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CENTERS FOR DISEASE CONTROL

CENTER FOR ENVIRONMENTAL HEALTH - AGENT ORANGE PROJECTS

1600 Clifton Road, N. E., Atlanta, Georgia 30333 (404)454-4472

Jerry B. Robert Dieterbach.

Project Description for:

EPIDEMIOLOGIC STUDIES OF THE HEALTH OF VIETNAM VETERANS. (THE "AGENT ORANGE PROJECTS.")
The overall investigation includes three separate but related components:

1) Agent Orange Study. (Study of the long-term health effects of exposure to herbicides in Vietnam.)
2) Vietnam Experience Study. (Study of the long-term health effects of military service in Vietnam.)
3) Selected Cancers Study. (Study to determine the risks of specific cancers among Vietnam veterans.)

BACKGROUND

Between August 1965 and February 1971 approximately 11.3 million gallons of the herbicide "Agent Orange" (so named because of the orange markings on the drums in which it was shipped) were sprayed over much of South Vietnam in military operations designed to deprive the enemy of cover and food. A chemical contaminant, 2,3,7,8-tetrachlorodibenzo-p-dioxin, more often called TCDD, or simply dioxin, was created during manufacture of and contained in the Agent Orange which was sprayed. Dioxin has been shown to be a highly toxic substance.

In January 1978 the Veterans' Administration (VA) received the first of what was to become many claims from veterans who felt that their current health problems had resulted from their being exposed to Agent Orange while serving in Vietnam. In January 1979 the U.S. Congress enacted legislation (Public Law 96-151) directing the VA to design and conduct an epidemiologic study to determine if exposure to Agent Orange had caused long-term adverse health effects in Vietnam veterans. In November 1981 the scope of the study was expanded (by Public Law 97-72) to include other factors in the "Vietnam experience," including medications and environmental hazards or conditions.

In January 1983 the responsibility for designing and conducting the investigation was transferred from the VA to the Centers for Disease Control (CDC). In May 1983 CDC scientists completed detailed guidelines (protocols) for the Agent Orange and Vietnam Experience studies, recommending that a third investigation be conducted at the same time to determine the risk of Vietnam veterans developing selected types of cancers.

Public "Notice of Research Project Initiation" was published in the Federal Register on March 13, 1984.

DESCRIPTION: AGENT ORANGE AND VIETNAM EXPERIENCE STUDIES

Although both of these historical, or "retrospective," studies are in some respects similar, each has a separate purpose. The Agent Orange study is designed to find out if troops who were exposed to the herbicide during service in Vietnam have suffered long-term adverse health effects as a result of that exposure. The Vietnam Experience study is designed to demonstrate whether or not there is any difference in the health of veterans of the Vietnam era who served in Vietnam compared to the health of veterans who served in other countries during the same period of time.

The studies require the cooperation of a large number of Vietnam era veterans willing to be interviewed about their health status and experiences before, during, and after those years. TO ENSURE STATISTICAL ACCURACY, NO VOLUNTEERS CAN BE ACCEPTED AS PARTICIPANTS IN THE STUDIES. Participants are selected following scientific guidelines established by the research protocols.

With the help of the Department of Defense and other agencies, CDC will identify a minimum of 30,000 qualified veterans to participate in the studies: 6,000 in each of five separately defined groups or "cohorts." The five cohorts are to be made up of veterans who:

1) Served during 1967-68 in a specified area of Vietnam, and were likely to have been exposed to Agent Orange.

2) Served during 1967-68 in the same area of Vietnam as cohort 1, and were less likely to have been exposed to Agent Orange.

3) Served during 1967-68 in another area of Vietnam than cohorts 1 and 2, and were not likely to have been exposed to Agent Orange.

4) Served in Vietnam during 1966-72. Randomly selected from all areas.

5) Served during 1966-72 in countries other than Vietnam.

Data for the Agent Orange investigation will be gathered from cohorts 1, 2, and 3. Cohorts 4 and 5 will provide data for the Vietnam Experience study.

AGREEING OR DECLINING TO PARTICIPATE IN THE STUDY WILL HAVE NO EFFECT UPON BENEFITS A VETERAN MAY BE RECEIVING OR TO WHICH HE MAY BE ENTITLED IN THE FUTURE.

All information given by each veteran will be held in complete confidence. The names of the participants will never be associated with their answers in the statistical summaries studied by scientists. Names and other identifying information, such as addresses and social security numbers or service numbers, will be kept in a separate file that no one will have access to but the U.S. Public Health Service and the private research firms working on this study. No other researchers or government agencies, including the Veterans Administration and the Department of Defense, will be able to learn if a veteran participated or what his answers were. This promise of confidentiality is guaranteed by Federal laws--42 U.S. Code 242(b), (k), and (m). Unless the veterans gives written permission to CDC to release personal information, no one, including the veteran's family, will ever be able to get the personal information provided by the veteran.

The interview takes about 40 minutes and is conducted by telephone by CDC's contractor, Research Triangle Institute (RTI), Inc. Veterans who are selected to be called by RTI receive a letter from CDC telling them to expect the call. From those being interviewed, approximately 2000 veterans from each cohort will have been preselected for the medical examination component of the study. The RTI interviewers have no control over which veterans will be asked to take the medical exams.

Only veterans who have already been interviewed by RTI will be selected to be asked to take the medical exams which will take 3 days to complete. Several weeks after being interviewed, each veteran selected will receive a letter explaining the examinations and a telephone call from Lovelace Medical Center asking when he can come to Albuquerque. Veterans can select dates convenient to themselves.

The 10,000 medical examinations are being conducted at non-hospital clinical facilities specially constructed for this project by another CDC contractor, the Lovelace Medical Foundation, in Albuquerque, New Mexico. All examinations are being done at the same place to ensure that standard testing procedures are used. The examination includes about 60 physical, psychological, and laboratory tests. Blood and urine samples are required, but no tests are included that most persons would find painful. Participants can refuse to take any test or to answer any question. Veterans who complete all the tests receive a $300 stipend.

Veterans' expenses for travel to and from Albuquerque, food and lodging, etc., will be paid by the government. Veterans will stay in private rooms at a first-class downtown hotel and have their evenings free. Each room will accommodate up to four persons without cost to the veteran. (The government cannot pay for family members' travel or food.) Physicians and other health providers working on the CDC studies will not provide any treatment for individuals. If a veteran's medical examination indicates the possible existence of a problem of any sort, the veteran will be advised immediately and encouraged to seek treatment from the VA, private, or other sources of medical services.

Veteran interviews for the CDC study began in September 1984, and will continue until about October 1987. The first medical examinations were conducted in March 1985. All examinations are expected to be completed by about January 1988.

RTI, Lovelace, and other non-government research firms have been contracted to collect the data for these studies. These firms are monitored closely by CDC officials. All analysis and interpretation of data is done by CDC. 800-334-3494

DESCRIPTION: SELECTED CANCERS STUDY

There is some scientific evidence that exposure to herbicides may increase the risk of several serious, but relatively rare, cancers in workers in industries which manufacture or use similar products. Because these cancers are so infrequently seen, the 30,000 veterans in the other study cohorts do not offer a large enough sample population upon which to base this investigation. Instead, two other groups will be studied in a "case-control" investigation. Because of the design of this study, veterans and non-veterans will be included in both the case and control groups.

The tumors selected for the study are: lymphoma, soft-tissue sarcoma, nasal and nasopharangeal cancer, and primary liver cancer. Other types of tumors may be added to the study later.

The first (case) group in the Selected Cancers Study will be made up of male patients who have actually had these tumors, and who could have been in the military during the Vietnam conflict. The second (control) group will include men of the same age and from the same current geographic area as the case cohort, but without the tumors. Using information from interviews and military records, CDC will determine which men in both groups are veterans, which veterans served during the Vietnam era, and which veterans may have been exposed to Agent Orange.

Comparison of data collected from both groups may indicate significant differences in their risk of these cancers which could be associated with military service, service in Vietnam, and exposure to Agent Orange.

INVESTIGATION RESULTS

The exact rate of progress of epidemiological studies of this size cannot be forecast. Collection and analysis of the large amounts of data needed for scientifically valid findings takes time; particularly when so many thousands of veterans must be identified, located, interviewed, and examined. CDC will report on each component of the study when it has been completed.

Final reports on the Agent Orange and Vietnam Experience components are expected by September 30, 1988. The final report on the Selected Cancers Study component is expected by September 30, 1989. CDC hopes that these studies will provide answers to many of the important questions being asked about Agent Orange and other factors related to service in Vietnam. But, as in every epidemiologic investigation--no matter how carefully designed and professionally conducted--the possibility exists that definitive answers to some questions may never be found.