Uploaded to VFC Website

November 2012

This Document has been provided to you courtesy of Veterans-For-Change!

Feel free to pass to any veteran who might be able to use this information!

For thousands more files like this and hundreds of links to useful information, and hundreds of "Frequently Asked Questions, please go to:

Veterans-For-Change

Veterans-For-Change is a 501(c)(3) Non-Profit Corporation
Tax ID #27-3820181

If Veteran's don't help Veteran's, who will?

We appreciate all donations to continue to provide information and services to Veterans and their families.

https://www.paypal.com/cgi-bin/webscr?cmd=_s-xclick&hosted_button_id=WGT2M5UTB9A78

Note: VFC is not liable for source information in this document, it is merely provided as a courtesy to our members.

Item ID Number	05618 ☐ **Not Scanned**
Author	Brandt, Edward N., Jr.
Corporate Author	
Report/Article Title	Memorandum from Edward N. Brandt, Jr. to Director, Centers for Disease Control, with subject: CDC Protocols for Studies of Vietnam Veterans, dated February 16, 1984
Journal/Book Title	
Year	0000
Month/Day	
Color	☐
Number of Images	0
Description Notes	Alvin L. Young filed these documents together with others in a folder labeled, "Agent Orange Working Group Science Panel, Current Folder."

DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service

Memorandum

Date FEB 16 1984

From Assistant Secretary for Health

Subject CDC Protocols for Studies of Vietnam Veterans

To Director, Centers for Disease Control

In my capacity as Chairman of the Agent Orange Working Group (AOWG), I have been reviewing all of the research underway. Attached is a copy of the recommendations of the AOWG Science Panel concerning the CDC protocols for the studies of Vietnam Veterans. I am especially concerned about the recommendation number 3. What are we doing about exposure data? How would we answer the questions posed in 3(a) and 3(b)?

Thanks.

Edward N. Brandt, Jr., M.D.

Attachment

Recommendations

The Science Panel of the Agent Orange Working Group recommends that the Centers for Disease Control, in conjunction with the Veterans Administration, proceed with the proposed Epidemiological Studies of Vietnam Era Veterans according to the following schedule:

1) The Vietnam Experience Study should begin forthwith using the procedures outlined in the protocols. Modifications should be made dependent on the identified potential problems with location and recruitment of study subjects during the pretest and pilot phases. Some more clearly defined diagnostic criteria for somatic and psychiatric health outcomes, e.g. Post Traumatic Stress Disorder, should be developed for incorporation in the examination procedures.

2) The Soft Tissue Sarcoma/Lymphoma Case-Control Study should proceed with the expressed cooperation of appropriate investigators within the National Institutes of Health, the Veterans Administration and the Armed Forces Institute of Pathology. Vietnam Veterans' concerns for these serious diseases can best be served by closer collaboration with the ongoing efforts of other agencies already studying this issue.

3) The Agent Orange Study presents some particular difficulties which cannot be evaluated at present. It is therefore recommended that the Agent Orange Study proceed through the pretest and pilot phases, at which time a major reevaluation be conducted to address two questions:

   a) Are the identified high and low exposure cohorts sufficiently different in exposure to Agent Orange and similar in other respects (especially combat experience) to make a scientifically meaningful interpretation of health outcomes?

   b) Will the results of medical examinations and laboratory tests add significantly to the health information pertinent to herbicide exposure which is obtainable by interview?

   If the answer to either of these questions is equivocal, or "no", then the Agent Orange study protocol should be revised accordingly.

Finally, there should be some assurance that the results from both cohort studies utilizing subjects who had served in the Army will be acceptable to Veterans' groups, the public and the Congress. This is particularly important if there is found to be no detriment to the health of Agent Orange exposed Army Veterans compared to unexposed Army Veterans with similar combat experience (within the limitations imposed by statistical power considerations).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Centers for Disease Control

Memorandum

Date MAR 7 1984

From Director
Centers for Disease Control

Subject CDC Protocols for Studies of Vietnam Veterans

To The Assistant Secretary for Health
Through: ES/PHS_____

This is in response to your memorandum of February 16 expressing concern about a recommendation made by the Agent Orange Working Group (AOWG) Science Panel relative to the Centers for Disease Control's (CDC) research protocols for study of the health of Vietnam veterans.

With reference to the Science Panel's recommendation 3(a), it is difficult at this time to define "meaningful" exposure to Agent Orange. It is, therefore, not possible to make any unequivocal statements in regard to the Science Panel's recommendation. However, the planned approach to the selection of troops--by a ranking of all Army combat units which were stationed in III Corps in 1967-1968--will help to ensure that men who had the lowest potential for exposure are compared with men who had the highest potential. We cannot predict now whether this will represent meaningful differences in exposure. If the study proceeds as planned and no health differences are observed, it will be impossible to say with certainty whether the lack of difference is due to poor exposure separation (as a result of misclassification because the military records which must be used to estimate exposure were not created for the purposes of an epidemiologic study) or due to a true lack of effect from whatever exposure did occur. If a difference is observed, then attribution to exposure will depend on an assessment according to the usual criteria used in making causal inferences from observational studies.

The physical examination (referred to in the Panel's question 3(b)) will be important from the standpoint of the credibility of the study results. The scientific community will be much more likely to accept certain positive findings if study participants are examined. For example, a laboratory finding of impaired immunological function will be more convincing than a finding of increased susceptibility to infections as measured by participants' responses during an interview; neurological abnormalities documented objectively during examinations will allow more definitive statements to be made than will findings such as finger numbness taken from participant's statements during interviews. Veterans also will be much more likely to accept the results of the study, even if negative, if physical examinations are done.

In November 1983 CDC responded to the AOWG comments, and to those made by three other scientific review groups. The comments were included in a document (copy attached) titled "Responses to Scientific Reviews of the Centers for Disease Control's Draft Protocols for Epidemiologic Studies of the Health of Vietnam Veterans." Copies of this documen were provided at that time to the AOWG Science Panel members through its Chairman Pro tem, Dr. Carl Keller. These responses to the Science Panel's recommendations were discussed at a December 5 meeting of the Panel which was attended by Dr. Vernon Houk, Director of the Center for Environmental Health and former Chairman of the Science Panel. The Panel agreed at that time that CDC's document adequately addressed the concerns expressed in the AOWG review and those contained in the other review groups' comments.

Our researchers recognized early that there is a potential for exposure misclassification in the Agent Orange component of the study. The protocol includes (page 11) a caution that "since many of the proposed [participant selection] procedures are untested, modification, indeed even a recommendation not to proceed with the Agent Orange [component], may be required after pilot study assessment."

Please let me know if you wish to discuss or want further information.

James O. Mason, M.D., Dr.P.H.
Assistant Surgeon General

Prepared by:CDC:Vernon N. Houk, M.D., FTS 236-4111