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This OTA Staff Memorandum has  
neither been reviewed nor approved  
by the Technology Assessment Board.

OTA Comments

Project Ranch Hand II Mortality Update - 1984

In 1983, the Air Force released the first results from its study of mortality among officers and enlisted men who served in Operation Ranch Hand. At that time, there had been 50 deaths among Ranch Hands and 250 among the comparisons. The 1984 update reports 4 additional deaths among Ranch Hands and 15 additional deaths among comparisons to bring the total number of deaths to 54 and 265 in the two groups, as shown on the table below.

The most important numbers in the table are in the columns "percentage dead," which show that the overall death rates in the two populations are identical, 4.3 percent. There are some small differences seen in comparing subunits of the two populations. For instance, non-black Ranch Hand pilots, navigators, flight engineers, and black "other enlisted men" have lower mortality rates than their comparison group counterparts. In contrast, non-black Ranch Hand "other officers" and "other enlisted men" fared poorer than the comparisons.

Death Rates of Ranch Hands and of a Comparison Group of  
Air Force Personnel Unexposed to Agent Orange

Comparisons		Ranch Hands					
Race	Occupation	No. of men	No. dead	Percentage dead	No. of men	No. dead	Percentage dead
Non-black <sup>1</sup>	Pilot <sup>2</sup>	350	12	3.4	1740	74	4.3
	Navigator <sup>2</sup>	82	2	2.4	390	14	3.6
	Other officer	25	1	4.0	123	3	2.4
	Flight engineer <sup>3</sup>	191	7	3.7	935	51	5.5
	Other enlisted man	532	28	5.3	2628	101	3.8
Black	Pilot	6	0	0	13	0	0
	Navigator	2	0	0	10	0	0
	Other officer	1	0	0	2	0	0
	Flight engineer	15	2	1.3	75	10	1.3
	Other enlisted man	<u>52</u>	<u>2</u>	<u>3.8</u>	<u>255</u>	<u>12</u>	<u>4.7</u>
Total		1256	54	4.3	6171	265	4.3

1. includes Caucasian, Asiatic, and Mexican men

2. officer

3. enlisted man

Source: adapted from Project Ranch Hand II Mortality Update - 1984, p.2.

When the data in the table are subjected to statistical analysis, none of the small differences seen between the Ranch Hands and comparisons is statistically significant. For instance, the percentage of dead Ranch Hand pilots is 3.4; that of comparison pilots, 4.3. While the percentages differ, they are based on such small numbers that the differences could be due to chance. For instance, if there were only 3 more deaths among Ranch Hand pilots, bringing the total to 15, the

percentage of deaths in the two populations would be identical. Statistical tests are used to estimate the likelihood that observed differences are not due to chance. According to those tests, the difference between 3.4 and 4.3 percent might very well be due to chance, and not to a true difference between death rates in the two groups. The best summation of those data is to say that there is no evidence for any real difference.

The Air Force also compared the death rates of Ranch Hand officers and enlisted men to the rates seen in active duty and retired Air Force personnel, the general male population, and civil servants. Only active duty Air Force personnel have a lower death rate than Ranch Hands, and that difference is readily explained because annual Air Force physical examinations weed out men with health problems. The remaining comparisons argue against excess mortality being associated with Operation Ranch Hand and exposure to Agent Orange.

As shown in the table below, the death rate from all causes in Ranch Hands was the same as the rate in comparisons. However, death rates from specific causes differ in the two populations. Rates calculated on the basis of the small numbers of deaths that have so far occurred are subject to fluctuations because the addition of one or two deaths to the number in either population can change the rate dramatically. Nevertheless, the comparison of rates provides additional information that Ranch Hands are not dying at unexpectedly high rates from specific causes.

Although Agent Orange has been suggested as the cause of many different diseases, it is probably most often associated with cancer. Therefore, one finding of great interest is that the death rate from malignant neoplasms (cancers) in Ranch Hands was 68 percent the rate seen in the comparison officers and enlisted men.

People who are convinced that Agent Orange causes cancer will not accept this finding as showing that Agent Orange doesn't cause cancer. Instead, they may suggest 20 to 30 years often pass between exposure to a cancer-causing substance and the appearance of the disease and that 20 years have not passed since heavy spraying of Agent Orange began. Therefore there is a possibility that the years to come may see an increase in cancer mortality related to Agent Orange. It is impossible to rule that out, but the absence of any current cancer excess is reassuring.

There are other differences in causes of death between Ranch Hands and comparisons; in particular the death rate from digestive system diseases was higher in Ranch Hands. When the Air Force published its first report of mortality, the difference was greater: 5 in the Ranch Hands and 11 in the comparisons. If the difference is due to chance, we expect that it will continue to narrow as more deaths occur in the years to come. For the time being, it is important to note that neither the lower cancer death rate nor the higher digestive system death rate is statistically significant. Proportionally more Ranch Hands were murdered, but it is difficult to understand how exposure to Agent Orange could be responsible for homicides; that statistically non-significant excess can be ignored. All in all, examination of cause specific death

rates does not suggest that Agent Orange exposure of Ranch Hands is causing an increase in death rates from particular diseases.

Scientifically, the Ranch Hand results are extremely important, coming from a careful study of a population known to have been exposed to Agent Orange. The comparison of their mortality rates to other Air Force personnel indicates that their exposure has not contributed to unusual causes or numbers of deaths.



Comparison of Specific Causes of Death Observed Among  
Ranch Hands and Comparison Air Force Officers and Enlisted Men

<u>Rates</u> <sup>1</sup>	Number of Deaths		<u>Ranch Hands' Death</u>
	in 1,256	in 6,171	Comparisons' Death Rates
Cause of Death	Ranch Hands	Comparisons	
Accidental	19	94	94%
Circulatory disorder	17	75	104%
Malignant neoplasms	6	43	68%
Digestive system disorder	5	13	192%
Suicide	3	16	94%
Homicide	2	4	250%
Respiratory disorder	0 <sup>3</sup>	5	
Parasitic infections	0	4	
Uncertain neoplasms	0	2	
Endocrine system disorder	1	1	
Genitourinary disorder	0	3	
Mental disorder	0	1	
Nervous system disorder	0	2	
Ill defined	<u>1</u>	<u>2</u>	
All causes	54	265	100%

1. death rates are equivalent to number of deaths divided by the number of men in the population. The comparison of death rates was made by dividing the Ranch Hands' death rate by the comparisons' death rate and multiplying by 100 to express the result as a percentage.

2. in this table, 100% means that the death rates in Ranch Hands and Comparisons were identical. Less than 100% means that the death rate from that particular cause was lower in Ranch Hands than in comparisons. Greater than 100% means that the death rate from that particular cause was greater in Ranch Hands than in comparisons.

3. rates were not calculated for causes in which the number of Ranch Hand deaths was 0 or 1.

Source: adapted from Project Ranch Hand II Mortality Update - 1984, p. 14.

Mortality Among Vietnam Veterans in Massachusetts, 1972-1983

The Massachusetts Department of Health conducted a study (report dated January 25, 1985) examining deaths that occurred from 1972 through 1983 among Vietnam veterans who were residents of Massachusetts.

According to the report:

This study was motivated by a concern that Vietnam veterans may be at increased risk of dying from violent, preventable causes, such as motor vehicle accidents, homicide, and suicide.

The investigators, Michael D. Kogan and Richard D. Clapp, did find excesses for deaths from "external causes," which includes all deaths not caused by disease. There were also some unexpected findings: excess deaths from kidney cancer, stroke, and of greatest interest, a large excess of deaths from connective tissue cancers, also called soft tissue sarcomas. The soft tissue sarcoma finding was, statistically, the strongest result of the study, though it was based on only 9 deaths among Vietnam veterans. The study has come to national attention largely because of that finding, providing the first corroborative evidence for a possible link between phenoxyacid herbicides and soft tissue sarcomas that has been shown heretofore only in studies of Swedish lumberjacks published in the late 1970s. Many other studies, including a study of Vietnam veteran deaths in New York State, have failed to find such an excess.

Based on our reading of the study, and on comments from the OTA Agent Orange Advisory Panel, the study appears to be well-designed to take advantage of death certificate information and of a list of Massachusetts veterans that discriminates between Vietnam veterans and veterans who did not serve in Vietnam. While the investigators used the information effectively, there are limitations inherent in the data sources that limit the strength of conclusions that can be drawn from this study. The investigators have pointed out the weaknesses and have not overstated their findings. They have plans to pursue the soft tissue sarcoma result using additional data sources. In addition, at least one other state, West Virginia, is conducting a study similar to the Massachusetts study.

The Massachusetts investigators, having no information about exposure, have not claimed any link of soft tissue sarcomas in Vietnam veterans and exposure to Agent Orange or dioxin. It is that possible connection, however, that has spawned intense interest in this study. The interest within the research community is sufficient, we believe, that other groups will be following up with similar veterans' mortality studies. We will, of course, keep abreast of the overall research effort, in the normal course of our Agent Orange and Vietnam Experience monitoring activities.

Kogan and Clapp used a "proportionate mortality ratio" (PMR) approach, which compares the proportions of deaths from specific causes in one group, with the proportions for those same causes of death in a comparison group. This study used two Massachusetts populations groups for comparison: 1) veterans who did not serve in Vietnam; and 2) non-veterans. Since most of the Vietnam veterans in Massachusetts are white males, the comparison groups were restricted to white males.

For all statistically significant findings, the investigators performed an additional analysis, a "standardized mortality odds ratio," which corrects some bias inherent in PMR analysis. The soft tissue sarcoma finding remains strongly significant.

Veterans were identified through a list of individuals who applied for and received a "military service bonus," from a state program similar to programs in other states, consisting of a one-time offer of money. Veterans who served for at least 6 months between July 1, 1958 and April 1, 1973, were eligible. Veterans who served in Vietnam were entitled to \$300, those who did not, \$200.

Both major data sources -- death certificates and the veterans bonus list -- are subject to certain biases, which may influence the outcome of the study. The reliability of information on death certificates is known to vary tremendously, often in unpredictable ways. When checked against hospital records, the cause of death is often misspecified, underlying causes often are not recorded, etc. In terms of this study, bias could be introduced if there were some subtle, systematic differences in the way diseases are diagnosed and death certificates filled out for Vietnam veterans compared with other men. For instance, because of the concern that soft tissue sarcomas might be related to dioxin exposure, it could be that a physician might be more inclined toward that diagnosis in ambiguous cases when the patient is a Vietnam veteran than when he is not. We have no way of evaluating the possibility of this type of bias in the Massachusetts study.

The veterans bonus list is also subject to bias. An estimated 95% of those meeting the criteria for military service received the bonus, according to the report. These individuals were self-selected, however, since it was necessary to apply for the bonus to receive it. If those applying were not representative of the total Massachusetts veteran population, a bias could be introduced, which could affect the study findings. Because such a large percentage of those eligible applied, we do not necessarily believe this to be a serious concern, though we do not know the details of how the 95% estimate was arrived at.

Taking into consideration all the possible limitations of the Massachusetts study, it still appears unlikely that chance or bias can account for the large excess of soft tissue sarcoma deaths. Whether the excess is causally associated with Vietnam service remains an open question, however. We are confident that the results of this study have given a stimulus to other groups to investigate the question of soft tissue sarcomas among Vietnam veterans, adding to an already busy agenda in soft tissue sarcoma research. At present, scientific curiosity coupled with a politically important issue is driving the system appropriately.

Congress of the United States

JOHN H. GIBBONS  
DIRECTOR

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MAR 21 1985

The Honorable G. V. Montgomery  
Chairman  
Committee on Veterans' Affairs  
United States House of Representatives  
Washington, D.C. 20515

Dear Mr. Chairman:

As requested in your letter of November 7, 1984, OTA has reviewed the protocol for the "Vietnam Experience Twin Study II" (VETS II). With expert guidance from OTA's Agent Orange Advisory Panel, which considered this subject on March 1, our opinion is that the study as designed should not be undertaken. At the same time we urge that the project known as "VETS I" continue to be given full support from the Veterans Administration and other government agencies.

VETS I, the Vietnam Era Twin Study, involves setting up a registry of about 12,000 twin pairs who served in the military during the Vietnam era, and gathering information about them, including health status, through a mailed questionnaire. VETS I is being carried out under contract to the Medical Follow-up Agency of the National Research Council (NRC). The task of identifying the twin pairs and getting current addresses for them is expected to be complete in fall 1986. During 1985 there will be a pretest of the questionnaire survey, which has been subcontracted to NORC, a survey research center at the University of Chicago. Results of the entire questionnaire survey are expected after the registry is complete. The survey questions broadly cover physical and mental health, as well as collecting demographic information. The registry, like a similar registry of World War II twins, will be available as a resource to the research community for a wide range of studies, not limited to military experience.

The plan for VETS II was to study the effects of the Vietnam Experience using identical twins who served in the military during the Vietnam era. A secondary objective was to study the effect of Agent Orange on Vietnam veterans. Comparisons would be made among 1) a group of twin pairs both of whom went to Vietnam; 2) a group in which one twin went to Vietnam and the other served elsewhere; and 3) a group in which both twins served outside Vietnam.

OTA considered the Vietnam experience and Agent Orange components separately, to determine if possibly one but not the other should be undertaken at this time. The Agent Orange component, involving a total of 130 twin pairs, and accounting for a large portion of the study budget, has two major flaws. First, the sample size is too small to detect any but very

common illnesses or minor differences in laboratory test measurements that are of no known clinical importance, now or in the future. There is a very low probability that such a young population will be exhibiting important illnesses at high frequencies. If Agent Orange is causing adverse health consequences in those exposed to it, this study would be extremely unlikely to detect them. The second problem is that there is currently no feasible method of determining Agent Orange exposure for the individuals selected for this study, and we are doubtful that a reliable method can be developed.

The Vietnam Experience portion of the study is largely a "fishing expedition." No strong hypotheses are being tested. Instead, the strategy is to collect a large amount of information, mainly about the psychological status of the individuals, and see if any patterns emerge. This approach is similar to that of CDC's Vietnam Experience Study, a study that includes 12,000 men: questionnaire examination of 6,000 Vietnam veterans and 6,000 Vietnam-era veterans who did not serve in Vietnam; and physical examination of a random sample of 2,000 of each group. There is considerable overlap between the CDC study and the VETS II study design, but the CDC study is the more powerful, despite the unique control offered by using identical twins. While it is not unusual for several studies to test the same hypothesis, and in fact results from multiple studies can strengthen the findings, it is not a good use of resources to conduct simultaneously several large "fishing expeditions." At some point the information from such studies should be used to generate specific hypotheses that can be appropriately tested in focused investigations.

OTA does not suggest closing the door to twin studies. They may play an important role when there are hypotheses to test, and may be particularly useful in the area of Post Traumatic Stress Disorder (PTSD). The CDC Vietnam Experience Study has been mentioned as one source of hypothesis-generating information. The other important sources are VETS I and the PTSD Needs Assessment. The PTSD Needs Assessment is a legislatively mandated activity being carried out under contract to the Veterans Administration. Its objectives are to better define the diagnosis of PTSD, and to determine the extent of PTSD in the Vietnam veteran population so health care resource needs can be estimated.

OTA strongly urges that a formal hypothesis-generating exercise be conducted when the results of the VETS I questionnaire become available. At that time there will also be the opportunity to consider additional information from other studies. Such an exercise could include presentation of the data to a large group of researchers, including both those who might be interested in conducting a study and experts who could help identify study possibilities. The OTA Agent Orange Advisory Panel is willing to participate in that activity at the appropriate time. To assure that the information from VETS I becomes available as quickly as possible, it is important that the NRC receive the cooperation it requires from federal agencies. We understand that there were some snags in getting information about identifying and locating twins, which may have impeded setting up the registry.

I want to make it clear that OTA places a high priority on learning as much as possible about the effects of Vietnam service and Agent Orange on veterans. We cannot, however, support conducting studies merely for the sake of "doing something," if our best professional judgement is that the studies are unlikely to provide valid answers. A decision not to go ahead with VETS II is a responsible one. We feel that VETS II is not an appropriate study given the present state of knowledge and in light of other research efforts already under way. This criticism and OTA's recommendation not to do the study are not an indictment of the investigators who proposed and planned VETS II. The concept of studying twins is not inherently flawed, and the groundwork that went into the VETS II protocol may well prove useful in the future.

Sincerely,

(sgd) John H. Gibbons

John H. Gibbons

bcc: Director  
Assistant Directors  
CPA  
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Tom McGurn