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Anthrax vaccine and Gulf War illness symptoms in Captain Jean Tanner's Dover Air Force Base survey

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Abstract

Air Force Captain Jean Tanner surveyed 252 members of her unit at Dover Air Force Base in 2000 to attempt to study the unusual symptoms being reported by a large number of her unit members, symptoms she believed to be related to their anthrax vaccinations. Her data are evaluated in terms of classifications for Gulf War illness used by the Centers for Disease Control (CDC) and by Steele (2000). Even assuming that her non-respondents had no symptoms whatsoever, nearly nineteen percent of the unit would have been classified as having Gulf War illness by the CDC definition. Levels of illness were associated with outcomes, including seeking treatment, disability, submission of vaccine reaction reports, and exemption from further anthrax vaccinations. Had Tanner used even relatively small control groups of unvaccinated subjects, it is likely she would have detected significant differences between vaccinated and unvaccinated subjects, unless a third factor, such as large scale spraying of the base with insecticide, were responsible for symptoms observed in both groups. The results cast doubt on the safety of at least the lots of anthrax vaccine that were used at Dover Air Force Base at that time.

Keywords: Anthrax vaccine, Gulf War illness, Dover Air Force Base

1. Background

Concerns regarding the long-term safety of the current anthrax vaccine have been raised frequently, as discussed elsewhere [1], despite a generally favorable review by a committee of the Institute of Medicine [2]. As early as May 1999, Colonel Renata Engler had raised the possibility of an active duty community (Dover Air Force Base) at which more than ten and perhaps as many as 25 service members had been affected with a Gulf War illness "like" complex of symptoms that were perceived by the service members as having developed a short time after some of their inoculations with the anthrax vaccine [3]. Between May 5th and 11th in 1999, the 436th Airlift Wing Commander, Colonel Felix M. Grieder suspended the vaccinations because of his concerns for the welfare of his unit's members [4]. U.S. Air Force Captain Jean Tanner and others also had concerns regarding what seemed to be a high level of systemic reactions to the anthrax vaccine administered at Dover Air Force Base in 1998-1999. This led to her independently conducting an unofficial survey of her own unit, the 9th Airlift Squadron The Institute of Medicine text addressed Tanner's study, but gave it little weight because it was not clear when the symptoms had occurred, and out of concern that selection effects in responding may have led to overestimates of the prevalence of symptoms [2:151-2].

2. Methodology

In January 2000, Captain Tanner sent a survey along with a cover letter to the home addresses of 265 members of her unit, excluding those members known to have not yet received the anthrax vaccine. Several of her surveys were returned for incorrect addresses and two were not included because the respondents had not had anthrax vaccinations, but 139 (52.5% of 265) members, including at least nine female service members, returned complete surveys while 113 did not, though their addresses were apparently correct. Subsequently, a copy of her survey, her raw data, a description of her study, and a list of the anecdotal comments of surveyed members have been posted on the Web (available for public study at www.anthraxvaccine.org). The surveyed unit members reported on the number of anthrax shots they had received, whether their symptoms disappeared within a few days after their inoculations, if they had been given other logical explanations for their symptoms, if they had sought treatment at the flight surgeon's clinic, if they had filled out a vaccine reaction (VAERs) report, if they had missed more than a day of duty due to the problem, if they had not returned to duty because of the problem, as well as whether or not they had experienced each of 16 specific symptoms. Captain Tanner's data includes a classification of the symptoms as "systemic" if they met military criteria for a systemic reaction to the vaccine. However, the symptoms were further reclassified into both the Centers of Disease Control (CDC) definition of Gulf War illness and Dr. Lea Steele's [5] more narrow definition of Gulf War illness by examining each case individually.

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3. Results

While 32.1% of the 252 potential subjects were classified as having systemic reactions to the vaccine, 18.7% met the CDC and 6.0% met Steele's criteria for symptoms of Gulf War illness. Concerns of the IOM [2] about selection effects are controlled by using all 252 subjects as the denominator for calculating percentages of Gulf War illness symptom clusters; by using all 252 subjects, a conservative estimate is obtained because it is assumed, probably incorrectly, that none of the non-respondents had experienced any Gulf War illness symptoms at any time. Table 1 indicates how the seriousness of the symptoms tended to increase the apparent consequences of those symptoms. Only six members (4.4% of 136 who provided data) who responded indicated that their symptoms disappeared within a few days of their inoculations. Only one of the 47 members classified by CDC's definition for Gulf War illness reported quick remission of symptoms while none of the 15 members classified by Steele's definition did so; that result counters the IOM's [2] concerns about uncertainty of the timing of symptoms – many of the symptom clusters that did not resolve themselves immediately were indeed very similar to Gulf War illness, which has persisted over long periods of time among veterans of the first Persian Gulf War.

4. Limitations

However, Tanner did not obtain a control group of service members who had never had any anthrax vaccine. Over 88% of her members reported having had four or more anthrax vaccinations, leaving very few members who had even had only one (1.5%) or two (1.5%) anthrax vaccinations. If she had obtained a control group of unvaccinated subjects who had not experienced symptoms, how large would such a group have had to have been in order to yield a statistically significant result? Using 252 subjects as the experimental group, it would only take 18 members (6.7% of the new total of 270 members, including 18 from the control group) in a control group (no vaccine, no illness by CDC definition) to achieve a statistically significant ($p < .05$) difference with a two-sided chi-square test ($df = 1$). Using Steele's more conservative definition, it would have taken a control group of 62 (19.7% of the total number of subjects including the new 62 members) members to achieve statistical significance ($p < .05$). In other words, the apparent impact of the anthrax vaccination is substantial enough that relatively small control groups would yield statistical significance.

5. Discussion

If the unit members surveyed by Tanner were reporting unrelated, random symptoms it is unlikely that those symptoms would have been classifiable into three levels of severity, two of which were related to Gulf War illness, with higher levels of severity corresponding closely to the variety of outcomes shown in Table 1. While recall bias is a potential issue with surveys conducted years after exposures to harmful factors, Tanner's study was conducted soon after members of her unit began reporting symptoms. The study was assessed conservatively on the unlikely assumption that those who did not respond had experienced no symptoms whatsoever. Had even a small control group been used in Tanner's study, it is quite likely that a significant relationship between anthrax vaccination status and outcomes would have been observed (unless, of course, those who had not been vaccinated were also experiencing the same level of symptoms as reported by Tanner's subjects). The possibility remains, of course, that some other toxic exposure may have occurred at Dover Air Force Base at that time (e.g., large scale spraying of the base with insecticide) which actually led to the symptoms reported, with anthrax vaccination having the misfortune of concurrent administration with that other exposure. More likely, in the author's opinion, is that at least the lots of anthrax vaccine used at Dover Air Force Base at that time were problematic in some way – not made properly, not stored in transit properly, not administered properly, or perhaps contaminated in some way. That possibility could be refuted, of course, by follow-up studies with members of Tanner's unit as compared to cohorts of service members not vaccinated, or by a careful reanalysis of the particular lots of vaccine used at that time.

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Table 1. Percentages of apparent consequences of Anthrax Vaccine as a function of the seriousness of post-vaccination symptoms.

Outcomes	Percentage seriousness of symptoms[a] A	B	C
Symptoms disappeared in a few days	7.6[b] (0.0)*	2.1 (5.6)	0.0 (5.0)
Member sought treatment at military clinic	44.4 (8.6)**	38.3 (25.0)	66.7 (25.0)**
VAERS report filed	19.8 (1.7)**	25.5 (5.4)**	46.7 (8.1)**
Missed more than one day of duty	28.4 (1.7)**	34.0 (8.7)**	60.0 (12.1)**
Not yet returned to duty	11.1 (1.7)*	14.9 (3.3)*	33.3 (4.0)**
Excused from further anthrax vaccinations	8.6 (0.0)*	12.8 (1.1)*	26.7 (2.4)**

[a]A = Classified as having had apparent systemic reactions to the vaccine; B = Classified as having Gulf War illness symptoms by CDC definition; C = classified as having Gulf War illness symptoms by Steele [5] definition.

[b]Percentages were obtained from crosstabulations of each symptom status with each outcome, assessing the relative percentage of those with or without the symptoms who reported each outcome. For example, 66.7% of those meeting Steele's criteria for Gulf War illness reported that they had sought treatment compared to 25.0% of those not meeting her criteria; likewise, 44.4% of those who reported systemic reactions also said they had visited a medical clinic for treatment compared to 8.6% of those who did not report systemic reactions. Pearson chi-square tests (degrees of freedom, df = 1) were used to compare the percentages of those who experienced various outcomes as a function of their symptom classification.

* $p < 0.05$
** $p < 0.01$

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