

CHAPTER 1

BACKGROUND

This chapter briefly describes the background of the Air Force Health Study (AFHS) and provides an overview of the study design and purpose of this report. Portions of this chapter have been paraphrased from the Baseline Morbidity Report, 24 February 1984.

In January 1962, President John F. Kennedy approved a program of aerial herbicide dissemination, for the purpose of defoliation and crop destruction, in support of tactical military operations in the Republic of Vietnam (RVN). Under this program, code-named Operation Ranch Hand and in operation from 1962 to 1971, approximately 19 million gallons of herbicides were dispersed on an estimated 10 to 20 percent of South Vietnam.^{1,2} Approximately 11 million gallons of Herbicide Orange, the primary defoliant of the six herbicides utilized in the program, were disseminated.

Operation Ranch Hand was the subject of intense scrutiny from the start due to the controversial nature of the program and political sensitivity to chemical warfare charges contained in enemy propaganda. The concerns, which were initially based on military, political, and ecological issues, shifted during 1977 to health issues. Numerous claims of exposure to herbicides, particularly Herbicide Orange and its dioxin contaminant, and subsequent adverse health effects among U.S. military service personnel have resulted in class action litigation and substantial controversy. Social concern for the Herbicide Orange issue continues to be manifest by continuing scientific research, media presentations, congressional hearings, and legal action.

The U.S. Air Force Medical Service's concern for the health of Air Force personnel exposed to herbicides was demonstrated in October 1978 when the Air Force Deputy Surgeon General made a commitment to Congress and to the White House to conduct a health study on the Ranch Hand population, the aviators who disseminated the majority of the defoliants in the RVN. The prevailing reasons for the study commitment included the availability of a definitive occupational exposure to herbicides, a sufficient sample size for survey and clinical research, the ability to ascertain the population at risk, and an opportunity for the Air Force Medical Corps to fulfill its adage "we care" to the Air Force community.

The Air Force School of Aerospace Medicine, Brooks Air Force Base, Texas, was tasked by the Surgeon General to develop the Study Protocol. In 1982, after extensive peer review, the epidemiologic study began, and the Protocol was published.

Since 1978, numerous animal and human studies of dioxin effects have been planned or initiated by governmental agencies, universities, and industrial firms. The key scientific issue in these studies was the extent of exposure, e.g., who was exposed and how much each individual was exposed. Unfortunately, population identification and exposure estimation, which are critical for a valid study of ground troops, have been scientifically elusive.

It is believed that of all the military personnel who served in the RVN, the Ranch Hand population was the most highly exposed to herbicides. Exposure estimates indicate that the average Ranch Hand received 1,000 times more exposure to Herbicide Orange and 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD) during his tour in the RVN than an average male would receive standing unclothed under a spraying aircraft in an open field. Based on the principle of dose-response, the Ranch Hands should manifest more and/or earlier evidence of adverse health. Thus, the results of the AFHS should serve as an indicator of herbicide effects in ground personnel.

STUDY DESIGN

The purpose of the study is to determine whether adverse health effects exist and can be attributed to occupational exposure to Herbicide Orange. The study, consisting of mortality and morbidity components, is based on a matched cohort design in a nonconcurrent prospective setting with followup studies. Complete details on the design are provided in the Study Protocol.

The nonconcurrent aspect of the design results from the fact that the Ranch Hands were exposed over time between 1962 and 1971. This staggered exposure is accounted for in the design of the studies to address latency considerations.

For the Baseline study, the population ascertainment process identified 1,264 Ranch Hand personnel who served in the RVN between 1962 and 1971. By the time the first followup began in 1985, an additional 11 Ranch Hands had been identified, bringing the total Ranch Hand population to 1,275. A Comparison group was formed, consisting of individuals assigned to selected Air Force units with missions of flying cargo to, from, and within the RVN during the same period. Using a computerized nearest neighbor selection procedure, a maximum of 10 Comparisons was selected for each Ranch Hand, matching on age, race, and military occupation. After personnel record reviews, each Ranch Hand who was determined to be eligible and fully suitable for study had an average of 8.2 Comparison subjects.

The mortality component addresses mortality from the time of the RVN assignment. A Baseline mortality study was conducted in 1982, and the mortality followup consists of annual mortality updates for 20 years. For the Baseline study and the first four updates, five individuals were randomly selected from the matched Comparison set for a 1:5 design. Subsequent to 1986, the design will be expanded to include all of the individuals in the Comparison set.

The Baseline morbidity component, begun in 1982, reconstructed the medical history of each participant by reviewing and coding past medical records. A cross-sectional element, designed to assess the participant's current state of mental and physical health, was based on comprehensive questionnaires and physical examinations given to the participants. For this component of the study, each living Ranch Hand and the first living member of his Comparison set were selected to participate in the examination. Sequential questionnaires, medical record reviews, and physical examinations in 1985, 1987, 1992, 1997, and 2002 comprise the morbidity study followup.

PURPOSE

The 1985 morbidity followup is the subject of this report. The objective of the morbidity followup is to continue the investigation of the possible long-term health effects following exposure to TCDD-containing herbicides. This report describes the procedures and results of the first morbidity followup of the AFHS. Analysis of reproductive and fertility data will be conducted by the U.S. Air Force and is not part of this report.

CHAPTER 1

REFERENCES

1. Young, A.L., J.A. Calcagni, C.E. Thalken, and J.W. Tremblay. 1978. The toxicology, environmental fate, and human risk of herbicide orange and its associated dioxin. Technical report OEHL-TR-78-92, USAF Occupational and Environmental Health Laboratory, Brooks AFB, Texas. 247 pp.
2. Buckingham, W.A., Jr. 1982. Operation Ranch Hand: The Air Force and herbicides in Southeast Asia, 1961-1971. Office of Air Force History, United States Air Force, Washington, D.C. pp. 9-69, 199-201.
3. Lathrop, G.D., W.H. Wolfe, R.A. Albanese, and P.M. Moynahan. 1982. Epidemiologic investigation of health effects in Air Force personnel following exposure to herbicides: Study protocol. Technical report 82-44, USAF School of Aerospace Medicine. 172 pp. Available from NTIS, Springfield, Virginia.