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Item ID Number 01704

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Report/Article Title Typescript: Status Report for Development of Exposure Cohorts to be Used in VA Epidemiology Study, September 3, 1982

Journal/Book Title

Year 0000

Month/Day

Color

Number of Images 6

Description Notes

September 3, 1982

Status Report for Development of Exposure Cohorts
to be used in VA Epidemiology Study

Of prime importance to the interpretation of any results from the proposed VA Epidemiology Study of Vietnam Veterans' Health Status which might be associated with exposure to Agent Orange or the "Vietnam Experience" will be an understanding of the process used to identify potential study subjects. It is understood that the procedures developed by the Army Agent Orange Task Force have been designed to make this selection both feasible and as efficient as possible, and entail a multistage process to minimize the very large number of records to be reviewed and data to be entered. Since one of the major goals of the pilot phase of this study is to determine whether and how meaningful exposure cohorts can be selected, the successful completion of the pilot phase will entail an evaluation of the cohort selection process as well as other aspects of the proposed study. In order to accomplish this goal, it is necessary that there be maintained a thorough documentation of the disposition of those units identified but not selected and the basis for inclusion or exclusion of all units considered. Furthermore, the procedures used to select study subjects for the pilot phase should mimic those to be used during the full study.

In order to insure a meaningful comparison of health outcomes among subjects "exposed" and "unexposed" to Agent Orange, cohorts should be similar with respect to other aspects of their Vietnam experience. Thus, the units from which individual subjects will be chosen should be "matched" in some ways. Sufficient similarity should be maintained if exposed and unexposed units are selected from the same branch of service and a similar type of unit, and operating in the same Corps

area, preferably in similar terrain. A more clearcut difference in exposure can best be assumed if unexposed units are selected from among those that were operating beyond the reasonable maximum drift for Ranchhand spraying and/or following a sufficient length of time for degradation of sprayed herbicide. Of course, it will be necessary to evaluate other potential exposures (e.g., perimeter spraying, dumps, etc.) for a final classification of both exposed and unexposed units.

Since the availability, completeness and accuracy of the various record systems is unknown at present, this will have to be determined during the pilot phase. This both prevents a more precise procedural guideline at this time and forces the AAOTF staff to make eligibility decisions at several steps in the cohort selection process. The detailed documentation of the basis for decision at each step in the selection of units from which subjects will be chosen will facilitate an evaluation of the cohort selection process for potential selection bias during the pilot phase and will be necessary for determining the feasibility of the proposed epidemiological study.

The following procedures are for selection of Vietnam service subjects with high and low likelihood of exposure to Agent Orange or other herbicides while in Vietnam and do not include the selection of a non-Vietnam cohort. The outlined steps have been included in the guidelines supplied by the AAOTF and should provide a list of subjects who can be recruited for a pilot study. The documentation requirements should provide information for an evaluation of the feasibility of identifying adequate cohorts to be used in a large full-scale morbidity study among Vietnam Veterans.

- I. Prepare a map of Vietnam with Ranchhand spray tracks indicated for the period 1967-1968 (this has already been provided).
- II. Define geographically homogeneous areas with both Ranchhand tracks and ground troop activity during the 2-year period.

This step should include areas which might be selected and the rationale for choosing selected areas, including the presence or absence of ground troops as determined from Command Post locations (if available).

- III. a. Obtain appropriate station lists for each area selected.
b. Determine potentially eligible units which were operating throughout all or most of the 2-year period in the same area.

This step should include documentation of all units identified from station lists determined to be potentially eligible and how this determination was made.

- IV. Determine availability and completeness of all eligible units' records of movement.

- V. a. Select units to be recorded as to daily movements.

This is a crucial step, and documentation of how and why a unit (or units) were selected should include the eligibility of all units which were potentially eligible and might have been selected. The potential for the selection of adequate numbers of units (or subjects) for a full scale study may depend on records' completeness and availability at this step.

- b. Record to machine readable format the daily location coordinates for selected units during the entire 2-year period.

- VI. Develop "enhanced" HERBS Tape by including information from herbicide applications not identified from Ranchhand missions. This will include perimeter sprayings, road clearings, helicopter missions, aborts and other identifiable applications. It should not be necessary to do more than those areas previously identified in Step II above and it will be necessary to include the entire period of study (2 years) for this effort in those areas to be studied.

A necessary part of evaluating the reliability of exposure estimates will be the assessment of errors in and completeness of the available records for herbicide applications. Documentation of the type and number of errors and changes as well as some method for assessing completeness will assist in this effort.

VII. a. Match daily location coordinates of selected units via computer with the "enhanced" Herbs tapes to determine the number and type of "hits" sustained by each eligible unit between January 1, 1967 and December 31, 1968. Each "hit" will be defined and recorded according to all of the following 5 parameters for each unit:

- i) Type of Agent (Orange, White, Blue, Unknown).
- ii) Date.
- iii) Type of application (Ranchhand, Helicopter, Aborts, Ground, incidents)
- iv) Time in days since application (1st, 2nd, 3rd, 4th through 60th).
- v) Distance from application site in km. (0-.49, .5-.99, 1.0-1.99, 2.0-4.99).

b. List the "hits" for each unit matched.

An index or weighting scheme will have to be developed (not by AAOTF) by this time. While it may not be possible to satisfactorily quantify exposure, at least a weighing rule must be developed in order to identify high and low exposure units. The last category in both time and distance parameters is intended to provide a buffer between exposure and non-exposure. A "hit" in either of these categories will not constitute an additional exposure in otherwise exposed units but will exclude otherwise unexposed units from being considered as unexposed. Thus, "low likelihood of exposure" units will not have been within 5 kms. within 60 days of a Ranchhand application target.

VIII. Select high and low likelihood of exposure units.

This step should be documented, but will depend on selection via the weighting system developed for the previous step. The rationale for selection should be indicated and should include other criteria for the type of units chosen as well

as herbicide exposure. Depending on the results of Step VII, it may be possible to identify "low likelihood of exposure" units with no "hits" of any kind. If this is the case, then a specific weighting system to discriminate between high and low exposed units will not be crucial for selection. "High likelihood of exposure" units can then be selected from among those units with at least several "hits" of various kinds (exclusive of buffer zone hits).

- IX. a. Obtain daily morning reports for the period January 1, 1967 to December 31, 1968, for each unit selected in the previous step.
- b. Track individuals through service with their respective units during this time period and record presence on "hit" days for their unit.

Some criteria for eligibility will have to be developed and documented, including the minimum number and quality of individuals' "hit" days, reliability of records for identification of individuals during this step, and their minimum length of assignment to the unit.

- X. a. Obtain service records for selected individuals and verify service information obtained via morning reports.
- b. Record personal information from service record and include location of medical record for each selected individual.

At this step, it may be desirable to retain the individual's identification as either exposed or unexposed during the period covered in these procedures. This should enable closer matching of the two groups based on individual characteristics obtained from the service record. It will be necessary to identify multiple tours of duty in Vietnam and perhaps other criteria pertaining to military service which will influence his final selection into either of the Vietnam service cohorts. Documentation of these inclusions and exclusions will be necessary in order to assess bias in the final selection.

Although most of these procedures are included in the guidelines supplied by the AAOTF, they are detailed here to identify the steps and type of documentation which will be useful in the evaluation of the exposure index and determination of the feasibility of selecting exposed and unexposed cohorts for the full scale study. Systematic departures from the procedures outlined here which may be necessary for the inclusion of subjects from each of the four branches of military service should be included in the documentation.

At this time, there are several important issues pertaining to the selection of potential study subjects for the full study which require further development before final specification can be agreed upon. Although results from the pilot study selection itself will contribute to the resolution of some issues, there are several problems which can be and must be resolved before completion of this phase. These are listed below and will be developed more completely in separate reports:

- 1) The inclusion and details for selection of a third non-Vietnam service cohort and (perhaps) a fourth "Vietnam Experience" cohort.
- 2) The individual criteria from personal service (201) records which may determine eligibility for the study (specifically- induction status and the possibility of multiple tours).
- 3) The exact time and distance parameters to be recorded for herbicide "hits" with the possibility of widening the buffer zone.
- 4) A weighting scheme for the quality of exposure to specific herbicides for the various time, distance and type of application "hits."
- 5) The advantages and feasibility of extending the 2-year (1967-1968) period currently provided for in the present procedures.