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Report/Article Title Minutes - Agent Orange Working Group (AOWG) Science Panel Meeting, November 16, 1984 with attachments (a) Alternate Methods for Assigning Agent Orange Exposure Status to Vietnam Veterans, (b) Epidemiologic Studies of the Health of Vietnam Veterans, Vietnam Experience Study, Interim Report, November 9, 1984, (c) Memorandum from Vernon Kouk to Edward N. Brandt, Jr. regarding Possible Study of Female Vietnam Veterans

Journal/Book Title

Year 1984

Month/Day

Color

Number of Images 34

Description Notes Duplicate items for Attachment B

Minutes of
November 16

Minutes of the November 16, 1984 meeting of the Science Panel of the Agent Orange Working Group

The Science Panel of the AOWG met in room 729G of the Hubert Humphrey building at 9:30 AM on November 16, 1984. Attendees were as listed on the attached attendance sheet and several items were discussed as follows:

- 1) Exposure Opportunity Index. An index to characterize the likelihood that an opportunity for exposure to Agent Orange occurred to individual veterans while in Vietnam has been developed by CDC and the Joint Services Environmental Support Group. Such an index was used in the CDC Birth Defects Study and will be used in other upcoming epidemiological studies of Vietnam veterans. The Science Panel will review the procedures employed for this index during a meeting to be held at the offices of the Joint Services Environmental Support Group, room 210, 1730 K St. N.W., Wash., DC., on November 29, 1984. A brief write-up of the development of these procedures was handed out as a preliminary to the next meeting and is included as a part of these minutes at Attachment A- Alternate Methods for Assigning Agent Orange Exposure Status to Vietnam veterans.
- 2) Results of the Pilot Test of the Vietnam Experience Study. An 'Interim Report' dated November 9, 1984, was prepared by CDC Agent Orange Projects staff and mailed to members of the Science Panel prior to the November 16 meeting. A copy of this report is included with these minutes at Attachment B and was discussed at length during the meeting. As can be seen in the report, there was little reason for concern over the locatability of identified Vietnam Era veterans nor their willingness to participate in the study. The pilot test yielded response rates well over those which had been anticipated. Proposed modifications to the questionnaire were discussed to the satisfaction of the Science Panel.

During the discussion of the questionnaire, it was pointed out that currently there is no provision for verifying, from medical records, any of the health information obtained at interview. A difference in the rate of self-reported adverse health conditions can be difficult or impossible to interpret where there is a potential for biased reporting between study groups. This is particularly true for reproductive outcomes reported by men. Recent experience with the results of the Air Force Project Ranch Hand II Morbidity Study Baseline Results should illustrate this, even with reproductive data reported by wives. The prospect of obtaining medical verification for all health and reproductive outcomes is a formidable task, even when appropriate information is obtained during the interview phase. For some outcomes of interest such as Birth Defects, restricting verification to participants in the examination phase may not provide sufficient statistical power.

On the other hand, it is feared that not collecting information on such outcomes may render the study unacceptable to some interested parties, particularly the Congress. At any rate, members of the Science Panel feel that some provision for the analysis, presentation and interpretation of self-reported health and reproductive outcome data must be developed before the study is too far underway. In the interest of not causing undo delay in the progress of the study, the Science Panel recommends that the data collection phase of the Vietnam Experience Study proceed as it is currently scheduled, and that the CDC Project Agent Orange Staff prepare plans for the scientific utilization of self-reported health data, including reproductive outcome data collected during the interview phase.

- 3) Female Vietnam Veterans Health Study. Members of the Science Panel were provided with a memorandum dated November 13, 1984 from the Director, CDC to Dr. Brandt regarding a 'Possible Study of Female Vietnam Veterans'. A copy of this memo is included with these minutes at Attachment C. The memo basically reiterates and acknowledges the concerns already expressed by the Science Panel in our report to the AOWG. Dr. McConnell pointed out that previous scientific information suggests that females are far more susceptible to chemical insult to the reproductive system and that any serious attempt to measure adverse reproductive effects due to pesticide exposure should focus on exposed women. Dr. Lipnick reported that so far it appears that none of the female veterans who served in Vietnam would be regarded as having been exposed to Agent Orange or other herbicide according to the available records. The Science Panel feels that a study of female Vietnam veterans must be regarded as a Vietnam Experience study and a decision to study this group should be based on needs other than a further understanding of the possible adverse health effects from exposure to herbicides and their contaminants.
- 4) VA Twin Study. A request from Dr. Houk to ask about the current status of the Twin Study reveals that the study has not yet been totally abandoned. It appears that the Science Panel may be asked to review the Examination Phase Protocol before a final decision is made. Members of the Science Panel will be kept informed.

The Science Panel meeting adjourned at 12:40 PM on November 16, 1984.

AOWG Science Panel Meeting
November 16, 1984

Carl Keller	Chair	NIEMS	496-3511
Peter Layde		CDC	236-4460
Michael Kafrisen		CDC	
LAWRENCE B. HOBSON		VA	389-5534
Barclay M. Shepard		VA	376-7528
John Jones		OTA	226-2070
MICHAEL GOUGH		OTA	226-2070
Jerome G. Bricker		OASD(CHA), DoD	697-8975
DOUG CLARK		U.S. ARMY	653-1829
DICK CHRISTIAN		U.S. ARMY	653-1828
ROB KANICK		US ARMY	653-1835
Reate Kimbrough		CDC	FTS 236-4323
Helen Mc Connell		NTP/NIEMS	" 629-3267
Rizwanul Haque		ORD/EPA	382-5967
Peter E. ...		HHS/US/OVA	245-6156
Stephen Malinger		OSHA/DOL	523-7031
Lt Col ROBERT CAPELL		AP/S&ES	267-5078
AL YOUNG		OBTB	395-3125
John Allen		OSD (HA), DoD	697-8976
Marilyn Fingulst		NIOSH	684 8411

Attachment A

Alternate Methods for Assigning Agent Orange Exposure Status
to Vietnam Veterans

Some time ago the Joint Services Environmental Support Group (then the Army Agent Orange Task Force (AAOTF)) began to develop methods to estimate potential exposure to Agent Orange among Vietnam veterans. The method to be used in the proposed Agent Orange Morbidity and Mortality Studies currently underway by CDC involves detailed day-by-day tracking of both military units and individuals while in Vietnam. Amassing the information necessary to do this requires considerable effort and yields simultaneous information on all of the members of a given military unit. The method is thus suitable for identifying cohorts, but is extremely inefficient for determining potential exposures of individuals selected by other means. Furthermore, the necessary records apparently do not exist for many units in Vietnam, particularly non-Army units, and is the major reason why the CDC Epidemiological studies are confined to veterans of the Army.

In order to obtain some information on the possible exposure to Agent Orange of veterans identified through other sources, an alternative method was proposed by the AAOTF. This method was generated by a desire to assign some exposure status to Vietnam veterans identified during the CDC Birth Defects Study, but was also considered apposite for other studies as well. The alternative method begins with the identification of the unit or units to which a given veteran was assigned and then obtains the quarterly reports of the unit or units during the time that the veteran was assumed to be present. The quarterly reports contain information on the place that the unit operated in or from during the quarter, and some indication of specific actions (along with their locational grid coordinates) which occurred during the quarter. These are then matched up with

known herbicide applications from the HERBS and Services HERBS tapes. In addition, the military occupational specialty of the veteran is considered in estimating the probability that he may have been exposed to Agent Orange during the application or incident in question.

The alternative method does not provide an estimate of the extent of possible exposure to Agent Orange. It was intended to provide an estimate of the likelihood that an individual veteran could have been exposed at all, and for this reason was called an Exposure Opportunity Index. "Exposed at all" essentially meant that the veteran had been within 2 kilometers within 3 days of an Agent Orange application or dump, or had handled, applied or cleaned up herbicide while in Vietnam. The value assigned to each veteran reflects the likelihood that he had had an opportunity for at least one such exposure.

Unfortunately, it is easy to mistakenly interpret higher values of the Index as greater exposures and inadvertently ascribe a dose response capability to the Index.

Another issue which must be considered when interpreting results based on use of the Exposure Opportunity Index is the potential for confounding with other important attributes of the Vietnam experience. In particular, more opportunities for exposure to Ranch Hand spray applications were likely to occur among the most mobile troops, and mobility of the occupational specialty is quite appropriately considered in assigning an estimate of the opportunity for exposure. Unfortunately, the more mobile troops were also more likely to have been exposed to combat, and thus combat experience can easily be confounded with the opportunity for exposure to Agent Orange afforded by entering a Ranch Hand mission spray area.

The major reasons for reviewing current and proposed procedures for assigning an Exposure Opportunity Index are to evaluate previous results and assist the Joint Services Support Group in formulating the use of the Index for upcoming studies. In particular, the Veteran's Administration Mortality Study and the Soft Tissue Sarcoma Studies of CDC and the VA-AFIP are due to begin this assessment in the near future. Included with this description of the alternate method for assigning exposure opportunity indices are a current DRAFT of the two level index under consideration by the support group and a short description of the indices as utilized in the recently completed CDC Birth Defects Study.

ATTACHMENT "D"**AGENT ORANGE EXPOSURE CRITERIA
For Use With
The Alternative Exposure Methodology****1. Exposure Opportunity Extremely Likely:**

- A. U.S. Army Chemical unit personnel and Army Aviation personnel involved in herbicide spray operations**
- B. All personnel who were within 2 kilometers or less distance from a Ranch Hand Agent Orange Herbicide mission track including aborted Agent Orange dumps within a 72 hour period immediately after the spraying or dump.**
- C. Documented ground handler of herbicide drums.**
- D. All personnel who worked on Ranch Hand herbicide leaks (e.g. base civil engineer personnel) and herbicide leak clean up operations.**
- E. U.S. Air Force Ranch Hand personnel**
- F. All personnel who were within 2 kilometers or less distance from either a helicopter and/or perimeter/ground spraying of Agent Orange and within a 72 hour period immediately after the spraying.**

2. Exposure Opportunity Extremely Unlikely:

- A. Personnel operating offshore and the ship does not have its home port in Vietnam (does not include riverine personnel).**
- B. Marine Corps, Navy, Air Force pilots and crewmembers (Non-Ranch Handers) who were not based in Vietnam.**
- C. All other personnel located or operating beyond a 2 kilometer distance of a Ranch Hand spray mission track or aborted Agent Orange dump within the 72 hour period after the spraying or dump or at a later time.**
- D. All personnel who were located or operating beyond a 2 kilometer distance from either a helicopter and/or perimeter/ground spraying of Agent Orange within the 72 hour period following the spraying or at a later time.**

An Opportunity for Exposure Index (OEI) as Used in the CDC
Birth Defects Study

The CDC Birth Defects Study results include regression coefficients for each of the birth defect categories against two indices of opportunity for exposure to Agent Orange. Both of the indices were derived by considering the likelihood that a veteran with a particular job assignment during a particular time at a particular place in Vietnam would have had an opportunity for at least some exposure to Agent Orange. The job assignment and the time and place of service were included in the telephone interview as well as in the personnel record files in St. Louis, MO. Index number one was based on the information contained in the personnel records. Index number two was based on information obtained during the interview. Any differences in the assigned values of the two indices for a particular veteran are generated by differences in the ascribed job, place and/or time of service in Vietnam according to the two data sources. The number of cases and controls with an assigned value for index number two is about 10% greater than for Index number one. As a result of the failure to locate personnel folders for some veterans before the end of the study, which of the two indices is the more accurate has not been resolved.

Table 5. Examples of Agent Orange Exposure Opportunity Index Scores*

Index Score = 1 (minimum opportunities for exposures)

1. Service in selected locations at specific times
(any job description except handling Agent Orange)
e.g., Cam Ranh Bay (66)
Qui Nhon (68-69)
Nha Trang (67-68)
2. Non-Ranch Hand pilots and aircrew (66-67)
3. Specified Controlled Environments
e.g., battalion surgeon (68)

Index Score = 2

1. Service in selected locations at specific times
e.g., Gia Le (69-70)
Phan Rang (other than 9-12/68, 3-9/70)
Qui Nhon (68-69)
2. Selected noninfantry occupations at specified places and times
e.g., company clerk — Duc Pho (68-69)
radio repairman — Chu Lai (66-67)
truck driver — Cu Lam Nam (68)
3. Noninfantry stationed at selected bases with perimeter spraying
e.g., wireman — Chu Lai (68-69)

Index Score = 3

1. Service at bases with perimeter spray operations, specified times
e.g., Chu Lai (68-69) — Camp Eagle (68-69)
LZ English (67-68)
2. Selected noninfantry occupations at specified locations and times
e.g., salvage specialist — Danang (69-70)
M.P. — Danang (68-69)
wheeled vehicle mechanic — Long Binh (66-67)

Index Score = 4

1. Infantry combat arms at specified locations and times
e.g., An Khe (66-67)
Tam Ky (67-68)
Tay Minh (69-70)
2. Selected noninfantry at specified locations and times
e.g., Helicopter pilot — Cu Chi (66-67)
M.P. — Long Binh (67-68)
3. Advisors of Army, Republic of Vietnam Divisions (68-69)
4. Special Forces Camps (field personnel)
e.g., Nha Trang (69-70)

Index Score = 5 (most numerous opportunities for exposure)

1. Infantry/combat arms at specified locations and times
e.g., A Shau Valley (69)
Tay Ninh (68)
Phuoc Vinh (67)
2. Service at specified locations and times with aborted Ranch Hand missions
or other herbicide mishaps
e.g., Bien Hoa AFB (7/67, 11/68)
Long Binh Post (67-69)
Phu Cat AFB (69-70)

*See text for description.

APPENDIX C

CDC BIRTH DEFECTS STUDY Page 359

ALL CASE BABIES

Group	Case	Control	Case	Control	Case	Control
Case	1	1	1	1	1	1
Control	2	2	2	2	2	2
Case	3	3	3	3	3	3
Control	4	4	4	4	4	4
Case	5	5	5	5	5	5
Control	202	202	202	202	202	202
CLEAR						
Case	319	319	319	319	319	319
Control	498	498	498	498	498	498
Case	346	346	346	346	346	346
Control	548	548	548	548	548	548

Attachment B

EPIDEMIOLOGIC STUDIES OF THE HEALTH OF VIETNAM VETERANS

CENTERS FOR DISEASE CONTROL
Agent Orange Projects
Chronic Diseases Division
Center for Environmental Health

Vietnam Experience Study

INTERIM REPORT
November 9, 1984

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I. INTRODUCTION

One year ago the Centers for Disease Control (CDC) published the approved protocol for the Epidemiologic Study of the Health of Vietnam Veterans. Since then the Agent Orange Projects (AOP) staff at CDC and officials of collaborating government agencies have made considerable progress in implementing the study protocol.

Several contracts have already been negotiated and signed for data collection activities. Solicitation and evaluation of proposals for several additional contracts have now been completed, and these contracts will be awarded within the next several months.

CDC has developed the operational methods and logistic systems necessary to conduct such a large study. The interview instrument (questionnaire) was developed based on consultations with appropriate experts, then refined and programmed on a Computer Assisted Telephone Interviewing (CATI) system.

Finally, a "pilot" test of the interview methods was conducted. As described in the protocol, the "pilot" study was the final process of assessing participation rates and the study instruments just before the start of the main cohort study. The pilot test indicated that the military record review, tracing, and interviewing methods to be used in the main study are successful.

The timing of this interim report was influenced by a request from the Office of Management and Budget (OMB) that AOWG review the pilot test and resultant modifications to the questionnaire to determine if the Vietnam Experience Study should proceed on schedule in January. CDC believes that the feasibility of the Vietnam Experience Study has been established by the pilot test and a series of pretests conducted earlier. Agent Orange Projects staff are prepared to begin the main study interviews for the Vietnam Experience Study in January 1985. Only relatively minor changes in the methods and questionnaire used in the pilot test will be necessary.

It should be emphasized that, at this time, CDC is only seeking concurrence to proceed with the main phase of the Vietnam Experience Study. Although the Agent Orange Study uses many of the same methods as the Vietnam Experience Study, it also requires the additional step of estimating the likelihood of exposure to Agent Orange. Moreover, sampling methods to identify study participants are more complicated in the Agent Orange Study than in the Vietnam Experience Study. Pretests of methods specific to the Agent Orange Study continue and will be reported to AOWG in early 1985, prior to beginning the main phase of the Agent Orange Study.

This report presents results of the pilot study of the questionnaire and veteran tracing and participation, a brief update on operational methods of the Vietnam Experience Study, and CDC's plans for initiating the main Vietnam Experience Study in January 1985.

II. PILOT TEST AND QUESTIONNAIRE MODIFICATIONS

On August 1, the Centers for Disease Control (CDC) awarded Research Triangle Institute (RTI) of Research Triangle Park, North Carolina, a contract to locate and interview five groups (cohorts) of Vietnam-era Army veterans as part of the overall Agent Orange Projects activity. The contract called for a pilot study of tracing methods and questionnaire administration on a random sample of 300 Vietnam-era veterans to be conducted between August 1 and December 31. The 300 veterans were identified by the U.S. Army & Joint Services Environmental Support Group (ESG).

The process of tracing veterans, i.e., locating a current address and phone number, began on August 20 following three weeks of preparatory work. After extensive training of the interviewers, telephone interviewing began on September 26. All tracing efforts for the pilot test, as well as computer assisted telephone interviewing (CATI), were cut off on October 28 to allow time for coding, editing, and other "clean-up" activities.

Table 1

STATUS OF PRE-TEST GROUP (AS OF 10-28-84)

Total	300
Completed interview	249
Unable to locate	25
Unable to contact	18
Initial refusals	7
Final refusals	1

As of October 28, 249 of the 300 veterans had been located and interviewed. This amounts to a 83% location/interview rate. This overall success rate is quite remarkable in a study of this nature and far surpasses CDC's goal of 70% for the pilot study. Table 1 shows a breakdown of the current status of the 300 veterans. From these figures, a location success rate can be calculated as 275/300 or 92 percent. This level may understate the rate expected in the main study since only 2 months was available for tracing activities in the pilot phase whereas up to 10 months will be available in the main study.

The participation rate among those contacted was 249/257 or 97 percent. This cooperation on the part of Vietnam-era veterans, indicates that, once veterans are located and contacted, an extremely high level of interview completion can be expected. The participation rate in the pilot test far exceeds that found in general population health surveys.

Contractors' interviewers have confirmed the positive reaction of veterans asked to participate. As rated by these interviewers, respondent cooperation was "good" or "very good" in 97 percent of the interviews. It should be noted that the interviewers are experienced in conducting health surveys.

The average duration of the first 219 interviews was 35 minutes; only 7 lasted 1 hour or more. These data indicate that the pilot study questionnaire is of an acceptable length and time considerations need not dictate changes for the main study.

RTI has delivered all data collected from the first 193 interviews to CDC. Of these, 159 (82 percent) veterans said they had received the introductory letter and Fact Sheet from CDC Director, Dr. James O. Mason. Veterans who had not received this material were read a summary including the elements of informed consent before proceeding with the interview.

There was no sign of systematic refusal to answer sections of the questionnaire dealing with "sensitive" topics such as income, alcohol consumption, illicit drug use, combat exposure, and various psychological experiences. Notably, there were only two refusals on income and only one on use of illicit drugs.

In response to concerns of the CDC Institutional Review Board, RTI interviewers were trained to note any signs of distress in respondents following the questions on combat exposure and psychological experiences. Of 97 Vietnam veterans who were asked the combat questions, only 7 were judged to have shown any sign of distress during this section. The effects of the psychological questions were recorded in only 81 of the 193 interviews due to a temporary malfunction of the CATI system early in the pilot test. Interviewers noted that eight of these 81 veterans revealed signs of distress. These figures should be interpreted cautiously since interviewers may have been overly sensitive to this issue in the pilot study and erred on the side of overreporting signs of distress.

In response to a requirement by OMB regarding the format of the Psychological section, CDC made these questions fit the model used in the Veterans Administrations Vietnam-era Twins Study (VETS). This format seemed to work well in the pre-test except for some respondent confusion regarding subtle differences in meaning among some of the questions.

Overall, the questionnaire and its implementation on the CATI system at RTI were very successful during the pilot phase. The questionnaire was of appropriate duration for a telephone interview and was well accepted by veterans being interviewed. The CATI system contributed to the interviewers' efficient administration of the instrument and permitted immediate detection and correction of inconsistent or questionable responses. Despite the size and complexity of the questionnaire, only one problem in the CATI program occurred. As mentioned above, the interviewer's assessment of respondent distress in the psychological section was not recorded for the first 81 interviews. This error was quickly corrected and no other problems with the CATI system arose.

For the study beginning in January, only minor changes will be made from the instrument version used in the pilot (Attachment A). The modifications are based on advice from interviewers who administered it and from analysis of veterans' responses during the first 193 interviews. A few questions have been deleted after being deemed unproductive. The most significant change is the restructuring of several sections to improve efficiency and comprehensibility.

III. STUDY OPERATIONS

The success of the pilot test is obviously extremely encouraging. By itself, however, a successful pilot test with 300 participants does not necessarily ensure success in the main study involving over 17,000 eligible veterans and at least 12,000 interviews in a one year time period. When the main interview phase of the Vietnam Experience component begins, CDC will monthly receive large amounts of data related to participating veterans from seven government agencies and numerous private contractors.

The obstacles to identifying, locating, and interviewing the thousands of veterans selected for the Vietnam Experience Study are formidable and could not be overcome without the excellent cooperation of a number of Federal agencies, particularly ESG, National Personnel Records Center (NPRC), Reserve Components Personnel and Administration Center (RCPAC), the Internal Revenue Service (IRS), Social Security Administration (SSA), National Center for Health Statistics (NCHS), data management components of the Veterans Administration, and the National Institute of Occupational Safety and Health (NIOSH). With the cooperation of these agencies the CDC Agent Orange Projects staff has developed and implemented the procedures described below to ensure that these data flow efficiently throughout the Vietnam Experience component of the investigation. Many of these procedures are well underway which will permit the main study interviews to begin on schedule.

For this study component 14 independent random samples, each with approximately 3,500 veterans, were selected from tapes supplied by the National Personnel Records Center. The tapes include the "universe" of all discharged Vietnam-era veterans whose records are stored at NPRC. Each monthly sample flows through the record abstraction, locating, and interviewing systems as an independent entity.

Labeled data collection forms are printed by CDC and sent to NPRC, RCPAC, and ESG. The records are collected by NPRC and forwarded to RCPAC. RCPAC does initial disqualification of the veterans on the basis of rank, period of service, number of tours, and so on, as spelled out in the protocol. Records of qualified veterans are sent to ESG, which abstracts information on qualified veterans and forwards the abstract forms to CDC for keypunching and editing. A "data flow diagram" for this qualification process is shown in Attachment B.

To find current locating information for qualified veterans, their names and social security numbers are sent to the IRS, SSA, the Veterans Administration's Beneficiaries Identification and Records Locating Sub-System (VA-BIRLS) and Home of Veterans Record Center (VA-Hines), and NCHS's National Death Index (NDI). IRS and VA-Hines provide recent address information; SSA, NDI, and VA-BIRLS provide vital status data (Attachment C).

Name and most recent known address information for qualified living veterans will be sent to our interview contractors in monthly lists of 1,433 veterans (Attachment D). After the interview, location information

for a random sample of those who have been interviewed will be sent to the contractor responsible for conducting the medical examinations for use in contacting veterans to be asked to participate in this clinical examination phase.

The current status of veteran identification and location efforts that have been conducted in preparation for the main phase of the Vietnam Experience Study are shown in Table 2. As shown, we have a "head start" on information needed by the interviewing contractor in January, due largely to the excellent cooperation of all participating agencies. Both the data in Table 2 itself, as well as the existence of effective cooperative mechanisms evidenced by that data, lead CDC to believe that logistic problems will not impede the timely completion of the Vietnam Experience Study.

Table 2

VIETNAM EXPERIENCE STUDY

Veteran Identification and Location
Status on November 9, 1984

<u>Task</u>	<u>Current Total</u>	<u>Number Required per Month</u>
Records Reviewed-RCPAC	23,947	3,500
Veterans Qualified-ESG	9,084	1,433
Vital Status Determination		
NDI	8,602	1,433
SSA	5,723	1,433
VA-BIRLS-	8,602	1,433
Recent Address Information		
IRS	7,166	1,433
VA-Hines	7,166	1,433
Total Ready for Interview Contractor	7,166	1,433

IV. PILOT STUDY - MAIN STUDY TRANSITION

Main study interviews for the Vietnam Experience Study are scheduled to begin on January 1. To meet this milestone and keep the study on schedule, the questionnaire must be in final form by December 1. RTI, our Interview Contractor, will implement the revised questionnaire on the CATI system and train interviewers on the new system in December. The final IRB approvals will also be obtained during that month. OMB has requested AOWG review of the pilot results and questionnaire modifications prior to implementing the main study interviews.

Based on the success of the pilot study and the implementation of the necessary procedures for the main study, CDC is confident that the Vietnam Experience component can be conducted successfully. With AOWG concurrence and OMB final approval, CDC will begin the main study interviews on schedule in January 1985. CDC will also send this interim report to OTA to assist that office in its monitoring function.

The clinical examination component of the Vietnam Experience Study consists of well tested clinical methods and laboratory techniques. The chief purposes of a planned pilot test of that component are: 1) to assess participation rates in the time consuming phase; 2) to ensure that the complex operational methods needed for the study run efficiently; and 3) to determine the acceptability of study procedures to the participating veterans. If difficulties occur in any of these areas, CDC will certainly consult with its review groups before proceeding with the main study examinations. If no difficulties arise, CDC intends to proceed directly with the main study clinical examinations. CDC will provide its review groups with a report on the examination pilot test, if so requested.

ATTACHMENT A - PROPOSED CHANGES TO QUESTIONNAIRE

1. Medical Section

To reduce the level of redundancy and respondent burden the following changes will be made: (a) eliminating the details on doctor visits during the past 3 months, and treatments ordered by a doctor, and (b) placing the questions on medications, limitations in activities, and hospital visits after all questions dealing with specific diseases and conditions. Also, some redundant questions on digestive system conditions will be eliminated.

2. Pregnancy Section

This section will be reorganized along lines suggested by the interviewers to reduce the time of administration and to structure the section more simply. The same information will be collected in the reformatted version. In addition, some new questions will be added dealing with early childhood health problems and miscarriages.

3. Other Sections

- a) The questions on herbicide exposure will be modified to obtain a better assessment of exposure from the veteran. Specifically, two vague questions will be deleted and another will be reworded.
- b) The section dealing with hospitalizations and doctor visits in the Army will be shifted to a later point in the questionnaire where it will fit better.
- c) The order of the psychological questions will be changed to avoid confusion among veterans, some of whom have failed to note a subtle distinction in meaning among certain questions.

- d) The following questions will be deleted:
 - i) Vocational training - minimal relevance to study
 - ii) Blood transfusions - minimal relevance to study
 - iii) Ever work in the making of herbicides (too rare an occurrence)
 - iv) Ever get malaria or receive malaria treatment in Vietnam
(this information should be reported in military medical section).
- e) The combat exposure questions will be supplemented with questions on the frequency of experiencing each of the five events.
- f) The section on illicit drug use will be modified to simplify its administration, but the same information will be collected.

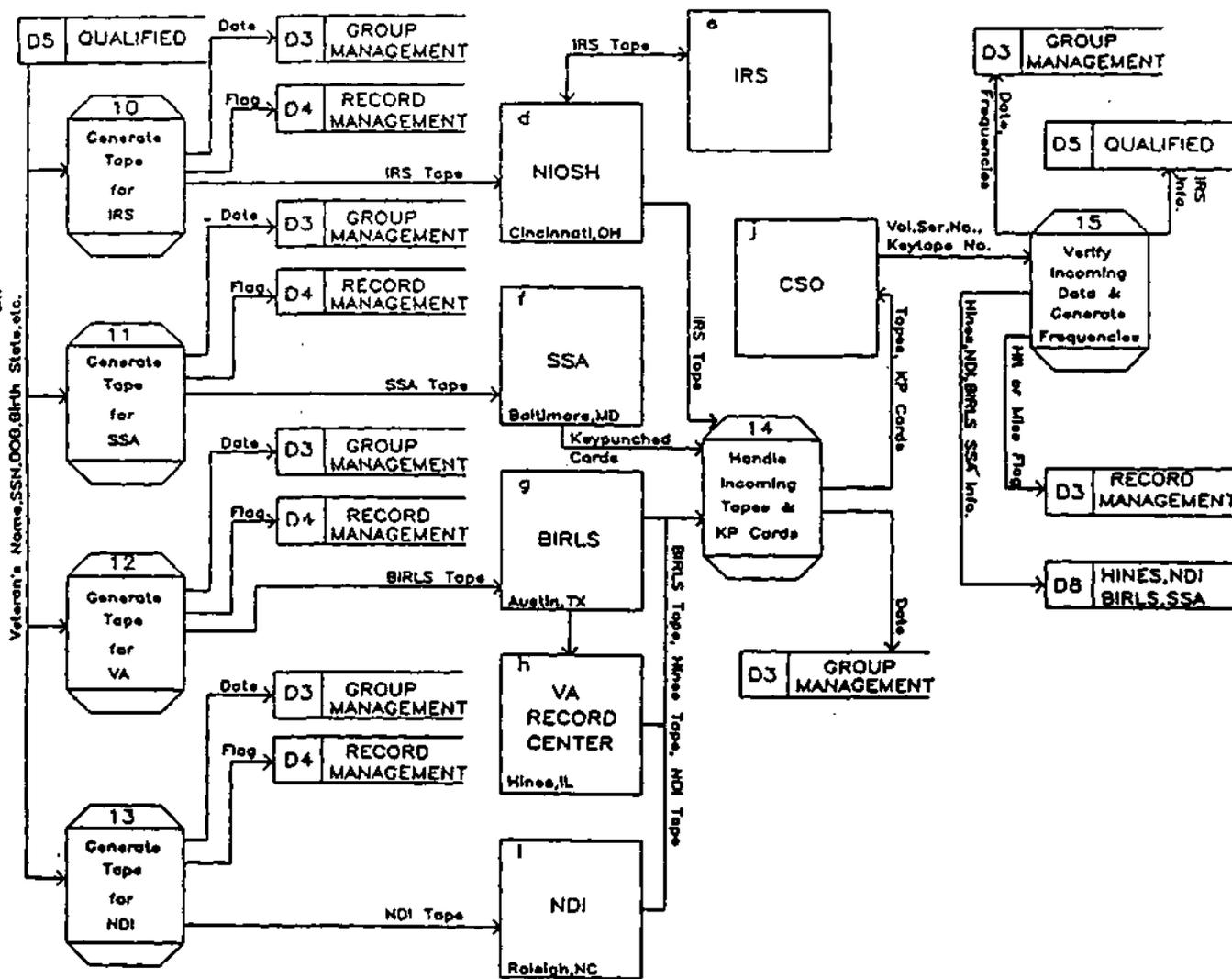
CDC:CEH:CDD:AOP:PLayde:dd

Document No. SEC2-183

11/8/84

Attachment C

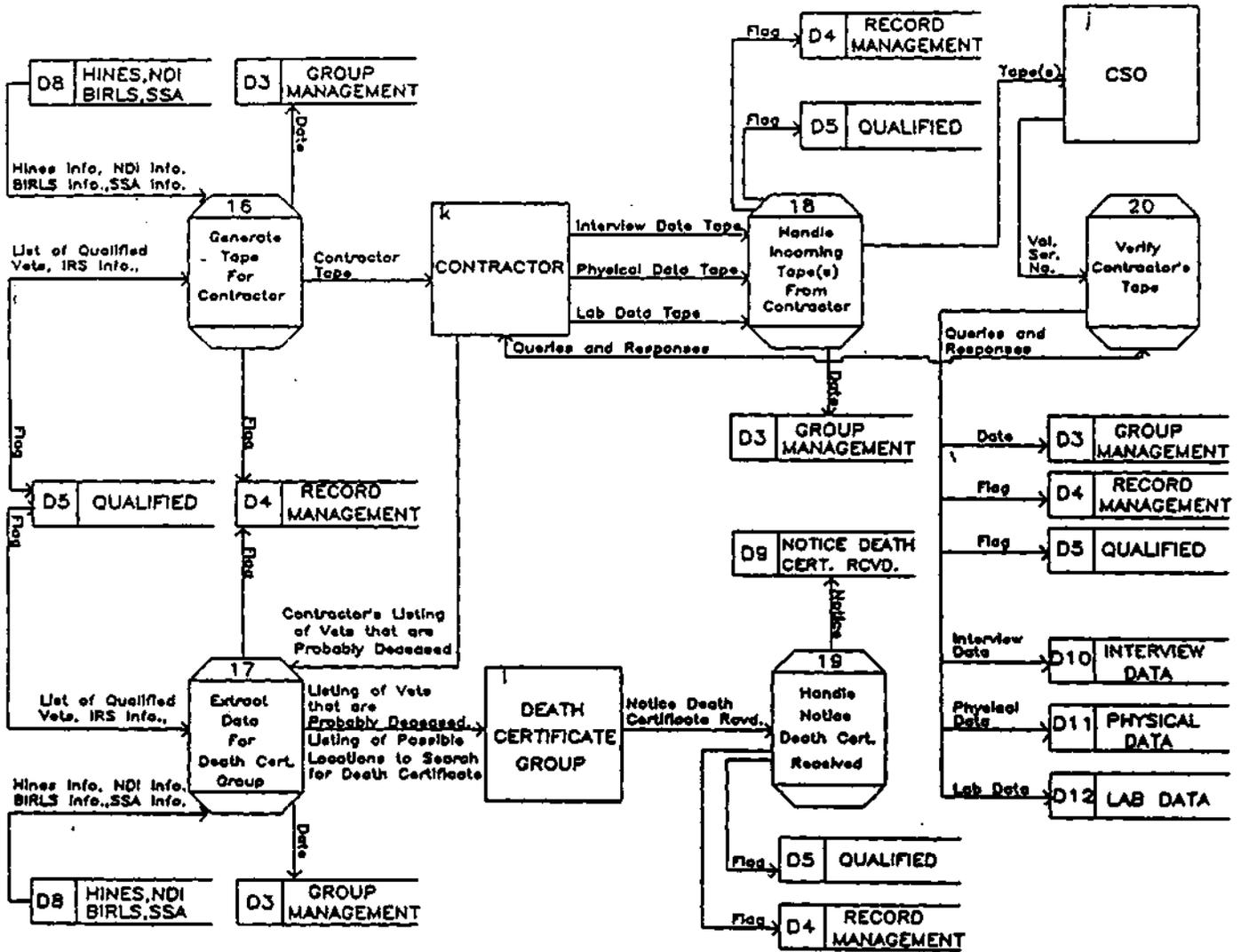
Veteran Tracing - Vietnam Experience Study
 Data Flow Diagram*



*Same as B.

Attachment D

Interview and Analysis Data Management - VES
 Data Flow Diagram*



*Same as B.

Attachment E

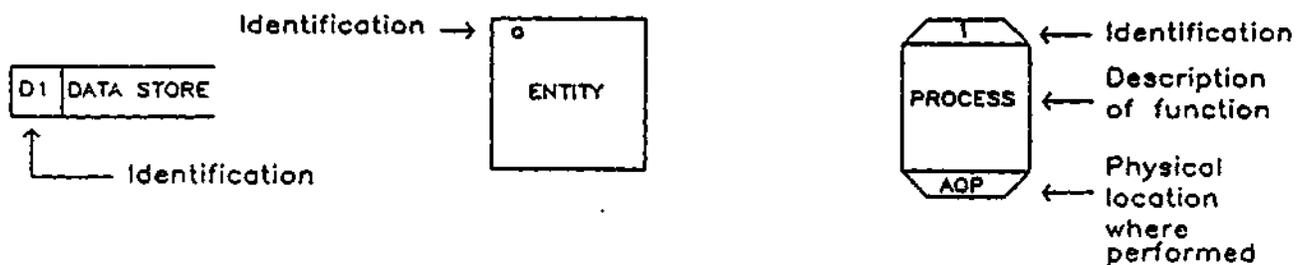
KEY

Data Flow Diagram (DFD) A picture of the flows of data through a system of any kind showing the external entities which are sources or destinations of data, the processes which transform data, and the places where the data are stored.

Data Store Any place in a system where data are stored between transactions or between executions of the system (includes files—manual and machine-readable, data bases, and tables).

Entity 1. External entity: a source or destination of data on a data flow diagram.
2. Something about which information is stored in a data store, e.g. customer, employees.

Process A set of operations transforming data, logically or physically, according to some process logic.



Attachment C

CENTERS FOR DISEASE CONTROL FACSIMILE TRANSMISSION

ADDRESSEE:

Carl Keller

NIEHS

ADDRESSEE TELEPHONE NUMBER 496-3511

FACSIMILE MODEL Xerox 495

FACSIMILE TELEPHONE NUMBER 492-2781

CENTERS FOR DISEASE CONTROL
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DATE 11-14-84 SUBJECT Possible Study of Female Vietnam Veterans

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NOV 18 1984

Memorandum

Date

From Director
Centers for Disease Control

Subject Possible Study of Female Vietnam Veterans

To Edward M. Brandt, Jr., M.D.
Chair Pro Tempore
Cabinet Council Agent Orange Working Group

Thank you for the opportunity to review and respond to the Agent Orange Working Group Science Panel's critique of the protocol outline for a study of female Vietnam veterans. The Science Panel mentioned two issues which they felt must be carefully considered before proceeding further with development of the study:

- 1) "the great potential for confounding exposures both during and after Vietnam to teratogenic agents other than herbicides and their contaminants," and
- 2) "what a study of female veterans will contribute in the way of scientific information which is not already being obtained from the ongoing male studies."

CDC shares the Science Panel's interest in having a research plan which addresses potentially confounding exposures. In this regard, it is important to consider the purpose of the study. As stated in the protocol outline, the proposed study is similar to the Vietnam Experience Study of men currently being conducted. All the exposures unique to the Vietnam environment, from parasitic diseases, to psychological stress, to waste anesthetic gases may influence the health of the Vietnam veteran cohort. Agent Orange is only one of many exposures included in this experience.

For analyses of the effects of Vietnam service in general, exposure to excess waste anesthetic gases in field hospitals in Vietnam would not be a confounder of the association of Vietnam service with health outcomes. Rather, the anesthetic gases are but one of the many exposures that are part of the Vietnam Experience. On the other hand, for analyses focusing on specific exposures experienced in Vietnam, such as Agent Orange, waste anesthetic gas exposure might be a confounder. Such analyses would be expected to control for operating room experience in Vietnam. Occupational exposures, including waste anesthetic gases, experienced after military service might also be potential confounding factors since they could differ between the Vietnam and non-Vietnam female veterans. Again, these exposures would be considered in the analysis.

To respond to the general concern about confounding, CDC would deal with potentially confounding factors in this study with the same approach used in the recent Birth Defects Study and the ongoing study of male veterans.

Detailed information would be gathered from personal interviews and record reviews about potential confounders, e.g., demographic, occupational, or other risk factors for disease that might occur with differing frequencies among Vietnam and non-Vietnam veterans. In the analysis such factors would be controlled for, eliminating any actual confounding effect of these variables.

The second concern of the Science Panel related to the research questions unique to women that would be addressed in the proposed study. As stated above, the study is primarily designed to look at military service in Vietnam, in general, as the main exposure of interest, rather than estimates of Agent Orange exposure. Two caveats should be mentioned regarding the study of Agent Orange exposure, per se, in relation to the health of female Vietnam veterans. First, because of the duties of most women who served in Vietnam, their likelihood of exposure to Agent Orange may be less than that of male Vietnam veterans. Most women who served in Vietnam were stationed at military hospitals or headquarter units that were at some distance from the heaviest Agent Orange sprayings. Second, if, as speculated by some scientists, Agent Orange residues became ubiquitous throughout Vietnam, female Vietnam veterans may have been exposed through food supplies, drinking water, etc. However, these types of exposures could not be quantified by relating the proximity of the woman's units to the Ranch Hand spraying missions or other applications of Agent Orange.

Three broad groups of health outcomes would be studied in relation to Vietnam service: reproductive outcomes, psychologic outcomes, and general health outcomes for which women may experience different risks than men.

Reproductive outcomes would include fertility, spontaneous abortions, and congenital malformations as well as diseases of female reproductive organs. Pregnancy outcomes of the women are of particular interest since maternal exposures are more commonly associated with adverse effects than paternal exposures. Diseases of reproductive organs may be related to the influence of various stresses and insults to the delicate hypothalamic-pituitary-ovarian axis. Also of note in this regard, certain subclinical parasitic diseases, such as malaria and amebiasis, may become manifest during the stress of pregnancy.

Psychologic outcomes such as anxiety, depression, and Post Traumatic Stress Disorder and behavioral outcomes such as substance abuse and criminal activity may exhibit different patterns in male and female Vietnam veterans. With a large proportion of acute care nurses among female Vietnam veterans, special consideration would be given to possible stressful effects of caring for a large volume of combat casualties. The psychosocial component of the female study is also crucial to the complete evaluation and interpretation of the other clinical data to be collected, specifically in the determination of behavioral outcomes as a cause versus an effect of physical and biochemical disorders (e.g. hepatitis, cirrhosis, memory disorders).

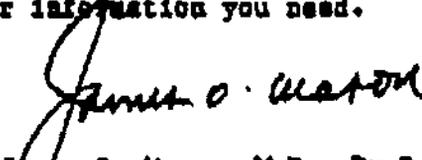
General health outcomes would include a variety of conditions of concern to female Vietnam veterans. These outcomes are similar to those being addressed in the ongoing study of male veterans. As was the case in the study of male veterans, there are few specific hypotheses based on previous scientific studies. CDC believes that a comprehensive health interview and physical examination would be needed to address the veterans' concerns thoroughly.

Page 3 - Edward N. Brandt, Jr., M.D.

The statistical power of the proposed study for important health outcomes would be good. The interview phase of the study is designed to detect increases of about twofold in the relative risks for health outcomes occurring with the frequency of 0.5% while the examination phase is designed to detect twofold increases in conditions that occur with a frequency of 1.5% or greater (power = 0.95, Alpha = 0.05, 1-tail). With that level of statistical power, most conditions that are of concern to women who served in Vietnam will be adequately addressed. Only relatively small increases in uncommon conditions would escape detection.

The intent of the study which CDC was asked to propose is to address the health concerns of female Vietnam veterans comprehensively and with sufficient statistical precision. That has determined the study design and sample size, rather than any single research hypothesis.

We will be pleased to provide any further information you need.


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

Note to Carl Keller:

Dr. Brandt asked that I send this to you to see if it can be discussed at the Science Panel meeting on November 16 and reported to him before the AOCG on December 4.

The final letter will have something like the following on the last paragraph:

"The cost of doing this study is significant. A decision to do this research, in a world of finite resources, may mean that money for other activities may not be available. We are neutral on the issue of doing this study. However, if a decision is made to proceed, we are confident that we can do a valid study acceptable to all groups if we are provided the necessary resources."


Vernon W. Mauk, M.D.
Director
Center for Environmental Health