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COHORT FORMATION FOR EPIDEMIOLOGICAL STUDY OF  
HEALTH EFFECTS OF AGENT ORANGE

1. Reasons for Cohort Formation

To determine whether exposure to Agent Orange, a phenoxy herbicide used in Vietnam, adversely affected the health of American military personnel, the physical and mental health of a group or cohort of exposed veterans must be compared with the health of a cohort of relatively unexposed veterans. If such groups can be accurately identified, a cohort or follow-up (historical prospective) study design is both possible and desirable. For greatest validity, the two cohorts should resemble one another as closely as possible except for their members' contact with Agent Orange.

2. Problems of Cohort Formation

Estimating exposure is the crucial step in forming the exposed and non-exposed cohorts that are the keystone of this study design. No records were kept of an individual's exposure to Agent Orange, however, because it was believed to be a safe herbicide. Records do exist for most of the dates and places where the herbicide was heavily used and separate records exist for the daily location of many specific military units. It is possible also to indicate the dates each man was with his unit by reconstructing rosters of the men in units with adequate records.

From these data it might be possible to estimate the extent of exposure for many individuals. The likelihood and intensity of exposure could be evaluated using at least the type and time of exposure, and distance from the point of herbicide application. The "type of exposure" includes such experiences as entry into an area recently sprayed by an aircraft, presence in a base camp during perimeter spraying, or being nearby when a plane dumped or jettisoned its load of herbicide in an emergency. The "time of exposure" refers to the period between the herbicide application and the unit's presence in the area.

The "distance" refers to the proximity of the unit to the point of application.

When enough information is available to determine the relative amount of exposure under various circumstances, the exposure at each episode can be "weighted" and the weighted values for each individual can be summed to give an "index of exposure". In an initial retrieval test of cohort selection, such an index can be applied to determine whether a heavily exposed and a non-exposed or minimally exposed cohort can be defined. If separation is obtained by criteria acceptable to the scientific community as well as knowledgeable veterans' representatives, the essential cohort selection will have been shown to be feasible.

### 3. Development of Exposure Cohorts

Of prime importance to a proposed epidemiology study of the effect of exposure to Agent Orange on the health status of Vietnam veterans will be a clear, thorough statement of the process used to identify study subjects. The procedure currently recommended by the Army Agent Orange Task Force (AAOTF) has been designed to make this selection feasible, efficient and as unbiased as possible. To minimize the very large number of records to be reviewed and data to be entered a multistage selection process is used. The basic selection or "sampling" frame will be the military unit which will be characterized as "exposed" or "not exposed". Individuals will then be identified from selected units and further studied to assure their experience is correctly represented by the unit's classification.

The retrieval test phase of this study will determine whether adequate cohorts of exposed and non-exposed can be defined. To accomplish this an audit trail will be maintained of all units identified, the proportion selected and the basis for exclusion of the non-selected units. Thus the retrieval test will also perfect the selection process to be used during the full study.

For a meaningful comparison of outcomes among subjects "exposed" and "unexposed" to Agent Orange, cohorts should be as similar as possible in other aspects of the Vietnam experience. Thus, units should be stratified to reduce heterogeneity. It should be sufficient to select exposed and unexposed units from the same branch of service, in a similar type of unit, and operating in the same Corps. If possible, similar terrain would be a useful fourth criteria. In the first step in finding unexposed units, candidates are selected from among those that were operating beyond the reasonable maximum drift for Ranchhand spraying. It will be necessary to evaluate other potential exposures (e.g. perimeter spraying, dumps, etc.) for a final classification into exposed or unexposed units.

The availability, completeness and accuracy of the various record systems is unknown at present and this will be studied during the retrieval test. However, the procedural guidelines or selection algorithm used by the AAOTF is to a large part based on assumptions about these records. This increases the likelihood the AAOTF staff will encounter unexpected variations. If this requires AAOTF staff to make eligibility decisions on units or individuals not anticipated in the algorithm, a brief anecdotal record of the nature of the problem and the convention adapted to solve it is most important. This will facilitate an evaluation of the cohort selection process for potential selection bias during the retrieval test and will determine 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. The documentation requirements provide information to evaluate the feasibility of identifying adequate cohorts for the full-scale study.

Specific attention is directed to the concept of "tracking time". An individual need only be in an exposed unit for enough "hits" to qualify as heavily exposed. Therefore the tracking time for these units would be just enough months to generate an adequate number of personnel exposed. They may be followed for a shorter period. On the other hand, the non-exposed or minimally exposed individual must be followed for his entire tour. An individual typically served exactly 1 year and could enter the unit throughout the year. Therefore, a non-exposed unit's tracking time must be more than 1 year to establish this category. How much longer again is determined by the number of non-exposed needed.

- I. Prepare maps of Vietnam with Ranchhand spray tracks (both defoliation and crop) for the period 1967-1968 (this has already been provided).
- II. Define geographically homogeneous areas with known ground troop activity with and without Ranchhand tracks during the 2-year period.

This is the first step and defines areas which might be selected. The rationale for choosing selected areas must include areas with and without Ranchhand tracks, similar location (and if possible terrain), and the presence of ground troops. If possible, all four Corps of RVN should be represented.

- III. a. Obtain appropriate station lists for each area selected.
- b. Determine potentially eligible units which were operating in selected areas during the 2-year period.

All units identified from station lists are potentially eligible.

*Station Lists - A*

- IV. 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, but, it will be necessary to include an adequate tracking time based on the unit's exposure status in those areas to be studied.

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

A necessary part of evaluating the reliability of exposure estimates will be the assessment of estimated completeness of the available records for herbicide applications. Documentation of completeness will assist in this effort, especially the number and type of obvious errors and suspected inaccuracies.

- VI. 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. Obviously only a small subsample (one or two areas perhaps) can be done in the retrieval test.

- b. Record to machine readable format the daily location coordinates for selected units for the entire tracking time.

- 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 four parameters for each unit:

- i) Date
- ii) Type of application (Ranchhand, Helicopter, Aborts, Ground, incidents) ~~5 days~~ (3 days or less)
- iii) Time in days since application (~~1 day~~) (~~1 day~~, ~~2-3 days~~, ~~4-5 days~~) (2 km or less)
- iv) Distance from application site in km (~~1 km~~, 2 km, ~~3-5 km~~)

b. List the "hits" for each unit matched and the weighted score.

An Appendix illustrating an index or weighting scheme is in preparation. While it may not be possible to quantify exposure with certainty, at least a weighting rule may be developed to classify 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 this time-distance zone will not constitute an additional exposure in otherwise exposed units but will be considered a possible exposure in units to be classed as low-likelihood-of-exposure. Thus, "low-likelihood-of-exposure" units will not be considered to have been exposed unless they have been within 1 km within 15 days or within 5 km within 1 day of a Ranchhand application target (if the retrieval test shows this is feasible). ~~For units expected to be exposed, the time and distance criteria outlined in iii and iv above to define a hit need only be measured at 3 days or less and 2 kms or less.~~

VIII. Select high and low likelihood of exposure units.

This step will depend on selection via the weighting system developed for the previous step as well as the results from the retrieval test. The rationale for selection will 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 an adequate tracking time during 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 individual's "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 an individual's 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.