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Author Halverson, Charles W.

Corporate Author Armed Forces Epidemiological Board

Report/Article Title Memorandum: From Charles W. Halverson on behalf of the Armed Forces Epidemiological Board, to the Assistant Secretary of Defense (Health Affairs), the Surgeon General, Department of the Army, Surgeon General, Department of the Navy, the Surgeon General, Department of the Air Force, with subject "Recommendations Concerning Protocol for Epidemiologic Investigation of Health Effects in Air Force Personnel Following Exposure to Herbicide Orange." dated October 15, 1979

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Description Notes Item includes attachment: memorandum for board members and advisors, from Anna M. Baetjer, with subject Report of the Evaluation of Protocol for "Epidemiologic Investigation of Health Effects in Air Force Personnel Following Exposure to Herbicide Orange." dated October 10, 1979.



DEPARTMENT OF DEFENSE
ARMED FORCES EPIDEMIOLOGICAL BOARD

SG-ES
MAD BPR

DASC-AFEB 79-4

15 OCT 1979

THE EXECUTIVE SECRETARY
ARMED FORCES EPIDEMIOLOGICAL BOARD
OFFICE OF THE SURGEON GENERAL
DEPARTMENT OF THE ARMY
WASHINGTON, D.C. 20315

MEMORANDUM FOR THE ASSISTANT SECRETARY OF DEFENSE (HEALTH AFFAIRS)
THE SURGEON GENERAL, DEPARTMENT OF THE ARMY
THE SURGEON GENERAL, DEPARTMENT OF THE NAVY
THE SURGEON GENERAL, DEPARTMENT OF THE AIR FORCE

SUBJECT: Recommendations concerning protocol for "Epidemiologic Investigation of Health Effects in Air Force Personnel Following Exposure to Herbicide Orange."

1. In response to a request from the Surgeon General of the Air Force, an Ad Hoc Subcommittee of the Armed Forces Epidemiological Board (AFEB) met on 30 August 1979 to evaluate the Air Force protocol for an epidemiological investigation concerning the health effects in Air Force personnel exposed to Herbicide Orange during the defoliation missions in Vietnam. The recommendations resulting from the Ad Hoc Subcommittee's deliberations were presented at the 27-28 September 1979 meeting of the AFEB. The Board concurred with the recommendations and therefore recommends that:

- a. *IT WOULD BE PREFERABLE TO HAVE THE ENTIRE PROJECT CONTRACTED OUT TO A UNIVERSITY GROUP. IF THIS CANNOT BE ACCOMPLISHED FOR THE ENTIRE STUDY, THERE ARE SEVERAL COMPONENTS OF THE STUDY THAT SHOULD BE CONTRACTED OUT. FOR EXAMPLE, THE TELEPHONE INTERVIEWING COULD BE CONTRACTED WITH ONE OR SEVERAL LEADING SURVEY RESEARCH CENTERS. THE PHYSICAL EXAMINATION OF THE SUBJECTS SHOULD ALSO BE CONTRACTED OUT TO ONE SINGLE CENTER OR TO A FEW GROUPS, EACH OF WHOM COULD GO TO SEVERAL CENTERS, OR TO A FEW GROUPS TO WHOM THE SUBJECTS WOULD BE TRANSPORTED. IN EITHER CASE AN OUTSIDE DATA MONITORING COMMITTEE SHOULD BE ESTABLISHED THAT WOULD MEET FREQUENTLY TO REVIEW THE VARIOUS RESEARCH INSTRUMENTS, DATA COLLECTION AND ANALYTICAL PROCEDURES. AN AUDIT COMMITTEE OF OUTSIDE SCIENTISTS SHOULD BE ESTABLISHED TO DEVELOP NECESSARY PROCEDURES FOR REVIEW OF THE INTERVIEWS AND DEATH CERTIFICATES THAT ARE COLLECTED IN THE STUDY EITHER TOTALLY OR ON A SAMPLING BASIS. IN ADDITION, SUCH A COMMITTEE WOULD HAVE THE RESPONSIBILITY OF BEING CERTAIN THAT THE QUALITY AND INTEGRITY OF THE DATA USED FOR ANALYSIS HAS BEEN MAINTAINED.*

DASC-APFB 79-4

SUBJECT: Recommendations concerning protocol for "Epidemiologic Investigation to Health Effects in Air Force Personnel Following Exposure to Herbicide Orange."

b. WITH RESPECT TO THE DETAIL AND INTENSITY OF THE STUDY:

(1) SEVERAL COMPONENTS OF THE INTERVIEW BE ELIMINATED OR CONDENSED; (2) ONE PSYCHOLOGICAL EXAMINATION BE ADOPTED; (3) THE PHYSICAL AND NEUROLOGICAL EXAMINATIONS BE SHORTENED; (4) THE DETAILED EXAMINATIONS BE DONE DURING THE FIRST AND FIFTH YEAR OF THE FOLLOW UP; (5) BETWEEN THE FIRST AND FIFTH YEAR OF FOLLOW UP, INFORMATION ON HEALTH STATUS BE OBTAINED BY MAILED QUESTIONNAIRE ANNUALLY REGARDING MORBIDITY, HOSPITALIZATION, ABSENTEEISM FROM THE JOB, ETC. THIS COULD BE ACCOMPLISHED BY CORRESPONDING WITH THE SUBJECTS AND THEIR EMPLOYERS.

c. THE CONTROL GROUP BE INCREASED IN SIZE SO THAT IT IS FIVE TIMES THE SIZE OF RANCH HAND. THE ENTIRE GROUP SHOULD BE FOLLOWED TO DETERMINE THEIR MORTALITY EXPERIENCE. FIVE SAMPLES SHOULD BE SELECTED FROM THIS GROUP, DESIGNATED A, B, C, D, AND E. GROUP A SHOULD BE THE PRIMARY GROUP FOR INTERVIEWING AND PHYSICAL EXAMINATION, WITH REPLACEMENTS FROM THE OTHER GROUPS, IF NECESSARY. THE FOLLOW UP OF THE ENTIRE GROUP IS NECESSARY IN ORDER TO BE ABLE TO DETERMINE AND TO ADJUST FOR THE MORTALITY EXPERIENCE DURING THE FOLLOW UP PERIOD OF THE STUDY. THE NUMBER OF DEATHS TO BE EXPECTED SHOULD BE ESTIMATED USING NATIONAL MORTALITY DATA (SPECIFIC FOR AGE, COLOR, ETC.) AND REDUCING THESE RATES BY ABOUT 20-25 PERCENT TO TAKE INTO ACCOUNT THE "HEALTHY WORKER" EFFECT.

d. EVERY EFFORT SHOULD BE MADE TO DECREASE THE VARIABILITY OF OBSERVATIONS AND DATA COLLECTED IN THE STUDY. AN EXPERIENCED SURVEY RESEARCH CENTER SHOULD BE USED TO COLLECT INTERVIEW INFORMATION. IF TELEPHONE INTERVIEWING IS UTILIZED, CONSIDERATION SHOULD BE GIVEN TO SELECTING SAMPLES FOR FACE-TO-FACE HOME INTERVIEWING (THIS WILL ALSO IMPROVE THE VALIDITY OF SUCH DATA). PSYCHOLOGICAL TESTING AND PHYSICAL EXAMINATIONS SHOULD BE PERFORMED AT ONE CENTER. IF SEVERAL CENTERS ARE NECESSARY FOR LOGISTIC REASONS (AND THEY SHOULD NOT BE AS MANY AS PRESENTLY STATED IN THE PROTOCOL), THEN PROCEDURES SHOULD BE DEVELOPED TO HAVE THE CASES AND THEIR MATCHED CONTROLS EXAMINED AT THE SAME CENTER, (I.E. EACH CENTER WOULD BE CONSIDERED AS A SEPARATE STRATUM). ON SAMPLES OF SUBJECTS, DUPLICATE EXAMINATIONS (BY DIFFERENT EXAMINERS) SHOULD BE PERFORMED. SINCE IT IS DIFFICULT TO DO THIS ON THE SAME DAY, THEY COULD BE DONE A MONTH OR TWO AFTER THE FIRST ONE. FOR LABORATORY WORK, DUPLICATE BLIND SPECIMENS (UNKNOWN TO THE LABORATORY) SHOULD BE SENT TO THE LABORATORY.

DASG- AFEB 79-4

SUBJECT: Recommendations concerning protocol for "Epidemiologic Investigation of Health Effects in Air Force Personnel Following Exposure to Herbicide Orange."

PRESENT PLANS CALL FOR OBTAINING INFORMATION ON MORBIDITY. DURING THE INTERVIEW, SUBJECTS SHOULD BE ASKED REGARDING THEIR HISTORY OF HOSPITALIZATIONS, WHICH SHOULD INCLUDE NAME AND ADDRESS OF HOSPITAL AS WELL AS TIME OF HOSPITALIZATION. THIS INFORMATION SHOULD BE VALIDATED BY WRITING TO A SAMPLE OF HOSPITALS TO OBTAIN COPIES OF HOSPITAL RECORDS, ETC. A SIMILAR PROCEDURE SHOULD BE CARRIED OUT FOR DIAGNOSES MADE DURING VISITS TO PHYSICIANS.

SINCE CHLORACNE IS REGARDED AS A SPECIFIC MARKER FOR HERBICIDE ORANGE EXPOSURE, AS PART OF EACH EXAMINATION PHOTOGRAPHS SHOULD BE TAKEN OF THOSE SPECIFIC PARTS OF THE BODY WHERE THIS CONDITION OCCURS FOR ALL SUBJECTS IN THE STUDY. IT WOULD THEN BE POSSIBLE TO HAVE A CENTRAL GROUP READ THESE PHOTOGRAPHS WITHOUT KNOWLEDGE OF WHETHER AN INDIVIDUAL WAS A CASE OR CONTROL OR HAD A DIAGNOSIS OF CHLORACNE.

2. Attached is the Ad Hoc Subcommittee report which presents the issues considered by the group and the rationale for these recommendations.

FOR THE ARMED FORCES EPIDEMIOLOGICAL BOARD:


CHARLES W. HALVERSON
CDR, MSC, USN

CF:
Board Members
ASD(HA) Spec Asst Prof Act
Ch, Prev Med Div, OTSG-DA
Dir, Occup & Prev Med Div, BUMED-DN
Ch, Prev Med, OTSG-DAF



DEPARTMENT OF DEFENSE
ARMED FORCES EPIDEMIOLOGICAL BOARD

10 OCT 1979

AFEB
ADDRESS REPLY TO

MEMORANDUM FOR BOARD MEMBERS AND ADVISORS

SUBJECT: Report of the Evaluation of Protocol for "Epidemiologic Investigation of Health Effects in Air Force Personnel following Exposure to Herbicide Orange"

1. In response to a request from the Surgeon General of the Air Force, copy attached, an Ad Hoc Subcommittee of the Subcommittee for Environmental Quality met to conduct a review of an epidemiological protocol to study the health effects in Air Force personnel exposed to Herbicide Orange in Vietnam.
2. On August 30, 1979, the Protocol-Project Ranch Hand II: Epidemiologic Investigation of Health Effects of Air Force Personnel Following Exposure to "Herbicide Orange" was presented to the Ad Hoc Subcommittee. During the presentation, questions and issues were raised and discussed with the various members of the group presenting the protocol. After the presentation, the Subcommittee met in executive session to discuss various issues and make recommendations. Participants are listed on Inclosure (1).
3. To facilitate interpretation of the issues and questions raised by members of the Subcommittee in this report, the issues will be first stated and/or discussed followed by the specific recommendation which represented the consensus of the Ad Hoc Subcommittee.
4. The members of the Subcommittee agreed in indicating that a considerable amount of careful thought had gone into the preparation of the protocol; that it was generally a very good protocol; that the individuals who were responsible for its preparation should be congratulated on the manner in which they dealt with a difficult project. The following are the various issues, questions and recommendations on various areas:

I. Credibility. A major problem faced by the Air Force in doing this study is the issue of credibility. If the findings of the study are negative, there will no doubt be accusations of cover-up since the Air Force as a whole may be regarded as not being unbiased in terms of outside groups including segments of the scientific community. It was generally felt that it would be preferable to have the entire project contracted out to a University group to take this criticism into account.

If this cannot be accomplished for the entire study, it is recommended that several components of the study should be contracted out. For example, the telephone interviewing could be contracted with one of several leading survey research centers (National Opinion Research Center, University of Michigan Survey Research Center). These groups are

AFEB

SUBJECT: Report of the Evaluation of Protocol for "Epidemiologic Investigation of Health Effects in Air Force Personnel following Exposure to Herbicide Orange"

experienced in surveys of this type. In addition, it has been the general experience that better cooperation with a higher response is obtained by an independent nongovernmental agency.

The physical examination of the subjects should also be contracted out to one single center or to a few groups, each of whom could go to several centers, or to a few groups to whom the subjects would be transported. These are also related to the issue concerning observer variability of interviewing and of examination, which will be discussed later.

Whatever method is used, the Subcommittee recommends that an outside Data Monitoring Committee be established that would meet frequently to review the various research instruments, data collection and analytical procedures. An Audit Committee of outside scientists should be established to develop necessary procedures for review of the interviews, death certificates that are collected in the study either totally or on a sampling basis. In addition, such a committee would have the responsibility of being certain that the quality and integrity of the data used for analysis has been maintained. (Note: This procedure has been successfully used recently in several clinical trials of drugs!)

871
 II. Overkill. In reviewing the content of the interview, psychological and physical examinations, the Subcommittee felt that they were too detailed and intensive, particularly with respect to their content. This is best exemplified by the psychological examination which would require testing subjects for 5-1/2 or 6-3/4 hours alone. The detailed neurological examination will also be time-consuming. The family history of disease, etc. lengthens the time of the interview. It was felt that not many people would subject themselves to such detailed interviewing and examinations, and their cooperation would be lost. Similarly, it was felt that examinations are being done too frequently. The totality represented what the Subcommittee termed "overkill".

The Subcommittee recommended that: (1) several components of the interview be eliminated or condensed; (2) one psychological examination be adopted; (3) the physical and neurological examinations be shortened; (4) the detailed examinations be done during the first and fifth year of the follow up; (5) between the first and fifth year of follow up, information on health status be obtained by mailed questionnaire annually regarding morbidity, hospitalization, absenteeism from the job, etc. This could be accomplished by corresponding with the subjects and their employers.

III. Selection of Controls. The Subcommittee felt that the size of the control group was numerically inadequate, especially for a mortality analysis. It was recommended that the control group be increased in size so that it was five times the size of Ranch Hand. The entire group should be followed to determine their mortality experience.

10 OCT 1979

AFEB

SUBJECT: Report of the Evaluation of Protocol for "Epidemiologic Investigation of Health Effects in Air Force Personnel following Exposure to Herbicide Orange"

M.K. /
Five samples should be selected from this group, designated A, B, C, D, and E. Group A should be the primary group for interviewing and physical examination, with replacements from the other groups, if necessary. The follow-up of the entire group is necessary in order to be able to determine and to adjust for the mortality experience during the follow-up period of the study.

The Subcommittee also recommended that the number of deaths to be expected should be estimated using national mortality data (specific for age, color, etc.) and reducing these rates by about 20-25% to take into account the "healthy worker" effect. This would at least provide some estimate of expected attrition due to mortality.

IV. Variability of Observations and Validity of Data. The Subcommittee was quite concerned with the variability of the various types of data to be collected in the study. Every effort should be made to decrease it. An experienced survey research center should be used to collect interview information. If telephone interviewing is utilized, consideration should be given to selecting samples for face-to-face home interviewing (this will also improve the validity of such data). Psychological testing and physical examinations should be performed at one center. If several centers are necessary for logistic reasons (and they should not be as many as presently stated in the protocol), then procedures should be developed to have the cases and their matched controls examined at the same center, (i.e. each center would be considered as a separate stratum). On samples of subjects, duplicate examinations (by different examiners) should be performed. Since it is difficult to do this on the same day, they could be done a month or two after the first one. For laboratory work, duplicate blind specimens (unknown to the laboratory) should be sent to the laboratory.

Essentially, every effort should be made to decrease the variability of measurements that are to be made. Present plans call for obtaining information on morbidity, etc. during the interview. Subjects should be asked regarding their history of hospitalizations, which should include name and address of hospital as well as time of hospitalization. This information should be validated by writing to a sample of hospitals to obtain copies of hospital records, etc. A similar procedure should be carried out for diagnoses made during visits to physicians.

A specific recommendation relative to variability should be mentioned. Since chloracne is regarded as a specific marker for herbicide orange exposure, it is recommended that as part of each examination, photographs be taken of those specific parts of the body where this condition occurs for all subjects in the study. It would then be possible to have a central group read these photographs without knowledge of whether an individual was a case or control or had a diagnosis of chloracne.

10 OCT 1970

AFER

SUBJECT: Report of the Evaluation of Protocol for "Epidemiologic Investigation of Health Effects in Air Force Personnel following Exposure to Herbicide Orange"

V. Exposure Index. As part of the protocol, an attempt will be made to develop an exposure index so that data could be analyzed in terms of degree of exposure. This was generally considered to be desirable. However, after the conditions under which Ranch Hand operated, several members of the Subcommittee felt that this would not be profitable because of inadequate information. No consensus was reached.

Anna M. Baetjer

ANNA M. BAETJER, D.Sc.
Director, Subcommittee on Environmental
Quality and Chairperson, Ad Hoc
Subcommittee on Herbicide Orange Protocol
Review