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Gonorrhea Vaccine Not Protective

By Nancy Tomich

WASHINGTON—Army researchers here are beginning the detailed process of determining why a vaccine developed to protect against gonorrhea infection worked so poorly.

The vaccine, tested earlier this year in a field trial among U.S. military personnel stationed in Korea, "clearly was not significantly protective," Col. Edmund Tramont, MC, USA, of Walter Reed Army Institute of Research, related.

Dr. Tramont and his colleagues brought back 30,000 specimens taken from 3,252 volunteers and from other military personnel who were seen by the study team for comparison purposes.

These specimens, he said, have been catalogued and filed and are ready to be checked for antibody response levels.



In addition, 1,000 organism specimens must be tested for antigenic variations.

The raw data, however, leave no doubt that the vaccine, as it currently is configured and administered, "is not protective enough to go to the field," Dr. Tramont said.

There earlier had been some concern that statistically significant results could not be obtained because the trial's volunteer rate was not as high as researchers had hoped (it was only 64 per cent of the level envisioned in the protocol). However, the raw data so clearly indicate the vaccine did not confer sufficient protection that those concerns do not come into play any more, another source said.

"Where we go from here will depend on what the antibody results tell us," Dr. Tramont related.

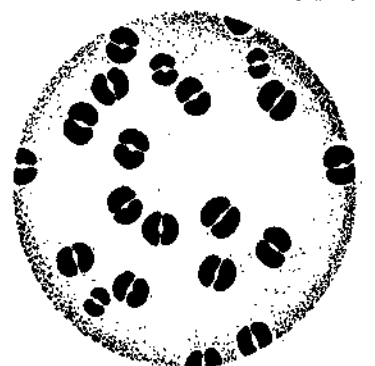
There are several possible explanations for the vaccine's failure to confer protection that have to be examined, he said.

One is whether the vaccine produced an antibody response that in fact should have been protective. If it did, and if studies show exposure was to the correct serotype, then there may be something wrong with the theory behind the vaccine itself.

The vaccine, developed jointly by researchers at WRAIR and the University of Pittsburgh, is the first one aimed at a local infection.

If the antibody response is low, however, then there must be something

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Neisseria gonorrhoea

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Vietnam Data Sought

VA Concludes Twins Study Feasible

By Terry Jemison

WASHINGTON—Researchers planning to compare sets of identical twins to consider health effects of Vietnam service have concluded there are more than enough pairs to get the study going and

have received approval to start finding them.

If both twins were in the military but only one brother served in Vietnam, researchers hope to determine if there are statistically significant differences between the two that would suggest health effects peculiar to the Vietnam jungle and combat environment itself.

Though "Vietnam service" is the risk factor of primary interest, agent orange exposure and post-traumatic stress disorder experiences also will be examined.

Both dizygotic and monozygotic (identical) twins would be involved in a morbidity and mortality analysis, with a five- to six-day battery of physical examinations for a small subgroup of the identical twins.



—U.S. Medicine photo

Dr. Seth Eisen, who will conduct the twins study, found the universe of potential subjects to be adequate.

DoD Develops Standardized THC Cut-Off

By Judy E. Fox

WASHINGTON—Standardized minimum requirements for confirming urine samples which previously tested positive for the presence of marijuana are being developed by the Department of Defense for use by all three military services.

The requirements are another step in the DoD effort to standardize the military's drug abuse testing procedures.

Thoracic Surgeons' Report: 'Questions' At Wilford Hall

WASHINGTON—A report issued by the Society of Thoracic Surgeons concludes there were some procedures performed by a cardiac surgeon at Wilford Hall Air Force Medical Center in which his technique was "questionable."

The report was prepared by the society under contract to the Air Force in an attempt to elucidate the situation at Wilford Hall during a time when Dr. William Stanford, then chief of cardiothoracic surgery, was criticized by some staff members as being "rough" in his surgical techniques. The staff members also charged that Dr. Stanford's patient mortality rate was excessively high and his graft patency rate excessively low.



They are of particular interest to researchers because they are genetically identical and more likely to have shared the same environment through the

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The carefully worded Thoracic Surgeons report, obtained by U.S. MEDICINE through a Freedom of Information Act request, says for certain procedures Dr. Stanford's mortality rate and results appear "questionable." For others, however, Dr. Stanford's results were acceptable, it states.

The report was submitted by the Society of Thoracic Surgeons to the Air Force in April. In July a supplement to the report, responding to questions raised by the Air Force inspector general about the original report, also was submitted.

A special committee was appointed

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Air Controller Stress Criteria Urged

WASHINGTON—The Federal Aviation Administration, which closed several of

the agency is how it can place more emphasis on monitoring and controlling

Yet the agency has cut the number of

VA Will Study Twins For Vietnam 'Effects'

(Continued from page 1)

developmental years than other pairs of individuals.

Primary investigator Dr. Seth Eisen of the St. Louis VA hospital, announcing the results of a feasibility analysis conducted to see if the study could be done, determined there are probably 17,000 twin pairs in the country that meet the criteria of military service with one a Vietnam veteran and the other not.

He and his associates concluded that about half of the pairs are monozygotic, and suitable for the "intensive health assessment" phase of physical examinations.

Dr. Eisen, briefing VA agent orange advisors, said his team and collaborators at the Hines, Ill., VA hospital cooperative studies program have received approval to begin identifying twins.

A formal protocol has not been finished, but the study hopefully will begin next year, he said. The health assessments could take 18 months, with data analysis requiring an additional six to 12 months, he predicted.

Dr. Eisen said investigators will not limit their interest to the pairs where one served in Vietnam while the other brother served at a stateside base, because the statistical power will be enhanced by comparing two other groups: Vietnam veterans compared to brothers who also saw Vietnam service as well as pairs where both brothers were in the military but neither served in Vietnam.

For example, if the researchers find that in the "non-Vietnam/Vietnam set" the Vietnam veterans have four times the risk of diabetes as their brothers, the fourfold risk elevation should similarly be reflected in both subjects throughout the Vietnam/Vietnam set while the rate of diabetes should be noticeably low in the both subjects of each non-Vietnam/non-Vietnam set.

Such tripartite analyses should offer "powerful support of the non-Vietnam/Vietnam twin pair findings," Dr. Eisen said.

While about 10,000 pairs would be used in the morbidity and mortality analysis, only 500 pairs would undergo the intensive physical examination phase, he told members of the VA advisory committee on agent orange.

One of the advisors, Dr. Marion Moses of Johns Hopkins University,

voiced concern about the ability to compare twins with important differences—for example if one is a heavy smoker and the other is not.

Dr. Richard A. Hodder of the Walter Reed Army Institute of Research added that one of the twins may have a "profile" of characteristics that kept him from Vietnam service.

Dr. Eisen said the life history prior to induction will be reviewed, but investigators hope "to minimize exclusion criteria" for study subjects.

State birth certificates will be reviewed to find twin pairs, who will be traced to determine if they had military experience. Upon determination of the Vietnam experience, they will be assigned to appropriate subgroups.

Dr. Eisen's announcement that researchers had determined that an adequate universe of potential subjects exists to continue the efforts was based on epidemiologic analysis of the birth years from 1939 to 1953.

During that time, 25 million males were born, and the epidemiologic data suggest that includes 400,000 twins—half monozygotic and half dizygotic. In about half of the pairs, neither brother will have had military service.

Of about 46,000 twin pairs who both had military service—the first study criterion—initial indications are that for 26 per cent, neither served in Vietnam; in 37 per cent of the cases, one did; for 23 per cent, both did; and for 14 per cent, that has not been determined.

He said the twins study is a good opportunity for VA to conduct research that the public will accept because the hypothesis is simple and the idea of comparing twins is interesting.

VA was pressured to give up its major epidemiological study of ground troops thought exposed to agent orange ostensibly because of congressional concern about the believability of research sponsored by the VA, which could face millions of dollars of compensation costs if scientists advise policymakers there is a link between diseases and service.

In other agent orange developments, the week the advisors met, the American Chemical Society was told that a registry of veterans who have undergone special VA agent orange examinations does not support the thesis there is unusual long-term morbidity associated with Vietnam service or agent orange exposure.

FAA Examines CAM

By Judy E. Fox

WASHINGTON—There are strong indications that the research branch of the Federal Aviation Administration's Civil Aeromedical Institute (CAMI) will be

Primary Site (ICD)	Number of Cases	Percent Distribution	
		Registry	SEER
Buccal Cavity and Pharynx (140-149)	46	7.9*	14.5
Digestive System (150-159)	68	11.6	12.2
Respiratory System (160-169)	60	10.3	8.5
Bone Tissue (171)	11	1.9	2.6
Skin (172)†	51	9.1	11.7
Male Genital System/Urinary System (185, 186, 187, 188, 189)	112	19.2	22.1
Lymphomas (200, 201, 202)	117	20.0*	15.0
Multiple Myeloma (203)	7	1.2	10.4
Leukemia (204-208)	30	5.1	5.0
Others and ill-defined sites	60	10.7	17.2
TOTAL	584	100	100

* SEER (Surveillance Epidemiology and Results): Percent distribution of malignant neoplasm cases diagnosed in 1973-77 by primary site, based on 39,499 all cases, males and all areas excluding Puerto Rico.

† Excluding basal and squamous carcinomas.

* The 95% confidence limits for differences in proportions do not include zero.

Data presented at chemical association meeting show number and per cent distribution of selected malignant neoplasm cases among 84,456 veterans recorded in the Agent Orange Registry and comparison to a reference population.

However, the registry is composed of self-referred veterans who have presented at VA hospitals concerned about the health effects of agent orange.

A senior researcher for the VA medical department's agent orange program office, Dr. Alvin L. Young, presented data from the registry, which involves more than 110,000 veterans examined by VA physicians. He described the analysis of data now complete for 85,000 cases.

Following media coverage of the data, the American Legion circulated a news release criticizing Dr. Young's statements as "totally irresponsible and misleading."

The Legion criticized Dr. Young because "he apparently did not clarify that his conclusions were not based on any study per se."

Dr. Young categorically denied the charge in the Legion's press release. "I clearly stated this was *surveillance* of veterans who were a self-selected group of men," he told U.S. MEDICINE.

In fact, he noted, THE NEW YORK TIMES story on the chemical society data reported that Dr. Young had said that his report on the registry, which it called a study, was not a true epidemiologic study.

In the paper, "Evaluation of Veterans for Agent Orange Exposure," co-authored by M. R. Flicker, Dr. Young reported that only three-fourths of the 85,000 veterans complained of symptoms, most frequently dermatologic and psychologic.

Other symptoms reported in at least 10 per cent of registered patients were headaches, peripheral neuropathy, asthenia and gastrointestinal disorder.

The majority of symptoms, the paper reported, "bear no correlation to the known toxicology of herbicide orange; in addition, no increased incidence of malignancy (has) been observed in this population, which, by virtue of its self-selected nature, may have been expected to exhibit artificially higher than baseline rates in the general population."

II Research Branch

But, he asserted, the committee did not recommend one of the three over the others—that decision will be made by FAA administrator Helms.

"The team was unable to come up with a consensus as to which alternative to choose but we all agreed that any of the three would be better than the way it is run now," Smith emphasized.

Another FAA source expressed his concern that if medical research becomes