

# Air Force Health Study

## *An Epidemiologic Investigation of Health Effects in Air Force Personnel Following Exposure to Herbicides*

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## EXECUTIVE SUMMARY

### FIRST FOLLOWUP MORBIDITY STUDY

The Air Force Health Study is an epidemiological study conducted to determine whether adverse health effects exist and can be attributed to occupational exposure to Herbicide Orange. The study consists of mortality and morbidity components, based on a matched cohort design in a nonconcurrent prospective setting with followup studies. The Baseline study was conducted in 1982, and the first followup morbidity study was performed in 1985. The purpose of this report is to present the results of the first followup study.

In the Baseline morbidity study, each living Ranch Hand was matched to the first living and compliant member of a randomly selected Comparison mortality set based on age, race, and military occupation, producing an approximate 1:1 contrast. The Comparisons had served in numerous flying organizations that transported cargo to, from, and within Vietnam but were not involved in the aerial spray operations of Herbicide Orange. Recruitment for the first followup was in accordance with the Study Protocol: All previous participants and refusals, newly located study members, and replacements (matched to noncompliant Comparisons on self-perception of health) were invited. Of the living Baseline study participants, 99.2 percent were contacted to enroll in the followup on a strictly voluntary basis. Participation was very high, with 93 percent of both the Ranch Hands and the Comparisons fully compliant at Baseline also participating in the followup. Overall, the 2,309 followup participants (1,016 Ranch Hands and 1,293 Comparisons) represented a loss to the study of 159 individuals but a gain of 199 new participants since Baseline. Statistical analyses of selection and participation bias supported the use of the total Comparison group for the main analyses presented in this report.

The followup study was conducted under contract to the Air Force by Science Applications International Corporation, in conjunction with the Scripps Clinic and Research Foundation and the National Opinion Research Center. Most of the data were collected through face-to-face interviews and physical examinations conducted at the Scripps Clinic in La Jolla, California. Other data sources included medical and military records and the 1982 Baseline data base. As a contract requirement, all data collection personnel were blind to exposure status, and all phases of the study were monitored by stringent quality control. The statistical analyses were based on analysis of variance and covariance, chi-square tests, Fisher's exact tests, general linear models, Kolmogorov-Smirnov tests, logistic regression, proportional odds models, t-tests, and log-linear models.

The questionnaire and physical examination data were analyzed by major organ system. The primary focus was on the assessment of differences between the Ranch Hand and Comparison groups based on data from the first followup. Additionally, dose-response relationships within the Ranch Hand group were examined, and longitudinal assessments of differences in the changes of the two groups between the examinations were conducted for selected variables.

In terms of general health, Ranch Hand enlisted groundcrew rated their health as fair or poor more frequently than their enlisted Comparisons; differences were not observed for the enlisted flyers or the officers. Physician examiners detected no differences for appearance of illness or distress or for the appearance of relative age. The Ranch Hands had significantly lower percent body fat. They also had a higher proportion of sedimentation rate abnormalities than the Comparisons, but mean sedimentation rates were not statistically different between the two groups.

No significant differences between the Ranch Hand and Comparison groups were seen in the 1982-1985 interval for skin or systemic cancers. However, when overall lifetime basal cell carcinoma rates were adjusted for risk factors involved in the cause of such cancers (e.g., sun exposure, skin color, skin reaction to sun), Ranch Hands had a significantly higher proportion of basal cell carcinoma than Comparisons. No group differences were observed for systemic cancer, although two cases of possible dioxin-related cancer were noted in Ranch Hands, bringing the lifetime total to two of these cancers in each group. Overall, the cancer findings were not viewed as disturbing but as reason for continued medical surveillance.

The neurological assessment of cranial nerve function, peripheral nerve function, and central nervous system coordination did not reveal any consistently significant group differences, although abnormalities tended to aggregate in the Ranch Hands. The Babinski reflex (found adverse in the Ranch Hands at the 1982 Baseline examination) was equal in both groups at the 1985 followup. Age, alcohol, and diabetes showed classical effects with many neurological measures.

In the psychological evaluation based on the Minnesota Multiphasic Personality Inventory, the Comparisons had significantly more abnormalities for the denial and masculinity/femininity scales, whereas the Ranch Hands manifested marginally more abnormalities in the hysteria and social introversion scales. The Ranch Hands showed more abnormalities on the Cornell Medical Index scales than did the Comparisons, but no differences were detected between the two groups on the functionally oriented Halstead Reitan Battery. There were no group differences for current or past neuroses or psychoses. Age, educational level, and alcohol history showed strong and expected effects on the psychological measures.

Both the interval and the lifetime history of liver disease were equal in both groups, as was a lifetime history of peptic ulcer disease. Of nine liver function and two porphyrin laboratory tests, the Comparisons had significantly higher serum glutamic pyruvic transaminase and uroporphyrin means, whereas the Ranch Hands had a significantly higher mean alkaline phosphate level and a borderline elevated coproporphyrin value. There was no evidence to suggest an increased likelihood of porphyria cutanea tarda in the Ranch Hand group.

In the dermatological assessment, not one case of chloracne was diagnosed on examination, nor was historical acne anatomically distributed in a pattern that suggested past chloracne in the Ranch Hand group. Exposure and longitudinal analyses were also essentially negative.

The cardiovascular evaluation showed no significant group differences for reported or verified hypertension, reported heart disease, or reported or

verified heart attacks. However, the frequency of verified heart disease was significantly greater in the Ranch Hands than the Comparisons. The assessment of the central cardiac function by systolic blood pressure and electrocardiogram did not reveal any meaningful group differences. Evaluation of peripheral pulses by the Doppler technique revealed group equivalence in marked contrast to the Baseline examination, which found significant pulse deficits in the Ranch Hands. This change was likely due to required tobacco abstinence before the pulse measurements. Overall, the groups were remarkably similar in cardiovascular health.

The assessment of eight hematological measures showed no significant group differences. In fact, the groups were more similar at the followup examination than at the Baseline examination. Age, race, and smoking were significant risk factors for most hematological measures.

The groups did not differ significantly in reported past kidney disease, although the Baseline questionnaire noted such in the Ranch Hands. Five laboratory measures of renal function were similar between groups in the unadjusted analyses. No pattern of results suggested a detriment to either group in the adjusted analyses.

For the endocrine function, TSH and testosterone means were significantly higher in the Ranch Hands, but these results were not supported by the categorical tests. The impaired category of the glucose tolerance test revealed an excess in the Comparison group. Examination results for past thyroid disease, thyroid and testicular abnormalities, and additional tests for cortisol level and  $T_3$  % Uptake were similar in both groups. Age, race, occupation, percent body fat, and personality type were often significant adjusting variables. Overall, the endocrine health status was comparable in both groups.

Comprehensive immunological tests composed of six cell surface marker studies and three functional stimulation studies showed no significant group differences in the unadjusted analyses. Age, smoking, and alcohol usage were generally strong covariates. The assessment of delayed hypersensitivity by skin testing was declared invalid because of excessive reader variation and shifting diagnostic criteria.

The pulmonary assessment, consisting of past history, physical examination, and x-ray results did not indicate any consistently different disease patterns in the two groups. Age and lifetime smoking history were important risk factors for most pulmonary measures.

The exposure index analyses, which were stratified by occupation, revealed sporadic differences between exposure levels; however, there were no consistent dose-response relationships that supported an herbicide effect for any clinical area.

Longitudinal analyses were conducted for 19 variables, and 5 showed significant differences in the changes of the groups between the Baseline and followup examinations. Of these 5 variables, 1 (sedimentation rate) was believed to be related to a change in laboratory methods, and the other 4 (Babinski reflex, depression, platelet count, and manual all pulse index) were attributed to true changes over time for the groups. In comparing all results between the examinations as well as the formal longitudinal analyses,

a subtle, but consistent, decrease in group differences over the 3-year period has been observed.

The process of inferring causality is complex and must be based on careful consideration of many factors. Any interpretations of the data must consider the biological plausibility, clinical significance, specificity and consistency of the findings, and a host of statistical factors, such as strength of the association, lack of independence of the measurements, and multiple testing.

By direct and indirect evidence, it is concluded that this study is free of overt bias and that the measurement systems used to obtain the data were accurate and valid. By an overall pattern assessment, it is further concluded that the Ranch Hand and Comparison populations are similar.

Finally, this first followup examination report concludes that there is insufficient evidence to support a cause and effect relationship between herbicide exposure and adverse health in the Ranch Hand group at this time. The study has revealed a number of minor medical findings that require continued surveillance. In full context, the results of this study must be viewed as additional reassuring evidence that, at this time, the current state of health of the Ranch Hand participants is unrelated to herbicide exposure in Vietnam.

## PREFACE

The release of this 1987 followup Morbidity Report marks more than 8-1/2 years of intensive Air Force research into the herbicide question. Since the commitment to Congress in October 1978 to conduct an epidemiologic investigation of Air Force personnel who aeriaily disseminated herbicides in the Vietnam War (code-named Operation Ranch Hand), the United States Air Force Surgeon General has issued the following publications: a Study Protocol, four annual mortality reports, the Baseline Morbidity Report, and this first followup morbidity report. Within the next 2 years, the second followup morbidity report, other annual mortality reports, and an expanded birth defects study are expected for publication. This level of commitment has used approximately \$40 million of contract research funds, excluding significant Air Force in-house expenditures.

Nearly 100 Government, academic, and industry scientists have guided and contributed to the Air Force Health Study (AFHS) since its inception. The Air Force's current advisory committee, chaired by Dr. Robert W. Miller of the National Cancer Institute, is responsible for providing assistance on all scientific and medical matters pertaining to the AFHS. The distinguished panelists are listed in Appendix A.

There are numerous scientific strengths in the AFHS, beginning with the unequivocal exposure status of the Ranch Hand population, estimated to have been, on the average, 1,000 times that experienced by an unclothed man directly beneath a spraying aircraft. In the other direction, the Ranch Hand population was probably less exposed to dioxin than many studied industrial populations (based upon a lack of chloracne), and may not develop adverse health consequences because of a possible threshold mechanism. However, the participants of the AFHS have a more defined exposure than the ground troops and constitute a larger population under study than industrial cohorts.

The chief strength of the AFHS is its design. The interwoven study elements of multiple mortality assessments, a Baseline morbidity study, and five followup morbidity studies over 20 years provide a comprehensive approach to the detection of attributable adverse health effects. The weakest feature of the design is the mortality assessment which, in the absence of significant case clustering, cannot detect group differences for very rare conditions (e.g., soft tissue sarcoma) because of the inherent constraints of the limited size of the Ranch Hand population. To some extent, this problem may be offset for the more prevalent cancers by combining both living and fatal cancers for future analyses. The strength of the mortality studies should increase with the aging of the study population and the concomitant increase in death with the passage of time.

All four mortality assessments have shown that the Ranch Hand population is faring about the same as the Comparison group, with no unusual causes of death, increased frequency of death, or evidence suggesting death at younger ages. Because of the healthy veteran effect, both groups are surviving significantly longer than similarly aged civilians. The morbidity assessment, released in 1984, disclosed only minor differences between the Ranch

Hands and the Comparisons, and these differences were not traditional indicators of dioxin-related disease. Both the content and the progress of the AFHS has been presented on many occasions to Congress, to the media, and to scientific meetings around the world. On the whole, the AFHS has been very well received in these circles, giving additional strength and credence to this work.

This report of the first followup study is important as it marks the sustained commitment of Congress and the Air Force to pursue the Agent Orange question to its logical scientific conclusion. From the medical and scientific perspectives, this followup examination gives the first opportunity to confirm or refute some of the Baseline findings, and to explore subtle longitudinal changes while controlling for confounding factors. The fifth-year followup examination, which will have been initiated when this report is released, will be conducted at an average time of 20 years postexposure for the Ranch Hands, a critical period for the emergence of attributable cancer. Followup studies such as these provide the most powerful scientific means of detecting emerging herbicide effects.

This report differs slightly from the Baseline Morbidity Report in several ways. The populations under study have changed slightly (see Chapter 2), since some Ranch Hands and Comparisons have voluntarily dropped out of the study, and additional study participants have joined (via the Comparison replacement strategy, or the addition of formerly noncompliant participants). Further, a greater variety of statistical techniques are used to explore bias considerations, subgroup categorical differences (see Chapter 7), and "best" model fitting via the use of two- and three-way interactions. In addition, specific medical tests were included in this examination to clarify whether less specific Baseline findings were relevant (e.g., Doppler measurement of arterial pulses).

Early in both the examination and analysis phases of this followup examination, it became clear that a joint Air Force-contractor approach to the analysis of the data was required. The Air Force elected to perform much of the analytical work of this report (e.g., bias, compliance, longitudinal, and pulmonary analyses). Thus, this study has transitioned from "independent" contract work to a genuine team effort between the Science Applications International Corporation (SAIC) and the Air Force scientific staffs. In the spirit of this enriching teamwork, SAIC has listed the Air Force scientific staff co-equally on the cover page of this report. Because of the highly professional scientific interchanges on many challenging aspects of the analytical work, it is believed that this report represents a scientific product unattainable by either team independent of the other.

A brief explanation of this report to the reader is in order. This report is written primarily for clinical epidemiologists, clinicians, and biostatisticians so that they may fully evaluate the data and analytic techniques herein. There are segments of this report that will be difficult for even the most experienced of these specialists to understand. Complete familiarity with the Study Protocol and prior mortality and morbidity reports is essential in the full understanding of this report. Thus, this report is not intended for rapid distillation by the layman or by media representatives. It should be noted that the intent of the introductions of the clinical chapters is to provide only a broad overview of the literature with respect to dioxin endpoints. In addition, the statistical analyses in this report were generally prescribed by the Air Force (based primarily upon

analyses performed for the Baseline Morbidity Report) and are not ad hoc analyses. The report format has been established to be complete, rigorous, and straightforward on all issues so that maximum scientific credibility will be maintained. As with the Baseline Report, the contractor, with Air Force authority, or the Air Force itself, will respond to telephone or written inquiries about the content of this report.

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<p>This report presents the results of the health assessment of the 1,016 Ranch Hands and the 1,293 Comparisons who participated in the 1985 followup examination of the Air Force Health Study. The purpose of the study is to determine whether long-term health effects exist and can be attributed to occupational exposure to herbicides. The result showed a subtle but consistent narrowing of medical differences between the two groups since the Baseline study in 1982; however, the Ranch Hands continue to manifest slightly more minor adverse health conditions than the Comparisons. Continued surveillance of these two groups is indicated. The report concludes that there is not sufficient evidence to implicate a causal relationship between herbicide exposure and adverse health in the Ranch Hand group.</p>			
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