/O, seizure D/O, tinnitus, visual disturbance
Diseases of the Circulatory System (390–459): arrythmias, coronary atherosclerosis, hemorrhoids, hypertension, nevus, valve D/O, varicose veins, vascular disease, venous thromboses
Diseases of the Respiratory System (460–519): asthma, bronchitis, deviated nasal septum, influenza, laryngitis, pharyngitis, pneumonia, rhinitis, sinusitis, strep throat, tonsillitis, upper respiratory tract infection
Diseases of the Digestive System (520–579): constipation, dental D/O, diarrhea, enteritis, esophageal D/O, gastritis, inguinal hernia, irritable colon, noninfectious gastroenteritis, oral aphthae, rectal/anal D/O, sialoadenitis
Diseases of the Genitourinary System (580–629): breast D/O, cervical D/Os, cystitis, female/male genital D/O, hematuria, hydrocoele, incontinence, infertility, menstrual D/O, orchitis/epididymitis, pelvic inflammatory disease, prostatitis, pyelonephritis, urinary tract calculi, urethritis, urinary tract infection, vaginitis
Complications of Pregnancy, Childbirth, and the Puerperium (630–676): hydatidiform mole, spontaneous abortion, threatened abortion
Diseases of the Skin and Subcutaneous Tissue (680–709): acne, alopecia, carbuncle, cellulitis, dermatitis, dyschromia, dyshydrosis, hair D/O, nail D/O, psoriasis, scar, sebaceous cyst, urticaria
Diseases of the Musculoskeletal System and Connective Tissue (710–739): arthritic D/O, backache, bursitis, disc disease, ensethopathy, joint pain, muscle spasm, myalgia/myositis, neuralgia, pain/cramp in limb, plantar fibromatosis, somatic dysfunction, spinal D/O, various specific musculoskeletal D/O
Congenital Anomalies (740–759): congenital heart anomaly, congenital pes planus, undescended testicle
Certain Conditions Originating in the Perinatal Period (760–779): antepartum malpres, newborn integument condition
Symptoms, Signs, and Ill-Defined Conditions (780–799): abdominal pain, abnormal Papanicolaou smear, abnormal weight gain, chest pain, cough, convulsions, dizziness, dysuria, edema, high blood pressure without hypertension, epistaxis, general symptoms, gastrointestinal symptoms, headache, insomnia, lymph node enlargement, malaise and fatigue, nausea and vomiting, nonspecific skin eruption, palpitations, pyrexia of unknown origin, sleep D/O, syncope and collapse, unknown cause morbidity
Injury and Poisoning (800–999): allergy (unspecified), insect bite, toxic effects, various injury diagnoses (laceration, concussion, fracture, wound, burns, etc.)

Our study population now included 4,045 exposed persons, defined as persons having a recorded SWA MTF visit between January 1 and September 10, 1998, and having at least one anthrax immunization recorded in DEERS. We also had 1,133 unexposed persons, defined as persons having a recorded SWA MTF visit between January 1 and September 10, 1998, with no recorded anthrax immunizations in DEERS.

Contrasting these two groups, we calculated the risk ratios with 95% confidence intervals (95% CI) for the outcome of postdeployment outpatient visits using STATA statistical software (Stata Corp., College Station, Texas). Postdeployment outpatient visits were operationally defined as any post-SWA ADS-recorded diagnoses within 6 months of the SWA encounter. We calculated the mean number of unique diagnosis codes per individual having a postdeployment outpatient visit and compared the means for the vaccinated and unvaccinated cohorts using Student's *t* test. We then calculated risk ratios with 95% CI for each of the 17 ICD-9 diagnostic group categories using an ever/never dichotomy. Potential confounders were assessed by evaluating differences in the distribution of demographic variables between vaccinated and unvaccinated cohorts. We stratified the overall diagnosis data based on gender, race, rank, and age to check for interaction. We evaluated race based on four categories as listed in the demographic table: Asian, black, other, and white. Race was unknown in 505 cases, which were also analyzed separately. We divided rank into four categories: junior enlisted (E1–E5), senior enlisted (E6–E9), junior officer (O1–O3), and senior officer (O4–O6). Age was evaluated in 5-year increments. We also examined each of the demographic categories to determine if there were any predictors for any post-SWA ADS-recorded diagnoses based solely on demographic data.

In addition to the broad ICD-9 categories, we also examined the data for specific diagnoses or narrower categories that have been associated anecdotally with anthrax immunization that might have been obscured by the broad groupings. Specifically, we examined diagnoses relating to autoimmune disorders, diabetes, thyroid disorders, arrhythmias, anemia, headache, migraine, infertility, menstrual disorders, dizziness/syncope, hearing loss, tinnitus, allergies, and unexplained illness.

Results

Descriptive epidemiology revealed some significant demographic differences between exposed (anthrax-vaccinated) and unexposed (unvaccinated) groups in this study (Table II). The proportions of men and women did not vary substantially between the groups. However, persons in the 19- to 23-year-old age group, black or white race, and junior enlisted personnel were significantly more likely to have been vaccinated. In contrast, 39- to 43-year-old personnel, junior and senior officers, and persons with no identified race were significantly less likely to be immunized. Therefore, we conducted stratified analyses to ensure that no confounding occurred based on these demographic factors.

The overall relative risk for any ADS-recorded diagnoses within 6 months after the SWA deployment was 0.96 (95% CI = 0.90–1.02). The total number of unique diagnoses for exposed individuals who had a diagnosis was 4,184, with a mean of 2.01 (SD 1.47), and the total number for unexposed persons was 1,302, with a mean of 2.14 (SD 1.66) ($p = 0.06$, *t* test).

We assessed gender, race, rank, and age using stratified analyses to check for confounding. Although female gender, black race, and junior enlisted rank were each found to independently predict the outcome of any post-SWA ADS-recorded diagnoses (with risk ratios of 1.38, 1.14, and 1.17, respectively) (Table III),

TABLE II

DEMOGRAPHIC DISTRIBUTION OF THE STUDY POPULATION

	Vaccinated (*n*)	Not Vaccinated (*n*)	Percent Vaccinated	Percent Not Vaccinated
Gender				
Male	3,390	962	83.8%	85.0%
Female	655	170	16.2%	15.0%
Race				
None specified	255	250	6.3%	22.1%
Asian	73	16	1.8%	1.4%
Black	553	108	13.7%	9.5%
Other	233	48	5.8%	4.2%
White	2,931	711	72.5%	62.8%
Rank				
Junior enlisted	2,081	451	51.4%	39.8%
Senior enlisted	1,643	506	40.6%	44.7%
Junior officer	207	101	5.1%	8.9%
Senior officer	114	75	2.8%	6.6%
Age (years)				
19–23	1,220	254	30.2%	22.4%
24–28	1,080	288	26.7%	25.4%
29–33	696	216	17.2%	19.1%
34–38	709	233	17.5%	20.6%
39–43	262	107	6.5%	9.5%
44+	77	34	1.9%	3.0%

TABLE III

RELATIVE RISK FOR ANY POST-SWA ADS-RECORDED DIAGNOSIS FOR VARIOUS DEMOGRAPHIC CATEGORIES WITHOUT REGARD TO ANTHRAX VACCINATION STATUS

Category	No.	Risk Ratio	95% CI	*p* Value (χ^2 Test)
Gender				
Male (reference)	4,352	1	1	-
Female	825	1.38	1.30–1.46	0.0000
Race				
None specified	505	0.99	0.90–1.09	0.84
Asian	89	1.03	0.85–1.26	0.76
Black	661	1.14	1.06–1.22	0.001
Other	281	0.92	0.81–1.05	0.21
White (reference)	3,642	1	1	-
Rank				
Junior enlisted	2,532	1.17	1.00–1.37	0.04
Senior enlisted	2,149	1.08	0.92–1.26	0.35
Junior officer	308	0.99	0.82–1.20	0.92
Senior officer (reference)	189	1	1	-
Age (years)				
19–23	1,474	1.11	1.02–1.20	0.01
24–28	1,368	1.07	0.98–1.16	0.13
29–33	912	1.03	0.94–1.13	0.52
34–38 (reference)	942	1	1	-
39–43	369	1.09	0.97–1.23	0.14
44+	111	1.05	0.87–1.27	0.62

they were not found to be confounders for the relationship between anthrax immunization and any post-SWA ADS-recorded diagnoses (Table IV). There were no statistically significant associations with the outcome of any postdeployment outpatient visits among any of the subgroups.

The relative risk was calculated for each of the ICD-9 diagnostic group categories along with a 95% CI (Table V). None of the categories showed a statistically significantly increased risk for persons who had received at least one anthrax immunization.

We then assessed the relative risk for the specific diagnoses noted above. Although we found that some of the diagnoses were relatively more frequent in the vaccinated group, many were more frequent in the unvaccinated group (Table VI). The only

TABLE IV

STRATIFIED ANALYSIS OF DATA (EXPOSURE = AT LEAST ONE ANTHRAX VACCINE, OUTCOME = ANY POST-SWA ADS-RECORDED DIAGNOSIS)

Category	No. Vaccinated (n = 4,045)	No. Not Vaccinated (n = 1,133)	Risk Ratio	95% CI	*p* Value (χ^2 Test)
Gender					
Male	3,390	962	0.95	0.88–1.02	0.13
Female	655	170	0.99	0.88–1.12	0.91
Race					
None specified	255	250	1.03	0.86–1.22	0.76
Asian	73	16	1.25	0.69–2.27	0.42
Black	553	108	0.88	0.75–1.02	0.12
Other	233	48	0.77	0.59–1.02	0.09
White	2,931	711	0.96	0.89–1.03	0.27
Rank					
Junior enlisted	2,081	451	0.91	0.83–0.99	0.04
Senior enlisted	1,643	506	0.99	0.89–1.09	0.81
Junior officer	207	101	0.99	0.76–1.27	0.92
Senior officer	114	75	0.83	0.61–1.12	0.22
Age (years)					
19–23	1,220	254	0.98	0.86–1.10	0.71
24–28	1,080	288	0.89	0.79–1.00	0.06
29–33	696	216	0.95	0.82–1.10	0.50
34–38	709	233	1.01	0.87–1.18	0.91
39–43	262	107	1.00	0.81–1.24	0.98
44+	77	34	0.88	0.61–1.28	0.53

TABLE V

RELATIVE RISK FOR ANY POST-SWA ADS-RECORDED DIAGNOSIS IN SPECIFIC ICD-9 CATEGORIES BASED ON ANTHRAX VACCINE STATUS

Diagnostic Group	No. Immunized (n = 4,045)	No. Not Immunized (n = 1,133)	Risk Ratio	95% CI	P Value (χ^2 Test)
One or more diagnoses	2,077	607	0.96	0.90–1.02	0.18
Infectious/parasitic	312	96	0.91	0.73–1.13	0.40
Neoplasms	55	16	0.96	0.55–1.67	0.89
Endocrine/nutritional/metabolic/immunity	75	21	1.00	0.62–1.62	1.00
Blood	8	1	2.24	0.28–17.9	0.43
Mental health	105	38	0.77	0.54–1.12	0.17
Nervous/sensory systems	390	134	0.82	0.68–0.98	0.03
Circulatory	83	25	0.93	0.60–1.45	0.75
Respiratory	553	183	0.85	0.73–0.99	0.03
Digestive	199	54	1.03	0.77–1.38	0.83
Genitourinary	202	49	1.15	0.85–1.57	0.35
Complications of pregnancy	10	6	0.47	0.17–1.28	0.13
Skin and subcutaneous	266	80	0.93	0.73–1.19	0.56
Musculoskeletal	450	134	0.94	0.78–1.13	0.51
Congenital anomalies	9	3	0.84	0.23–3.10	0.79
Prenatal period conditions	2	1	0.56	0.05–6.17	0.63
Ill-defined conditions	297	93	0.89	0.72–1.12	0.33
Injuries and poisoning	457	131	0.98	0.81–1.17	0.80

TABLE VI

INCIDENCE RATES FOR SPECIFIC DIAGNOSES

Diagnosis	Vaccinated (n)	Rate per 10,000	Not Vaccinated (n)	Rate per 10,000	Risk Ratio	95% CI
Autoimmune disease	0	0.0	0	0.0	–	–
Systemic lupus erythematosus	0	0.0	0	0.0	–	–
Thyroid disorder	10	24.7	2	17.7	1.40	0.31–6.38
Diabetes	6	14.8	1	8.8	1.68	0.20–13.9
Arrythmias	12	29.7	3	26.5	1.12	0.32–3.96
Anemia	3	7.4	1	8.8	0.84	0.09–8.07
Headache (unspecified)	40	98.9	15	132.4	0.75	0.41–1.35
Migraine headache	20	49.4	6	53.0	0.93	0.38–2.32
Infertility	13	32.1	2	17.7	1.82	0.41–8.06
Menstrual disorder[a]	23	351.1[a]	6	352.9[a]	0.99	0.41–2.40
Dizziness/syncope	11	27.2	5	44.1	0.62	0.21–1.77
Sleep disorder	10	24.7	1	8.8	2.80	0.36–21.9
Hearing loss	5	12.4	5	44.1	0.28	0.08–0.97
Tinnitus	3	7.4	2	17.7	0.42	0.07–2.51
Allergy	124	306.6	42	370.7	0.83	0.59–1.17
Unexplained illness	43	106.3	13	114.7	0.93	0.50–1.72

[a]Females only.

statistically significant association was that hearing loss was found more frequently in the unvaccinated group.

Discussion

This study had several significant limitations. We were limited to using data already available in several large, linked databases. We had no influence over the accuracy of the data entered into these databases and made no attempt to verify it. Any systematic inaccuracies in these data sets will likely be nondifferential based on the exposure variable of vaccinated/unvaccinated unless data validity varied during the same time interval in which the vaccination policy was introduced. Misclassification of vaccination status was believed to be minimal because automated vaccination records were being used and accuracy was routinely checked because of the high visibility of the program.

Because personnel with recent SWA encounters were more likely to be immunized against anthrax as a result of the chronology of the program, we had to ensure that there was equal opportunity for those individuals to be seen in an Air Force MTF. Therefore, we had to limit the period for post-SWA ADS-recorded diagnoses to 6 months, thus decreasing the total number of diagnoses. Nonetheless, this provides a useful assessment of adverse events manifesting within this interval.

If vaccination led to medical problems and departure from the service within 6 months of vaccination, such people would not be included in this analysis. This situation is unlikely, however,

because generally the process for a medical discharge through the medical evaluation board takes longer than 6 months.

Our results demonstrate several things: (1) SWA-deployed personnel vaccinated against anthrax were no more likely to have a recorded ADS diagnosis during 6 months of observation than those who were not vaccinated; (2) vaccinated persons who did have a postdeployment outpatient visit were no more likely to have more total diagnoses than unvaccinated persons with at least one diagnosis; and (3) anthrax vaccination status was not associated with an increased rate of ambulatory visits for any of the 17 ICD-9 diagnostic categories or for any of the 16 specific diagnoses evaluated.

Age was not a predictor for any postdeployment outpatient visits. We had expected the risk for an outpatient diagnosis to increase with increasing age, but that was not found in this population of personnel returning from SWA. As in other studies showing that women seek health care more often than men,[12] women in this population were more likely to have at least one post-SWA ADS-recorded diagnosis than men. The findings that junior enlisted personnel and African-American personnel are more likely to have an ADS diagnosis is interesting but would have to be explored more closely using a different study design.

This study was undertaken to provide a prompt answer using existing large, linked databases to the question, does anthrax immunization cause adverse reactions that are treated on an outpatient basis over a 6-month interval? We have shown that personnel immunized against anthrax do not have a greater risk of being diagnosed with a disorder at an Air Force MTF than similar unvaccinated personnel. This is true at the aggregate level for each of 17 specific categories of disease and for specific disease entities such as autoimmune disorders and unexplained illness diagnoses that have been the focus of concern among the public.

We found no indication of an increased propensity for personnel immunized against anthrax to seek medical care after immunization beyond what is expected in their unvaccinated peers. In fact, we found that persons who have been immunized have virtually the same medical problems as those that have not been immunized. Numerous studies are currently under way that use much larger populations and follow personnel for longer periods of time (J.G., unpublished data).

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