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Item ID Number 05695 **Not Scanned**

Author

Corporate Author

Report/Article Title Report of the Agent Orange Working Group Science Subpanel on Exposure Assessment

Journal/Book Title

Year 1986

Month/Day May 28

Color

Number of Images 0

Description Notes Handwritten notes and corrections by Alvin Young. Alvin L. Young filed these documents together with others under the label, "Agent Orange Exposure Project."

REPORT OF THE AGENT ORANGE WORKING GROUP
SCIENCE SUBPANEL ON EXPOSURE ASSESSMENT

May 28, 1986

At its meeting on January 29, 1986, the Agent Orange Working Group (AOWG) directed the Science Panel to evaluate whether a cohort of Vietnam veterans with a high probability of exposure to Agent Orange could be assembled for a scientifically valid Agent Orange study. Accordingly, a Subpanel of the AOWG was assembled to review pertinent information on exposure assessment, to examine the additional pilot data which has been developed by the U.S. Army ~~and~~ and Joint Services Environmental Support Group, and to evaluate the feasibility of a scientifically valid study of the possible long-term health effects which may have been caused by exposure to Agent Orange among combat veterans who served in Vietnam.

The Subpanel consisted of the following members:

Alvin L. Young, Ph.D. Chairman
Office of Science and Technology Policy
Executive Office of the President

Donald ^GBarnes, Ph.D.
Office of Pesticides and Toxic Substances
Environmental Protection Agency

Aaron Blair, Ph.D.
Occupational Study Section
~~Natural Causes Institute~~
~~Natural Cancer~~

Jerome ^GBricker, Ph.D.
Environmental Support Group
U.S. Army (Consultant)

OASD (HEALTH AFFAIRS), DOD
Retired Annuitant Expert

Richard S. Christian, C.R.M.
Environmental Support Group
~~Army Agent Orange Task Force~~

U.S. ARMY AND
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Marilyn Fingerhut, Ph.D.
~~Epidemiology Division~~ ^{INDUSTRY WIDE STUDIES BRANCH}
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Carl Keller, Ph.D.
National Institute of Environmental Health Sciences
National Institutes of Health

John E. Murray
Major General, USA (Retired)
Fairfax, Virginia

Barclay M. Shepard, M.D.
Agent Orange Projects Office
Veterans Administration

Peter Layde, M.D. (Observer)
Center for Environmental Health
Center for Disease Control

The Subpanel met on February 26; March 10; March 28; April 10; April 21; May 2; May 19, and May 27, 1986. This report is the subpanel's evaluation prepared for the Agent Orange Working Group.

BACKGROUND

Public Law 95-151 (1980) directed the Veterans Administration (VA) to conduct an "epidemiological" study of United States veterans to assess the possible health effects of exposure to herbicides and dioxin during the Vietnam Conflict. Public Law 97-72 (1982) expanded this mandate to include the study of other environmental hazards or conditions which may have occurred in Vietnam. In January 1983, the design, conduct and analysis of health studies responsive to these laws was transferred by an Interagency Agreement from the VA to the Centers for Disease Control (CDC). In November 1983, CDC completed protocols on three complementary studies to address the health concerns of Vietnam veterans: The Vietnam Experience Study, the Agent Orange Study, and the Selected Cancers Study. CDC is currently conducting the Vietnam Experience Study and the Selected Cancers Study.

6 The Agent Orange Study was designed to look at the influence of ~~proximity to~~ Agent Orange applications on the health of Vietnam veterans. Achieving this goal was problematic because a critical component of such a study was that there existed an accurate assessment of Agent Orange. Unfortunately, the hostile environment in Vietnam precluded quantitative assessments of human exposure, and the collection of detailed military records dedicated to military herbicide operations. Thus the November

were those appropriate

but not necessarily appropriate
for follow-on health studies.

1983 protocol for the Agent Orange Study proposed an approach to estimating the opportunity for exposure to Agent Orange. At the time it was anticipated that large numbers of Vietnam combat veterans had been heavily and frequently exposed to Agent Orange. There was even concern that unexposed individuals would be very difficult to identify. Thus, the basic approach was to score veterans' opportunity of exposure based on their proximity to known herbicide applications. Veterans' daily location were to be abstracted from records of the men's units. The protocol noted that changes in methods might be required as new data became available. In addition, certain reviewers of that protocol, including members of the Agent Orange Advisory Panel of the Congressional Office of Technology Assessment (OTA) and the AOWG Science Panel, expressed concern about the validity of the approach to exposure assessment and the extent of opportunity for exposure to Agent Orange in this cohort. Since the November 1983 protocol, CDC has provided OTA and the AOWG Science Panel with two interim reports on the status of the exposure assessment issue. After reviewing these materials, neither the AOWG Science Panel nor OTA believed that sufficient data had been presented on the extent of exposure opportunities among those thought most likely to be exposed nor on the details of revised study methods to warrant proceeding with the Agent Orange Study at this time. Both review groups asked that a new comprehensive protocol for the Agent Orange Study be prepared by CDC in order to address concerns in the areas of 1) exposure assessment, 2) selection of study participants, and 3) data analysis. In addition, the Department of Health and Human Services (HHS) was directed to delay commencement of interviews of the Agent Orange Study which was scheduled to begin in January 1986, until a revised protocol could be evaluated by appropriate review groups.

DEFINITION OF THE PROBLEM

The original Study Design by CDC provided that a comparison of health outcomes was to be made between a cohort of men who had little or no opportunity for contact with herbicide and a cohort of men who were highly likely to have been exposed to Agent Orange while in Vietnam. Both cohorts were to be selected from among U.S. Army draftees or single tour enlistees with rank E1 through E5 and who were assigned to combat units operating in III Corps in Vietnam during the period October, 1966 through March, 1969.

Form 1

a combination of spray frequency of encounters

It was proposed that in the absence of direct measurements of exposure cohorts would be based on the amount of time spent in areas which were being or had been sprayed with Agent Orange.

From documents obtained by the Army's Environmental Support Group, military records are sufficient to locate the position of the combat battalions by geography and time that served in III Corps. Indeed, daily locations for company-sized Army units can be abstracted from military records and the location of virtually all the recorded herbicide applications has been identified and computerized. The number of days that a company was close to a spraying can therefore be determined by computer matching of daily locations. Duty rosters for companies are available which identify individuals available for duty each day.

This report is organized around several issues which the Subpanel has reviewed, including how much Agent Orange might cause health effects, how much was present under varying conditions of exposure, possibilities for misclassification of exposure status, and results and evaluation of pilot data. These issues are discussed below in the form of questions, each with a brief summary discussion. Additional and more complete information is provided in the various appendices to this report.

This required the linking of records of spray missions with the records of troop deployment. (150-200 individuals)

The Army Environmental Support Group has performed such a linkage and they have demonstrated that...