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**STATUS AND RESULTS OF FEDERAL EPIDEMIOLOGIC STUDIES
OF POPULATION EXPOSED TO TCDD**

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Executive Office of the President
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ABSTRACT

In 1980 the United States Government embarked upon a series of epidemiologic and health surveillance studies designed to elucidate health effects attributable to dioxin exposures associated with the manufacture or use of 2,4,5-T or Agent Orange herbicides. The coordination and oversight of this effort was assigned to the White House Agent Orange Working Group. The health concerns of individuals exposed to 2,3,7,8-TCDD are varied; hence, the approach encompassed studies comparing morbidity, reproduction and mortality patterns between exposed and nonexposed populations. Ten Federal agencies provide the financial and scientific resources required to conduct the 15 ongoing major human studies.

INTRODUCTION

The potential human risks that may be associated with exposure to 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD) and related compounds continue to be of concern to the public and scientific communities (11). For the past six years the United States Government has sponsored and conducted numerous epidemiological and health surveillance studies of populations exposed to phenoxy herbicides and other trichlorophenolic-derived products contaminated with TCDD. Much of this research has focused on Vietnam veterans exposed during the Vietnam Conflict to Agent Orange. Two previous reports have documented the nature and status of these studies (11, 12). The present report updates the status of these studies and other significant epidemiologic studies conducted by the scientific community.

ASSESSMENT OF EXPOSURE TO TCDD

A major concern in the conduct of epidemiologic studies of human populations assessing the impact of TCDD is the lack of accurate exposure data. One must at the least be able to identify a study cohort with a high likelihood of exposure. There are at least four major methods that have been employed in assessing exposure to TCDD and structurally-similar compounds.

1. Records: Christian and White (1) have reported on the use of military records to determine likelihood of exposure to Agent Orange in Vietnam. The records consist of recorded herbicide applications for selected geographic sites and the daily movement of military units. When plotted as a function of time (days) from application and distance (km), a likelihood or "opportunity for exposure" index can be developed. Agent Orange Exposure Opportunity Index scores were used in the Centers for Disease Control's (CDC) study of "Vietnam Veterans' Risks for Fathering Babies with Birth Defects" (4). Another form of records include work histories and personal work records. These were used extensively by Suskind and Hertzberg (9) to identify the TCDD exposed cohort in the clinical epidemiologic study of the population in the Nitro, West Virginia Dioxin Episode, an episode involving a large work force exposed to TCDD during the production of trichlorophenols.

2. Environmental Contamination: The confirmation of TCDD in environmental matrices to which a population is exposed is another method to identify populations at risk. Following the 1976 Seveso, Italy, Dioxin Episode, Pocchiari et al. (8) measured TCDD in the atmosphere, soil and water, and in plant and animal tissues from the contaminated zones. The extensive monitoring program throughout the affected area has been crucial to establishing the population at risk for the numerous epidemiologic and health surveillance studies conducted at Seveso.

Most recently, Webb et al. (10) conducted a pilot health study of a group of individuals presumed to be exposed to TCDD at sites in Missouri sprayed in 1971 with waste oils containing TCDD. The exposed individuals were selected because they "lived in, worked at or, recreated at" areas where high soil levels (ppb, ppm) of TCDD were reported.

3. Adipose Tissue Levels of TCDD: Young (13) has recently summarized the results of the analysis of dioxins and furans in human adipose tissue. A level of 1.8 ppb TCDD was reported in the fat tissue of a woman exposed to TCDD at Seveso, Italy, while means levels of 7-10 ppt were found in 25 of 33 Vietnam era veterans. Levels of TCDD in adipose tissue were similar between those veterans who served in Vietnam and those who did not.

The Veterans Administration (VA), the Environmental Protection Agency (EPA) and the CDC continue to develop techniques and conduct surveys for identifying exposed populations based on TCDD residues in tissues.

4. **Biologic Markers:** The major biologic markers to TCDD exposure are the cutaneous signs of chloracne, hyperpigmentation, actinic elastosis of the skin and possibly porphyria cutanea tarda. Dunagin (3) and Suskind and Hertzberg (9) concur that chloracne (a severe and generalized acneiform eruption) is the most sensitive indicator of significant dioxin exposure, and that the condition may persist for years.

Kuratsune (6) has reported that individuals that developed Yusho disease (from exposure to dibenzofurans) show an unusual chromatographic pattern of PCBs remaining in their blood. This pattern is distinct from non-Yusho persons and has an intermediate state among less severely poisoned patients. Kuratsune indicated that these characteristic patterns can be recognized as Yusho disease even in individuals that show almost none of the clinical signs and laboratory findings characteristic of the poisoning. The patterns persist, since 70 percent having the patterns in 1973 still maintained them in 1980.

RATIONALE FOR STUDIES

The questions asked by Vietnam veterans exposed to Agent Orange and its associated dioxin are the same questions asked by individuals exposed to either the herbicides or the contaminant, namely:

- Are they more likely to have children born with birth defects?
- Are they dying in increased numbers, at earlier ages of unexpected causes?
- Are they more likely to develop connective tissue cancer (i.e., soft tissue sarcoma)?
- Are they more likely to develop other forms of cancer?
- Do they have residual levels of dioxin in their body tissues, and is it likely that these residues will cause subsequent health problems?
- Are there other long-term problems peculiar to phenoxy herbicides and/or TCDD exposure?

Thus, the health concerns of individuals exposed to the herbicides and 2,3,7,8-TCDD are varied. Any approach must encompass studies comparing morbidity, reproduction, and mortality patterns between exposed and nonexposed populations. Moreover, for Vietnam veterans, an added dimension is present - if Agent Orange and its associated dioxin is not the causative agent, other factors associated with the Vietnam War may be responsible. Consequently, the goal of some research efforts is to determine whether Vietnam veterans as a group are experiencing more or different health problems than are their counterparts who did not serve in that part of the world. In such a complex situation, no single study can provide all the answers. Thus, there is a need for a number of different approaches to examining the health of the Vietnam veteran and others exposed to TCDD.

COMPLETED STUDIES AND INTERIM REPORTS

During 1984 two major case-control studies were completed assessing Vietnam service and the risk of fathering children with congenital anomalies. The first report, released in early 1984, was an Australian study by Donovan et al. (2). Infants with anomalies diagnosed at, or shortly after, birth were individually matched to control infants born without an anomaly, in the same hospital, to a mother of similar age, and about the same date. The fathers in 8,517 such case-control pairs were identified, and compared with a list of men who served in the Australian Army between 1962 and 1972 - the period of Australian involvement in Vietnam. Fathers identified as having served in the Army during this period were then classified according to whether or not they had served in Vietnam. One hundred and twenty-seven fathers of infants who were born with anomalies and 123 fathers of control infants were Vietnam veterans. Donovan et al. concluded that there was no evidence that Army service in Vietnam increased the risk of fathering children with anomalies diagnosed at birth.

The second birth defects study was reported in August 1984 by Erickson et al. (4) and involved assessing Vietnam veterans' risks for fathering babies with major structural birth defects. Case group index babies were obtained from the register of the CDC's Metropolitan Atlanta Congenital Defects Program for the years 1968-1980. Control group index babies-babies born without defects-were selected from among the 323,421 babies who were live born in the area to resident mothers during 1968 through 1980. The control group index babies were frequency matched to the case group index babies by race, year of birth, and hospital of birth ("sampling design variables"). The number of case group families eligible for the study was 7,133, as were 4,246 control group families.

Information regarding military service in Vietnam was obtained through interviews with mothers and fathers of babies in case and control groups and from review of military records. Four hundred and twenty-eight fathers of case group index babies were Vietnam veterans and 268 fathers of control group babies were Vietnam veterans; the non-Vietnam veteran case and control group fathers numbered 4,387 and 2,699, respectively. The study provided strong evidence that Vietnam veterans, in general, have not been at increased risk of fathering babies with the aggregate of the types of defects studied. Vietnam veterans who had greater estimated opportunities for Agent Orange exposure did not seem to be at greater risk for fathering babies with all types of defects combined. However, for a few specific types of defects the estimated risks were higher for subgroups of Vietnam veterans that may have had a greater likelihood of exposure to Agent Orange. These seemingly higher risks could be chance events, the result of some experience in the Vietnam service of the father, or the results of some other unidentified risk factor.

Greenwald et al. (5) have completed a case-control study of soft tissue sarcoma and Vietnam service. They compared the Vietnam service and military service of 281 men with sarcomas of soft tissue to those of a control group of men derived from New York driver's license files and matched on a 5-year period of birth and the zip code of residence. Of the 281 cases, 116 men had military service as compared to 157 of 281 live controls and 60 of 130 dead controls. After adjusting for general military service, the chances of being diagnosed for soft tissue sarcoma among Vietnam veterans was less than that for controls. Thus, Greenwald et al. concluded that this study revealed no statistically significant positive association between sarcomas of soft tissue and either service in Vietnam or military service in general. No significant associations were found for self-reported Agent Orange or other variables that might be related to herbicide exposure.

During 1984 two independent studies were published of the industrial population exposed to TCDD in the Nitro, West Virginia Dioxin Episode. Suskind and Hertzberg (9) conducted a clinical epidemiologic study to determine the long-term health effects of workplace exposure to 2,4,5-T herbicide containing TCDD. The population consisted of two cohorts: 204 clearly exposed with 86 percent having previously reported clinical evidence of chloracne, and 163 not exposed. Among the exposed, clinical evidence of chloracne persisted in 56 percent of the cases with some individuals continuing to show chloracne for 30 years. Suskind and Hertzberg also found associations between chloracne and the presence of actinic elastosis of the skin and a history of gastrointestinal tract ulcers.

Examining essentially the same population, Moses et al. (7) found a significant increased prevalence of abnormal gamma-glutamyl transpeptidase (GGT) in those with chloracne, compared to those without. Although mean triglyceride values were higher in those with chloracne, the difference was not statistically significant. Neurological examination showed a statistically significant higher prevalence of abnormal sensory findings in those with chloracne. Increased prevalence of reported sexual dysfunction and decreased libido in those with chloracne compared to those without were statistically significant after age adjustment. No differences were found between those with and without chloracne in serum cholesterol, total urinary porphyrins, or in reproductive outcome.

CURRENT STUDIES

Epidemiologic Studies

In 1980 the United States Government embarked upon a series of epidemiologic studies designed to elucidate health effects attributable to dioxin exposure associated with the manufacture or use of 2,4,5-T or Agent Orange herbicides. The coordination and oversight of this effort was

assigned to the White House Agent Orange Working Group. As noted, the health concerns of individuals exposed to 2,3,7,8-TCDD are varied; hence, the approach encompassed studies comparing morbidity, reproduction and mortality patterns between exposed and nonexposed populations. Ten Federal agencies have provided the financial and scientific resources required to conduct the 15 ongoing major human studies. Table 1 summarizes the ten major epidemiologic studies currently ongoing within the Federal Government. As noted, the CDC Birth Defects Study has been completed and other studies are now approaching final stages of data collection and analyses.

Health Surveillance Studies

Five studies sponsored by the Federal Government are of a health surveillance nature. These studies are summarized in Table 2 and expanded descriptions are provided below.

1. VA Patient Treatment File (PTF) Review: Questions have been asked many times by Congress and others whether Vietnam veterans come to the VA hospitals with different or unique health problems as compared to their counterparts who did not serve in Vietnam. An initial review of a sample of 73,000 Vietnam era veterans [Fiscal Year (FY) 69-82] and another review of a random sample of 1,000 veterans' (FY 83) military records and PTF medical data revealed no significant difference in the distribution of diagnoses between Vietnam veterans and non-Vietnam veterans treated in VA hospitals. This effort of monitoring health problems of Vietnam veterans hospitalized in the VA facilities will continue.

2. Agent Orange Register Review: The Agent Orange Register is a computerized information retrieval system that abstracts both medical and non-medical information from the Agent Orange Registry. The medical information includes symptoms attributed by the veteran to exposure to Agent Orange and pertinent diagnosis made by VA physicians. The non-medical information includes self-reported information on their military service histories and their recollection of exposure to Agent Orange.

Because of the self-selective nature of the Registry participants, this group of veterans cannot, with any scientific validity, be viewed as being representational of Vietnam veterans as a whole. The information in the Registry can, however, be used to detect suggested health trends and provide some descriptors as to the characteristics of the group itself.

The Agent Orange Register of 86,000 Vietnam veterans was reviewed and results were reported elsewhere (14). The monitoring of the Agent Orange Register is continuing.

3. A Review of the Soft Tissue Sarcoma (STS) Cases in Patient Treatment File (PTF) for Vietnam Era Veterans: In a parallel effort to the VA/AFIP Soft Tissue Sarcoma Study noted in Table 1, the VA in collaboration with the Armed Forces Institute of Pathology (AFIP) is

reviewing the STS cases in the PTF for Vietnam era veterans. This review has a three-fold purpose, namely, to determine 1) the number of cases of STS among Vietnam era veterans treated in VA hospitals since 1969; 2) the relative frequency of these STS cases among veterans who actually served in Vietnam as compared to Vietnam era veterans who served elsewhere; and 3) the accuracy of STS diagnosis made by VA pathologists.

* The first phase of this effort was initiated in 1983 when the VA reviewed the PTF and found that a total of 418 Vietnam era veterans were treated in VA medical centers between 1969 and 1982 with a diagnosis coded as 171 in the International Classification of Disease (ICD). This is the code number used for malignant neoplasm of connective and other soft tissue. Military service information, in particular Vietnam service status, for each of these veterans was obtained from a review of the veteran's military record at the National Personnel Records Center in St. Louis, Missouri.

The second phase of the survey was a review of the pathology reports on each of these cases by a single VA pathologist with a particular interest and experience in this group of malignancies. The reviewing pathologist was totally unaware of the Vietnam service status of any of the cases. In several instances the pathologist did not agree with the classification that was entered in the PTF. In a few of the cases, the military record for the purpose of establishing Vietnam service status was not available.

The result of this phase of the study was a group of 214 confirmed cases of STS on whom Vietnam service status could be established. Among this group the proportion of those having served in Vietnam as compared to those who served elsewhere was precisely the same as a much larger sample of Vietnam era veterans treated in VA medical centers, i.e., 40 percent having served in Vietnam and 60 percent having served elsewhere.

In order to further strengthen this survey, phase three is now being initiated. This will be a review of the tissue slides from all of the original cases coded as 171 appearing in the PTF. At the AFIP, Washington, D.C., an expert pathologist will review all of these cases in order to obtain maximum assurance of accuracy in the diagnosis.

4. AFIP Agent Orange Registry: The AFIP has been collecting and reviewing tissue specimens of Vietnam veterans from VA medical centers and military hospitals since 1978. AFIP plans to evaluate the specimens for clustering of cases with similar organ-diagnosis combinations, findings that are unusual for any site or organ, and unusual ages for a particular diagnosis. To date, tissue specimens from over 2,000 veterans have been collected.

5. VA/EPA Adipose Tissue Study: Since 1970, the EPA has been collecting human adipose tissue from the general population and has analyzed these tissues for residues of selected pesticide-related chemicals and polychlorinated biphenyls (PCBs). Within the bank of

approximately 8,000 tissue specimens available for further chemical analysis there are specimens from 528 males born between 1937 and 1952. Many of these individuals will have served in the military during the Vietnam-era and some may have served in Vietnam during the period of Agent Orange use. A retrospective analytical study of selected chlorinated dioxins and furans will provide data on background levels of these chemicals in the U.S. male population and hopefully will determine if service in Vietnam has had an effect on the levels of TCDD in adipose tissue. The study is being conducted in three phases. In phase I the names and/or social security numbers of 494 of the 528 males noted above were obtained and military service status of these individuals was determined. Phase II has been the development of analytic methods for the determination of selected dioxins and furans. Phase III will be the analysis of the adipose tissue. A detailed research protocol has been prepared and the analysis of tissues is ready to begin.

CONCLUSIONS

A massive research program is underway in the United States on the long-term health effects of exposure to the phenoxy herbicides and the associated dioxin contaminants, especially 2,3,7,8-TCDD. The program is designed to answer the numerous health concerns associated with exposure. Hence, it consists of studies on reproduction, morbidity, and mortality as well as studies of tissue levels of dioxins.

The scientific community must continue to conduct valid research on the impact of dioxin on human health to provide a reliable basis for appropriate decision-making. The United States Government stands firmly committed to working closely with other governments as well as with the private sector, to obtain as many answers as quickly as possible, consistent with sound scientific principles, to resolve this perplexing issue. The resolution of the controversy, however, will be achieved only following the public's acceptance of the outcome of scientific investigations. To that end, scientists must accept the responsibility for not only conducting quality research, but also for translating the results of their efforts for legislators, the courts, the media, and ultimately the public at large.

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TABLE 1: The Ten Major Epidemiologic Studies of U.S. Vietnam Veterans, Agent Orange and TCDD Exposure, and Vietnam Experience Currently Ongoing in the United States

Title	Responsible Federal Agency and Study Location	Type of Study	Total Study Population Size	Completion Date
Air Force Health Study	United States Air Force School of Aerospace Medicine, San Antonio Texas	Matched Cohort Study of RANCH HAND Personnel and Controls, Mortality, Morbidity and Reproduction	2,500	a) Baseline Reports 1983 - 1984 b) Long-term follow-up planned.
VA Mortality Study	Veterans Administration Agent Orange Projects Office, Washington, D.C.	Mortality Study of Vietnam-Era Veterans	60,000	Mid-1985
Vietnam Experience Twin Study	Veterans Administration Medical Center, St. Louis, Missouri	Morbidity Study of Identical Twins	1,200	1986
Birth Defects Study	Centers for Disease Control, Atlanta, Georgia	Case-Control Study of Anatomical Birth Defects	8,400	Completed August 1984
Agent Orange Epidemiologic Study of Ground Troops	Centers for Disease Control, Atlanta, Georgia	Three-Cohort Morbidity Study of Vietnam Veterans	18,000	1988

TABLE 1: The Ten Major Epidemiologic Studies of U.S. Vietnam Veterans, Agent Orange and TCDD Exposure, and Vietnam Experience Currently Ongoing in the United States (Continued).

Title	Responsible Federal Agency and Study Location	Type of Study	Total Study Population Size	Completion Date
Vietnam Experience Epidemiologic Study	Centers for Disease Control, Atlanta Georgia	Matched Cohort Morbidity Study of Vietnam and non-Vietnam Veterans	12,000	1987
VA/APIP Soft Tissue Sarcoma Study	Veterans Administration Agent Orange Projects Office, Washington, D.C.	Case-Control Study of Soft Tissue Sarcoma	250 cases 750 controls	Late 1986
NIOSH Dioxin Registry	National Institute for Occupational Safety and Health, Cincinnati, Ohio	Mortality Study of Workers at 12 Production Sites Where Dioxin Containing Products Were Manufactured	6,000	1985
NIOSH Industrial Morbidity Study	National Institute for Occupational Safety and Health, Cincinnati, Ohio	Morbidity Study of 2 Production Sites Where Dioxin Containing Products Were Manufactured	500	1986
NCI Kansas Soft Tissue Sarcoma Study	National Cancer Institute, Bethesda, Maryland	Case-Control of Soft Tissue Sarcoma	100 cases 300 controls	Early 1985

TABLE 2: The Five Major Current Health Surveillance Projects of U. S. Vietnam Veterans, Agent Orange and TCDD Exposure, and Vietnam Experience

Title	Responsible Federal Agency and Study Location	Type of Surveillance	Target Population	Status
VA Patient Treatment File Review	Veterans Administration Agent Orange Projects Office, Washington, D.C.	Review of VA hospital inpatient medical records	Vietnam era veterans who have been hospitalized in VA medical facilities	On-going
Agent Orange Register Review	Veterans Administration Agent Orange Projects Office, Washington, D.C.	Review of the records of the medical examinations at VA hospitals	Vietnam veterans who have reported to VA hospitals for an Agent Orange examination	On-going
A Review of the Soft Tissue Sarcoma cases in Patient Treatment File for Vietnam Era Veterans	Veterans Administration Agent Orange Projects Office, Washington, D.C.	Review of pathology reports and the tissue specimens of patients diagnosed as having International Classification of Diseases ICD 171	Vietnam era veterans who have been hospitalized in VA medical facilities	On-going
AFIP Agent Orange Registry	Armed Forces Institute of Pathology, Washington, D.C.	Review of tissue specimens	Vietnam era veterans	On-going
VA/EPA Adipose Tissue Study	Veterans Administration and the Environmental Protection Agency, Washington, D.C.	500 samples of human fats	U.S. Vietnam era males	1986