

TABLE 2-1. (continued)

Analysis of Personal Characteristics and Habits by Group

Variable	Statistic	Group				p-Value
		Ranch Hand		Comparison		
Family History of Heart Disease	n	995		1,299		
	Number/%					
Yes		240	24.1%	294	22.6%	0.432
No		755	75.9%	1,005	77.4%	
Family History of Heart Disease Before Age 50	n	995		1,299		
	Number/%					
Yes		33	3.3%	38	2.9%	0.678
No		962	96.7%	1,261	97.1%	
<u>Risk Taking Variables</u>						
Scuba Diving	n	995		1,299		
	Number/%					
Yes		120	12.1%	180	13.9%	0.228
No		875	87.9%	1,119	86.1%	
Auto, Boat, or Motorcycle Racing	n	995		1,299		
	Number/%					
Yes		131	13.2%	176	13.5%	0.838
No		864	86.8%	1,123	86.5%	
Skydiving	n	995		1,299		
	Number/%					
Yes		14	1.4%	31	2.4%	0.124
No		981	98.6%	1,268	97.6%	

TABLE 2-1. (continued)

Analysis of Personal Characteristics and Habits by Group

Variable	Statistic	Group				p-Value
		Ranch Hand		Comparison		
Mountain Climbing	n	995		1,299		0.424
	Number/%					
	Yes	85	8.5%	98	7.5%	
	No	910	91.5%	1,201	92.5%	
Hang Gliding	n	995		1,298		0.342
	Number/%					
	Yes	8	0.8%	17	1.3%	
	No	987	99.2%	1,281	98.7%	
Plane Racing or Acrobatics	n	995		1,299		0.364
	Number/%					
	Yes	46	4.6%	49	3.8%	
	No	949	95.4%	1,250	96.2%	
Surfboard Riding	n	995		1,299		0.016
	Number/%					
	Yes	95	9.5%	87	6.7%	
	No	900	90.5%	1,212	93.3%	
Long-Distance Sailing	n	994		1,299		0.820
	Number/%					
	Yes	48	4.8%	59	4.5%	
	No	946	95.2%	1,240	95.5%	

TABLE 2-1. (continued)

Analysis of Personal Characteristics and Habits by Group

Variable	Statistic	Group		p-Value
		Ranch Hand	Comparison	
Fast Downhill Skiing	n	995	1,299	
	Number/%			
	Yes	174 17.5%	206 15.9%	0.326
	No	821 82.5%	1,093 84.1%	
<u>Other Variables</u>				
Education	n	987	1,293	
	Number/%			
	High School	508 51.5%	642 49.7%	0.414
	College	479 48.5%	651 50.3%	
Blood Type	n	988	1,292	
	Number/%			
	A	389 39.4%	525 40.6%	0.302
	AB	39 4.0%	37 2.9%	
	B	103 10.4%	154 11.9%	
	O	457 46.3%	576 44.6%	
Presence of Pre-SEA Acne	n	987	1,289	
	Number/%			
	Yes	317 32.1%	391 30.3%	0.386
	No	670 67.9%	898 69.7%	

TABLE 2-1. (continued)

Analysis of Personal Characteristics and Habits by Group

Variable	Statistic	Group				p-Value
		Ranch Hand		Comparison		
Personality Type (1985) (discrete)	n	956		1,221		
	Number/%					
	A Direction	432	45.2%	523	42.8%	0.292
	B Direction	524	54.8%	698	57.2%	
	Mean Test Score		$\bar{x}=3.7$		$\bar{x}=3.7$	0.999
Presence of PTSD (1985)	n	959		1,219		
	Number/%					
	Yes	10	1.0%	6	0.5%	0.216
	No	949	99.0%	1,213	99.5%	
Military Status	n	995		1,299		
	Number/%					
	Active Duty	52	5.2%	71	5.5%	0.973
	Retired	572	57.4%	730	56.2%	
	Separated	303	30.5%	411	31.6%	
	Reserve Forces	59	5.9%	75	5.8%	
	Deceased	9	0.9%	12	0.9%	

TABLE 2-1. (continued)

Analysis of Personal Characteristics and Habits by Group

Variable	Statistic	Group		p-Value		
		Ranch Hand	Comparison			
1986 Individual Income	n	986	1,285			
	Number/%					
	None	102	10.3%	129	10.0%	0.760
	≤\$9,999	43	4.4%	56	4.4%	
	\$10,000-\$14,999	45	4.6%	63	4.9%	
	\$15,000-\$19,999	59	6.0%	82	6.4%	
	\$20,000-\$24,999	108	11.0%	134	10.4%	
	\$25,000-\$29,999	125	12.7%	154	12.0%	
	\$30,000-\$34,999 ^a	91	9.2%	139	10.8%	
	\$35,000-\$39,999	99	10.0%	120	9.3%	
	\$40,000-\$44,999	65	6.6%	98	7.6%	
	\$45,000-\$49,999	55	5.6%	63	4.9%	
	\$50,000-\$54,999	46	4.7%	65	5.1%	
	\$55,000-\$59,999	22	2.2%	45	3.5%	
	\$60,000-\$64,999	30	3.0%	30	2.3%	
	\$65,000-\$69,999	12	1.2%	18	1.4%	
	\$70,000-\$74,999	23	2.3%	13	1.0%	
	\$75,000-\$79,999	12	1.2%	11	0.9%	
	\$80,000-\$84,999	8	0.8%	10	0.8%	
	\$85,000-\$89,999	8	0.8%	12	0.9%	
	\$90,000-\$94,999	3	0.3%	5	0.4%	
	\$95,000-\$99,999	4	0.4%	6	0.5%	
	>\$100,000	26	2.6%	32	2.5%	

TABLE 2-1. (continued)

Analysis of Personal Characteristics and Habits by Group

^aEstimated by randomized response techniques.

^bBlacks excluded.

^cEthnic Background: A: English, Welsh, Scottish, or Irish
 B: Scandinavian, German, Polish, Russian, Other Slavic, Jewish, or French
 C: Spanish, Italian, or Greek
 D: Mexican, American Indian, or Asian
 E: African

^dComposite Sun Reaction Index: High: Burns Painfully and/or Freckles With No Tan
 (from Reaction of Skin
 After at Least 2 Hours
 After First Exposure and
 Reaction of Skin After
 Repeated Exposure)
 Medium: Burns and/or Tans Mildly
 Low: All Other Reactions

^eDiabetic Class: Normal: <140 mg/dl 2-hour postprandial glucose
 Impaired: >140 - <200 mg/dl 2-hour postprandial glucose
 Diabetic: Verified past history of diabetes or >200 mg/dl 2-hour postprandial glucose

^fDied after the 1987 followup examination.

^gMedian income category for Ranch Hands and Comparisons.

MATCHING VARIABLES

In accordance with the Study Protocol, the Ranch Hands and Comparisons were matched by age, race, and military occupation while in Southeast Asia (SEA). Group differences in the matching variables could have arisen due to differential participation; however, there were no significant differences between the Ranch Hands and Comparisons for age, race, or occupation, as shown in Table 2-1. Mean ages of the Ranch Hands and Comparisons in 1982, the year of the Baseline examination, were 43.88 years and 43.67 years, respectively. As shown in the discrete analysis, the percentage of participants born in or before 1922 and born in or after 1942 was slightly higher for the Comparisons than the Ranch Hands. Although the Ranch Hands and Comparisons are matched by race, a higher percentage of Black Comparisons than Black Ranch Hands chose to participate in the 1987 followup. A higher percentage of Ranch Hand enlisted flyers and a lower percentage of Ranch Hand enlisted groundcrew than the Comparisons participated. The percentage of officers in both groups was the same.

DRINKING HABITS

In the assessment of drinking habits, current alcohol use, lifetime alcohol history, current wine use, and lifetime wine history were analyzed.

Although the results of the analyses on current alcohol use did not reveal any significant differences, a higher percentage of Comparisons than Ranch Hands was classified as heavy drinkers (>4 drinks per day). Of the Comparisons, 3.5 percent drank four or more drinks per day, as compared to 2.8 percent of the Ranch Hands. The mean number of drinks per day was 0.79 for the Comparisons and 0.74 for the Ranch Hands.

The analyses of lifetime alcohol history also did not detect any significant differences between the two groups. Based on lifetime alcohol consumption, the Ranch Hands had a higher mean than the Comparisons (30.88 drink-years vs. 30.03 drink-years); however, the percentage of heavy drinkers (>40 drink-years) was higher for the Comparisons than the Ranch Hands (23.4% vs. 21.6%).

Based on the discrete analysis of current wine use (yes/no), significantly more Comparisons than Ranch Hands reported that they drank wine at the time of the 1987 followup (44.6% vs. 38.6%, $p=0.005$). However, the average wine consumption was similar for the two groups (Ranch Hand mean=0.10 drinks/day vs. Comparison mean=0.11 drinks/day).

The discrete analysis of lifetime wine history also detected a significant difference between the Ranch Hands and Comparisons ($p=0.037$), with more moderate wine drinkers in the Comparison group. Of the Ranch Hands, 53.4 percent, 42.1 percent, and 4.6 percent were nonwine drinkers (0 drink-years), moderate wine drinkers (>0-10 drink-years), and heavy wine drinkers (>10 drink-years), respectively. The corresponding percentages for the Comparisons were 48.4, 47.5, and 4.2, respectively. The mean of the Ranch Hands was 2.18 drink-years, as contrasted with a mean of 1.96 drink-years for the Comparisons; these means were not significantly different.

SMOKING HABITS

The analyses of smoking habits were based on the reported use of cigarettes, cigars, pipes, and marijuana. Both current and lifetime cigarette smoking habits were examined. Analyses of cigar and pipe smoking were based on current use. For marijuana use, data on past history and use within the past 30 days were analyzed.

The results of the current cigarette smoking analyses showed that the Ranch Hands smoked significantly more cigarettes per day than the Comparisons, an observation also noted at the 1985 examination. The Ranch Hands smoked an average of 9.1 cigarettes per day, as contrasted with an average of 7.7 cigarettes per day ($p=0.014$) for the Comparisons. In the discrete analysis of current cigarette smoking, a marginally significant difference was detected ($p=0.086$), with a greater percentage of current smokers in the Ranch Hand group. At the time of the 1987 followup, 64.1 percent of the Ranch Hands did not smoke (participants either never smoked or formerly smoked), as contrasted to 69.1 percent of the Comparisons.

Although no significant differences were identified based on lifetime cigarette smoking history, the mean number of pack-years for the Ranch Hands was higher than the mean for the Comparisons (15.0 pack-years vs. 13.9 pack-years).

The results of the analyses of current cigar and pipe smoking revealed similar patterns in the two groups.

Data concerning marijuana use were collected by a random response technique¹ to overcome the problem of participants either refusing or giving misleading replies to these highly sensitive and personal questions. With this technique, a coin was flipped by the respondent, who then answered either a marijuana question or a neutral unrelated question, which had an answer of known probability. The outcome of the coin toss was unknown to the interviewer. Thus, the question to which the reply was given could not be traced, although the proportion of the population that had smoked marijuana could be estimated. These questions were asked at the 1985 followup. Since the questions were highly sensitive, they were only included in the 1987 health interval questionnaire for the 1987 participants who did not attend the 1985 followup. Responses from 1985 and 1987 were combined to compute the percentages provided in Table 2-1 for the 1987 followup participants. The groups were found to be similar on both past history and use of marijuana within the 30 days prior to being questioned. Approximately 30 percent of both groups reported ever having used marijuana, and fewer than 10 percent were current smokers.

SUN EXPOSURE CHARACTERISTICS

With the increased emphasis on skin malignancy, information was collected for the following eight variables that characterize sun exposure and reaction to sun exposure: average lifetime residential latitude, ethnic background, skin color, hair color, eye color, reaction of skin to sun at least 2 hours after several preceding episodes of sun exposure, reaction of skin to sun after repeated exposure, and a composite sun exposure index. Data on average

lifetime residential history and skin, hair, and eye color were collected during the 1985 followup. In the 1987 followup, these data were collected only for the participants who did not attend the 1985 followup. These variables were candidate covariates for the skin neoplasm analyses. Since Blacks were excluded in the analyses of skin neoplasms, they were also excluded in these analyses.

Analysis of the average lifetime residential latitude revealed that significantly more Comparisons than Ranch Hands had an average lifetime residential latitude of less than 37 degrees North, the geographical median latitude of the continental United States (50.2% vs. 42.6%, $p<0.001$). A line across the United States from San Francisco, California, to Richmond, Virginia, approximates 37 degrees North latitude. Thus, the Comparisons have a more southerly average latitude than the Ranch Hands.

No significant differences between the Ranch Hands and the Comparisons were detected in the analyses of the other sun exposure variables.

EXPOSURE TO CARCINOGENS

Information was collected from the participants on whether they had been exposed to selected carcinogens (yes/no). The carcinogens were grouped into two sets. The first set consisted of asbestos, ionizing radiation, herbicides, insecticides, industrial chemicals, and degreasing chemicals. The 15 carcinogens in the second set were anthracene, arsenic, benzene, benzidine, chromates, coal tar, creosote, aminodiphenyl, chloromethyl ether, mustard gas, naphthylamine, cutting oils, trichloroethylene, ultraviolet light (not sun), and vinyl chloride. A composite carcinogen exposure variable was constructed from the second set of carcinogens. This variable was coded as yes if the participant had been exposed to any of the carcinogens in the second set.

Significant group differences were detected for three of the six variables in the first set. More Comparisons than Ranch Hands reported that they had been exposed to ionizing radiation (27.1% vs. 20.0%, $p<0.001$). The percentage of participants who reported being exposed to herbicides and insecticides was higher for the Ranch Hands than the Comparisons ($p<0.001$ for both), a reasonable expectation based on the nature of the Ranch Hand mission in Vietnam. Of the Ranch Hands, 94.0 percent reported being exposed to herbicides, as contrasted to 33.1 percent of the Comparisons. The relatively high percentage of Comparisons reporting exposure to herbicides is of interest and will be clarified by the results of the serum dioxin assays. For insecticides, 72.0 percent of the Ranch Hands and 56.7 percent of the Comparisons reported that they had been exposed to insecticides. No differences were detected between the two groups for asbestos, industrial chemical, and degreasing chemical exposure.

The results of the analyses on the second set of carcinogens revealed borderline significant differences between the Ranch Hands and Comparisons for arsenic, chromate, and naphthylamine exposure. Based on the analysis of the composite carcinogen exposure variable, the difference between the two groups was also marginally significant. More Comparisons than Ranch Hands reported that they had been exposed to arsenic (2.4% vs. 1.3%, $p=0.070$). Of the Ranch Hands, 6.0 percent reported chromate exposure; the percentage of Comparisons

who reported chromate exposure was 4.2 percent ($p=0.052$). Naphthylamine exposure was also higher in the Ranch Hands than in the Comparisons (3.6% vs. 2.2%, $p=0.064$). Based on the analysis of the composite carcinogen exposure variable, more Ranch Hands than Comparisons reported being exposed to at least one carcinogen in the second set (27.2% vs. 23.6%, $p=0.058$).

PERSONAL AND FAMILY HEALTH

Six measures of personal health that were candidate covariates in selected adjusted analyses were also examined: cholesterol, high density lipoprotein (HDL), cholesterol-HDL ratio, diabetic class, differential cortisol response, and percent body fat. Differential cortisol was based on information gathered at the 1985 followup, and the analysis was consequently restricted to those participants who attended both the 1985 and 1987 examinations. No significant group differences were detected in the analyses of these variables.

Family history of heart disease was also examined. The results of the analyses showed that the family history of heart disease before age 50 or without an age restriction was similar in the two groups.

RISK-TAKING BEHAVIOR

Risk-taking behavior patterns of the study population were assessed by a series of questions that emphasized participation in potentially dangerous recreational activities. Nine activities were analyzed: scuba diving, racing (auto, boat, or motorcycle), skydiving, mountain climbing, hang gliding, plane racing or acrobatics, surfboard riding, long-distance sailing, and fast downhill skiing. The results showed that significantly more Ranch Hands than Comparisons reported that they had ever participated in surfboard riding (9.5% vs. 6.7%, $p=0.016$). No significant differences between the two groups were detected in the analyses of the other eight activities.

OTHER CHARACTERISTICS

The two groups were also contrasted on education, blood type, presence of pre-SEA acne, personality type, presence of post traumatic stress disorder (PTSD), current military status, and 1986 individual income. The analysis of personality type and PTSD was restricted to those 1987 followup participants who attended the 1985 followup. The results of the analyses showed that the Ranch Hands and Comparisons were similar on all seven variables.

SUMMARY

The study population for the 1987 followup of the AFHS consisted of 2,294 participants: 995 Ranch Hands and 1,299 Comparisons. The personal characteristics and habits of the Ranch Hands and Comparisons were contrasted. The variables selected to characterize the two groups included all of the candidate covariates in the adjusted analyses of clinical endpoints.

The two groups were contrasted on the matching variables (age, race, and occupation); drinking habits, smoking habits, sun exposure characteristics, exposure to carcinogens, selected personal and family health variables, risk-taking behavior, and other characteristics (education, blood type, personality type, PTSD, current military status, and 1986 individual income).

No differences between the two groups were found for the matching variables, personal and family health variables, and other characteristics. The Ranch Hands and Comparisons reported similar current and lifetime alcohol use; however, the average current alcohol use was higher for the Comparisons and the Ranch Hands had a higher average lifetime alcohol history. These differences were not significant. Significantly more Comparisons than Ranch Hands drank wine at the time of the 1987 followup; however, the mean numbers of wine drinks per day were not significantly different. For lifetime wine history, the distribution of wine drinkers (nonwine drinkers, moderate wine drinkers, and heavy wine drinkers) was significantly different for the two groups. The Comparisons had a higher percentage of moderate wine drinkers than the Ranch Hands. However, the mean number of wine drink-years for the two groups was similar.

At the time of the 1987 followup, the Ranch Hands smoked significantly more cigarettes than the Comparisons. The Ranch Hands had a higher average lifetime cigarette smoking history than the Comparisons, but this difference was not significant. The two groups had similar current cigar, current pipe, and past and recent marijuana smoking habits.

The two groups reported similar sun exposure characteristics. However, significantly more Comparisons than Ranch Hands had an average lifetime residential latitude of less than 37 degrees North.

Differences in reported exposure to carcinogens were assessed for 21 carcinogens or groups of carcinogens and one composite exposure variable constructed from reported exposure to 15 of the 21 carcinogens. As anticipated, significantly more Ranch Hands than Comparisons reported being exposed to herbicides and insecticides. Reported ionizing radiation exposure was significantly higher in the Comparisons. Marginally significant differences were detected in reported exposure to arsenic (Comparisons>Ranch Hands), chromates (Ranch Hands>Comparisons), and naphthylamine (Ranch Hands>Comparisons). More Ranch Hands than Comparisons reported being exposed to at least one of the carcinogens used to construct the composite exposure variable; the difference was marginally significant. No differences were detected for the other 15 carcinogen variables.

The risk-taking behavior of the two groups was characterized by participation in nine potentially dangerous recreational activities. Significantly more Ranch Hands than Comparisons reported that they had ever ridden surfboards. No differences in participation in the other eight activities were identified.

In summary, the 995 Ranch Hands and 1,299 Comparisons who participated in the 1987 AFHS followup were found to have similar personal characteristics and habits.

CHAPTER 2

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CHAPTER 3

QUESTIONNAIRE METHODOLOGY

This chapter discusses the development and the implementation of the participant questionnaires used in the 1987 followup: the 1987 interval questionnaire and the 1982 Baseline questionnaire.

The 1987 participant interval questionnaire was designed to capture the participant's health history in the interval since his participation in the 1985 followup. Data collection was comparable to the Baseline and 1985 followup efforts: The questionnaire was very similar, and it was administered using the same face-to-face methodology to virtually the same population. In the Baseline study, interviews were conducted in the participants' homes, and the 1985 and 1987 followup interviews were conducted at the physical examination site. The revised methodology was more efficient and better subject to quality control.

Since some study subjects refused to participate in 1982 and 1985 and other participants were new to the study, the Baseline questionnaire used during the Baseline phase was administered to these new participants. For the convenience of these participants, the Baseline questionnaires were administered in the homes of these individuals or at the physical examination site, at the discretion of the participant.

Questionnaire development and administration and scheduling of participants were conducted by the National Opinion Research Center (NORC), a social science research center at the University of Chicago.

QUESTIONNAIRE DEVELOPMENT

The goal of questionnaire development was to maintain to the maximum extent possible the question wordings, context, and procedures that were used in the 1982 Baseline study and 1985 followup. The largest task of questionnaire development was asking for interval histories on crucial questionnaire items to update the information provided by the 1985 questionnaires. The 1982 Baseline questionnaire captured information on demographics, education, occupation, medical history, study compliance, toxic exposures, and reproductive experience. In general, histories and one-time questions (where the response does not change over time) were obtained in the Baseline questionnaire, which is completed for each participant the first time he participates in the study. For the 1985 interval questionnaire, new questions on risk factors for skin cancer and personality type were added. In addition, enhancements were made to improve data collection for birth defects and drinking habits, and questions to capture a more detailed smoking history were added.

In general, the 1987 interval questionnaire built upon the changes made in the 1985 interval questionnaire and was expanded to include detailed drinking history and sleep disorder questions. Since some of the study subjects did not participate in the 1985 followup, the 1987 interval questionnaire was structured to capture one-time questions, such as ethnic

background, and histories, such as smoking history, which were first asked in the 1985 followup, on the new and rejoining (those who completed the Baseline questionnaire but did not complete the 1985 interval questionnaire) participants only. Questions that updated the histories were asked of the participants who attended the 1985 followup.

A copy of the 1987 participant interval questionnaire is provided in Appendix A.

Even when given a precise "starting date," respondents frequently repeat information given earlier, neglect to report new information because they thought they had previously reported it, and otherwise misplace events in time or forget them completely. The best means of preventing such errors is through the use of bounded recall, in which the respondent is reminded of information he has already reported and new information is sought with reference to an updated information sheet. An information sheet containing a computer-generated summary of key respondent answers to the Baseline and 1985 surveys was used to provide bounded recall for participants. Among the data elements included were date of birth, highest educational degree, military status at last interview, marital status at last interview, and name of spouse.

The questionnaire was pretested on 11 men who participated in the pretest examination.

INTERVIEWER TRAINING

Twelve interviewers were recruited and trained to administer the interval questionnaires by NORC's field management and Chicago office staffs in April 1987. Six of the interviewers had administered interval questionnaires in the 1985 followup. The onsite NORC interview staff was not informed of the exposure status of any study participant either before or after contract completion. The site supervisor reported to the Project Director in Chicago on a weekly basis, and quarterly visits were made to the site by the Director. The site supervisor observed a sample of interviews for each interviewer and reviewed and edited questionnaires for completeness.

In July 1987, personal interviewers were recruited to conduct Baseline interviews for new participants and previous refusals. The interviewers were trained in the Chicago NORC office, using questionnaires and procedures established for the Baseline survey. They were supervised by an assistant survey director in the NORC office, who edited each completed questionnaire and talked with each interviewer regularly.

SCHEDULING OF PARTICIPANTS

NORC recruited and trained four schedulers to perform the initial contacts with study subjects. Their training included background information on the details and purpose of the study, simulation of the actual scheduling of calls, documentation of results, and conversion of refusals. An initial letter was sent by the Air Force to each study subject, informing him of the upcoming 1985 followup. The NORC scheduler then followed this letter with a call to attempt to schedule the participant.

Refusals occurred at a number of steps in the scheduling process. As in the 1985 followup, a team of conversion specialists was assigned to contact refusing study subjects and attempt conversion of them to full compliance. Help in conversion was also received from individuals at the U.S. Air Force School of Aerospace Medicine.

The Air Force Health Study (AFHS) Protocol¹ specifies the replacement strategy for noncompliant Comparisons. Basically a noncompliant Comparison was replaced by a new Comparison from a matched set of up to 10 candidate Comparisons whose self-perception of health matches that of the noncompliant Comparison, if one was found. In 1985, a telephone survey of uncontacted Comparisons was conducted to gather data on the general health status of the 7,963 replacement candidates for the active Comparison group. The sample consisted of men who served in C-130 units in Southeast Asia between 1962 and 1971, but who did not participate actively in the Baseline phase of the study. The key question was, "Compared to other people your age, would you say that your health is...excellent, good, fair, poor?" The data from the 1985 telephone survey of uncontacted Comparisons were used to select a replacement whose self-reported health status matched that of the noncompliant Comparison. If a willing replacement was not found in the refusal's matched set by this method, the perception of health status variable was dichotomized into excellent/good versus fair/poor, and a new replacement was selected from the Comparison set. If this second attempt at identifying a suitable replacement failed, no replacement was made. The selection procedure is illustrated in Figure 3-1. In this example, the first randomly ordered Comparison was contacted but refused to participate. In the second attempt, the Comparison was deceased. The third Comparison volunteered to participate in the morbidity study.

The Baseline interviewer contacted the potential new study participant by telephone for scheduling the Baseline interview. The Baseline questionnaire was administered in the home or at the examination site by one of the interviewers who had been trained in administering that questionnaire. Of the 74 participant Baseline questionnaires administered during the 1987 followup, 37 were conducted at the examination site.

The supervisors of the Baseline interviewers and schedulers conducted the locating efforts for new and interval participants. Procedures similar to those used in 1982 and 1985 were followed: a postal search, followed by a local telephone directory search, a motor vehicle registration search, and personal locating efforts in the area of last known residence when appropriate. The Air Force also provided locating support through its records.

DATA COLLECTION

Upon arrival at the Scripps Clinic and Research Foundation, the participant received a schedule including the time and place for the 1987 interval interview, and an interviewer was appointed to conduct the interview.

As in all of the personal interviews for the AFHS, interviewers were required to ask questions exactly as written, were not allowed to interpret questions or inject personal commentary, and were not allowed to skip between

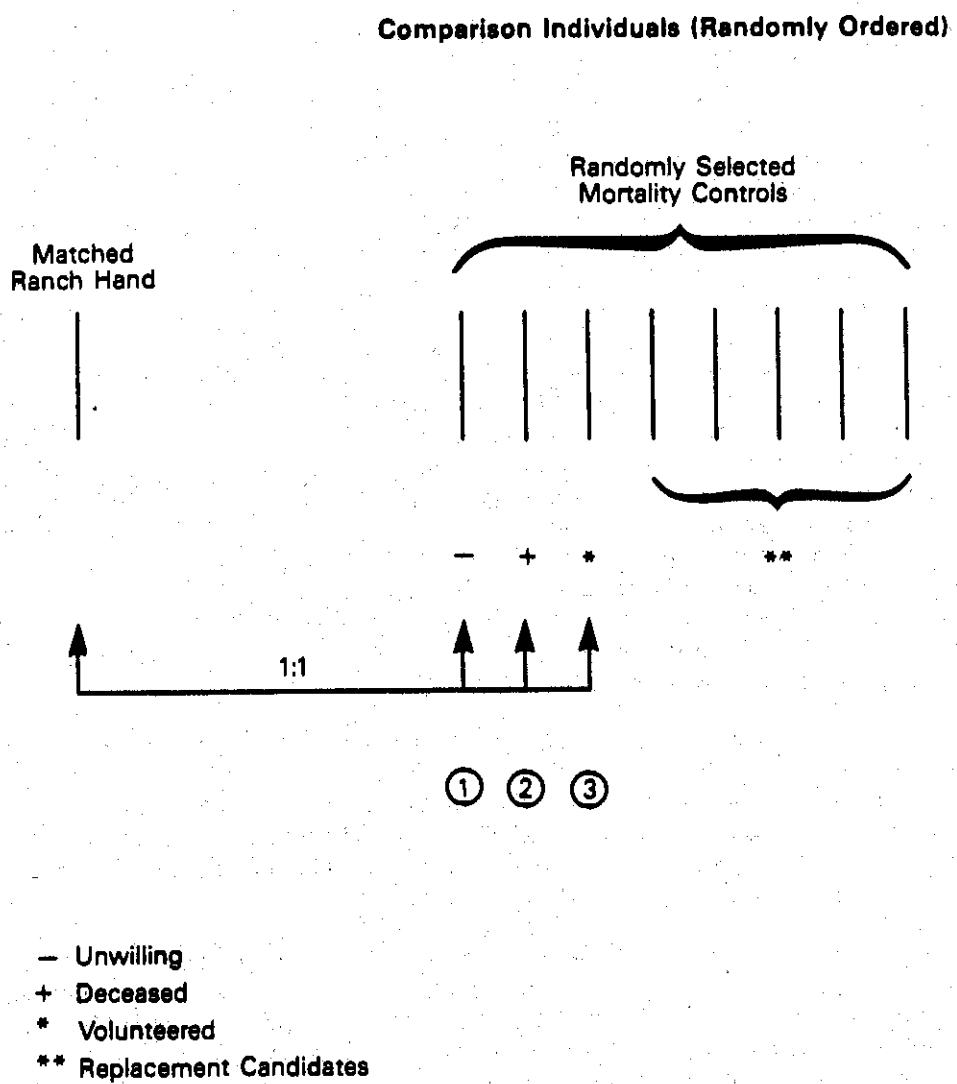


Figure 3-1.
Selection Procedure for the Questionnaire, Physical Examination, and Followup Study

sections of the questionnaire. They were also instructed to probe "don't know" answers at least once. During the interview, medical record release forms were signed; if the participant did not have all of the information with him to complete the form during the interview, the participant was given blank forms and instructions to take with him to complete the forms at home and return them to the Air Force.

One box of completed questionnaires was broken during shipment prior to the automation of the data, and two questionnaires were lost. After repeated unsuccessful attempts to locate the missing questionnaires, the two participants were reinterviewed by telephone.

DATA PROCESSING

All questionnaires completed at the examination site were reviewed and edited by the interviewer site supervisor. In addition, a second review for completeness to ensure that there were no blanks except for logical branching was conducted. These reviews were conducted prior to the participant's departure from the examination site so that any missing information could be retrieved from the participant onsite. The information sheets, completed questionnaires, medical records, and copies of the physical examination forms were organized by participant and sent to the Air Force for medical coding.

After completion of the medical coding, the questionnaires were forwarded to the NORC Chicago office for data processing. Upon receipt, the questionnaires were logged into the receipt and control system and batched for processing. Responses to the open-ended questions were coded and the data were automated. During data entry, the data were checked against valid values and ranges, and missing critical items were flagged. Any further data retrieval was conducted by telephone contacts. In addition, 10 percent of the items in each questionnaire were verified. In the next step, an editing program was executed, which checked for a wide range of errors through single column and intercolumn specifications for valid ranges; interitem consistency; and logic, date, and arithmetic checks. The editing program produced an error sheet for each questionnaire where a discrepancy was identified. The questionnaires were reviewed to resolve the discrepancies on a case-by-case basis. No changes were ever made to the hard copy data; corrections were entered into the data base, and the editing program was rerun. This process was repeated until no errors were detected.

CHAPTER 3

REFERENCES

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CHAPTER 4

PHYSICAL EXAMINATION METHODOLOGY

The 1987 followup examination was provided to all eligible participants who were invited, scheduled, and traveled to the examination site in La Jolla, California. The individuals invited included (1) those who had been invited to the Baseline and/or 1985 followup studies and attended one or both studies, those who chose not to participate, those who completed the Baseline questionnaire only, or those who were unlocatable in 1982 and/or 1985 and (2) Comparisons who had not been invited previously, but who were selected as replacements for noncompliant Comparisons in the 1987 followup. As noted in the Baseline Report, all potential study participants were verified as eligible for the Air Force Health Study (AFHS) following a detailed review of military personnel records. Replacement individuals were selected, by matching data on the self-perception of health from the noncompliant Comparison (obtained from the 1985 telephone survey) with those of the replacement candidate (see Chapter 3 for details).

The followup examination consisted of the following major elements:

- Review-of-Systems Questionnaire
- Psychological Testing
- Physical Examination
- Laboratory Testing
- Specialized Testing, e.g., Phlebotomy for Measurement of Serum Dioxin
- Psychological and Medical Outbriefings.

The Combat Experience Questionnaire and skin, hair, and eye color determinations, which were components of the 1985 followup examination, were conducted for all participants who did not attend the 1985 followup.

Details of the above examination elements were carefully prescribed by the Air Force and set forth as contractual requirements. Clinical variations were neither desired nor authorized; all proposed examination procedural changes were reviewed in detail by Air Force technical and contractual personnel prior to the start of the examinations. An important objective of the technical review was to ensure that bias was not created by any procedural change. The requirement to maintain blind examinations was particularly stringent: The clinical staff was prohibited from knowing or seeking information as to the group identity (Ranch Hand, Comparison) of any participant. At the end of the examination, each participant was asked to note on the critique form whether such information was sought by any member of the clinical or paramedical staff. A total of five participants indicated that an examining physician asked about specific duties in Southeast Asia (SEA); all of these were within the first few weeks of the 1987 followup. Following these occurrences, the critique form was modified to request that the onsite monitor be contacted if any inquiry about specific duties in SEA was made.

As discussed in the 1985 followup report, in mid-1986, strong correlations between dioxin levels in fat tissue and serum were demonstrated by the Centers for Disease Control (CDC) and other institutions.¹ Because of these

results, the Air Force engaged in a collaborative study with CDC to determine the serum dioxin levels of the participants of the AFHS. Of the 2,008 volunteers, blood was successfully drawn from 1,999 participants for this purpose. Due to the time required to analyze the samples, the measurements of serum dioxin levels were not available for analysis and inclusion in this report. These data will be analyzed and reported separately.

EXAMINATION CONTENT

Examination content, as designed by the Air Force, emphasized detection of medical endpoints suspected of being associated with exposure to phenoxy herbicides, chlorophenols, or dioxin. In 1985, findings of the Baseline examination were used by the Air Force to direct changes in the 1985 followup examination. Since the 1987 followup examination was initiated prior to the full analysis of the data from the 1985 examination, most modifications to the examination format and procedures were founded upon quality control issues and the desire to make the clinical content of the examination more responsive to the medical needs of the participants. The general content of the physical examination and psychological test battery is shown in Table 4-1, and the complete laboratory test series is displayed in Table 4-2.

As in the Baseline and 1985 studies, quality control requirements for both laboratory testing and clinical procedures were extensive. Although details are provided in Chapter 6, the following categories provide an overview of the extent of the quality emphasis. For laboratory testing, single reagent lots and control standards were used when practical, duplicate specimens were routinely and blindly retested, testing overlaps were mandatory when test reagents required change, and fast initial response cumulative sum were used to detect rapidly any subtle test drift over time. In addition, 50 specimens from the Baseline serum bank were retested to assess the comparability of laboratory methods. The Scripps Clinic and Research Foundation (SCRF) clinical team was carefully instructed to assure clinical quality. The quality control elements included: a pretest of the examination process; detailed clinical inspection techniques by SCRF, Science Applications International Corporation (SAIC), and Air Force physicians and personnel; preprinted mark-sense examination forms; clinical quality assurance meetings to detect and correct problems; and blindness of exposure status at the examination.

Based on the 1985 followup, clinical quality control enhancements were made to improve measurement techniques in the 1987 followup. The digit preference noted in systolic and diastolic blood pressure readings in the 1985 followup led to the use of automated blood pressure recording; all other parameters of the blood pressure readings (e.g., sitting position, three recordings, nondominant arm at heart level) were not changed. The problem in skin test reading encountered in the 1985 followup was met by a rigorous quality control plan that included the following elements: refresher training for readers; a reading of the four skin tests of all participants by both readers, each blind to the results of the other; a reread of 10 percent of all tests by each of the readers, each blind to the previous reading, and a weekly report citing numbers and proportions of participants with possible anergy, reversal of induration-erythema measurements, and untoward skin reactions or other reading problems (e.g., participant refusal). In addition, new skin

TABLE 4-1.

Elements of the 1987 Followup Physical Examination

Elements	Remarks
General Physical Examination	Internist
Neurological Examination	Neurologist
Dermatologic Examination	Dermatologist
Electrocardiogram	Resting, 4-Hour Fasting and Nicotine Abstinence
Chest X Ray	Radiologist
Immunologic Studies	40% Random Sample
Skin Test Studies	80% Sample
Psychological Evaluation: Millon Clinical Multiaxial Inventory (MCMI) Symptom Checklist 90-R (SCL-90-R)	
Pulmonary Function	Internist with Subspecialty in Pulmonary Disease
Audiometry Examination	Audiologist
Vision Screening and Tonometry	Technician
Patient Outbriefing and Discussion of Individual Results	Medical Diagnostician, Internist, and Ph.D. Psychologist

TABLE 4-2.

Laboratory Test Procedures of the 1987 Followup Physical Examination

Clinical Laboratory

Fasting Glucose	2-Hour Postprandial Glucose
Blood Urea Nitrogen (BUN)	Creatine Phosphokinase (CPK)
Cholesterol	Total Bilirubin
HDL Cholesterol	Direct Bilirubin
Triglyceride	Total Protein
Aspartate Aminotransferase (AST) formerly Serum Glutamic-Oxaloacetic Transaminase (SGOT)	Protein Electrophoresis
Alanine Aminotransferase (ALT) formerly Serum Glutamic-Pyruvic Transaminase (SGPT)	Routine Urinalysis
Gamma-Glutamyl Transpeptidase (GGT)	T ₃ % Uptake
Alkaline Phosphatase	T ₄
Lactic Dehydrogenase (LDH)	Testosterone
Thyroid Stimulating Hormone (TSH)	Hepatitis B Surface Antigen
Prothrombin Time	Hepatitis B Surface Antibody
Serum Protein Profile	Follicle Stimulating Hormone (FSH)
Complete Blood Count (CBC)	Rapid Plasma Reagins (RPR)
Luteinizing Hormone (LH)	Sedimentation Rate
	Fecal Occult Blood

Immunologic Laboratory

Cell Surface (Phenotype) Analyses
Lymphocyte Mitogen (PHA) Stimulation Assays
Mixed Lymphocyte Culture (MLC) Fresh
Natural Killer Cell Assay by Specific Cellular Cytotoxicity Using K-562 Target Cells
Natural Killer Cell Assay (Using Interleukin-2) by Specific Cellular Cytotoxicity Using K-562 Target Cells

test forms were developed for the 1987 followup to facilitate accurate recording and transcription; specific clinical criteria were formulated to require consultation by an allergist; and the skin test measurement criterion for possible anergy, consistent with current World Health Organization guidelines, was adopted for the clinical interpretation of all skin test readings. It was anticipated that this clinical quality control program would standardize both readings and interpretations, and would produce a uniformly superior data set.

In 1985, participant rapport-building techniques were added to boost participation in future followup studies, such as participant critique forms and recreational opportunities afforded to any accompanying family members. These were continued for the 1987 followup, and additional aspects such as unscheduled time for the participant and a number of preventive medicine evaluations including tonometry, vision screening, audiometry, and hemoccult testing were added. For those testing hemoccult positive, the opportunity for a proctosigmoidoscopic examination at no cost to the participant was offered.

CONDUCT OF EXAMINATIONS

All examinations were conducted in accordance with the Examiner's Handbook, provided in Appendix B, from May 1987 to March 1988. Except for weeks with national holidays, two groups of participants, averaging about 29 per group, were examined weekly. Due to the number of participants who refused the examination because of weekday business commitments or because of single-parent responsibilities, one special weekend examination was arranged late in the examination cycle. The examination was identical to the regular 2-1/2-day process, except that it was compressed into 2 days by reducing the number of participants in the group.

The logistics effort required in contacting, transporting, and examining 2,294 study members was formidable. Preexamination contacts consisted of the telephone calls for recruitment to the examination and to determine whether special requirements existed (e.g., wheelchair assistance, weekend examination schedule), and calls to arrange transportation. Once scheduling was reasonably firm, the SAIC logistics coordinator sent each participant a detailed information package outlining dietary requirements, a hemoccult kit, inbriefing schedules, important telephone numbers, a request for medical records, and local maps designating examination-site eating and recreational facilities.

The logistical flow of the entire examination process was complex. Figures 4-1 and 4-2 outline participant flow for the first 2 examination days. As depicted in these figures, each group of participants (generally containing equal numbers of Ranch Hands and Comparisons) was transported early in the morning to SCRF on the first 2 days in a fasting state; tobacco, alcohol, and coffee abstinence for at least 7 hours were also required. Following initial inbriefing and blood draw on the first day, each participant was randomly assigned to the examination group or to the psychological testing group. On the second day, these groups were reversed. After randomization, each member was given an individualized 3-day schedule outlining his medical, interviewing, and laboratory appointments. The schedule carefully noted the specific required periods of fasting and tobacco abstinence (see Figures 4-1 and 4-2).

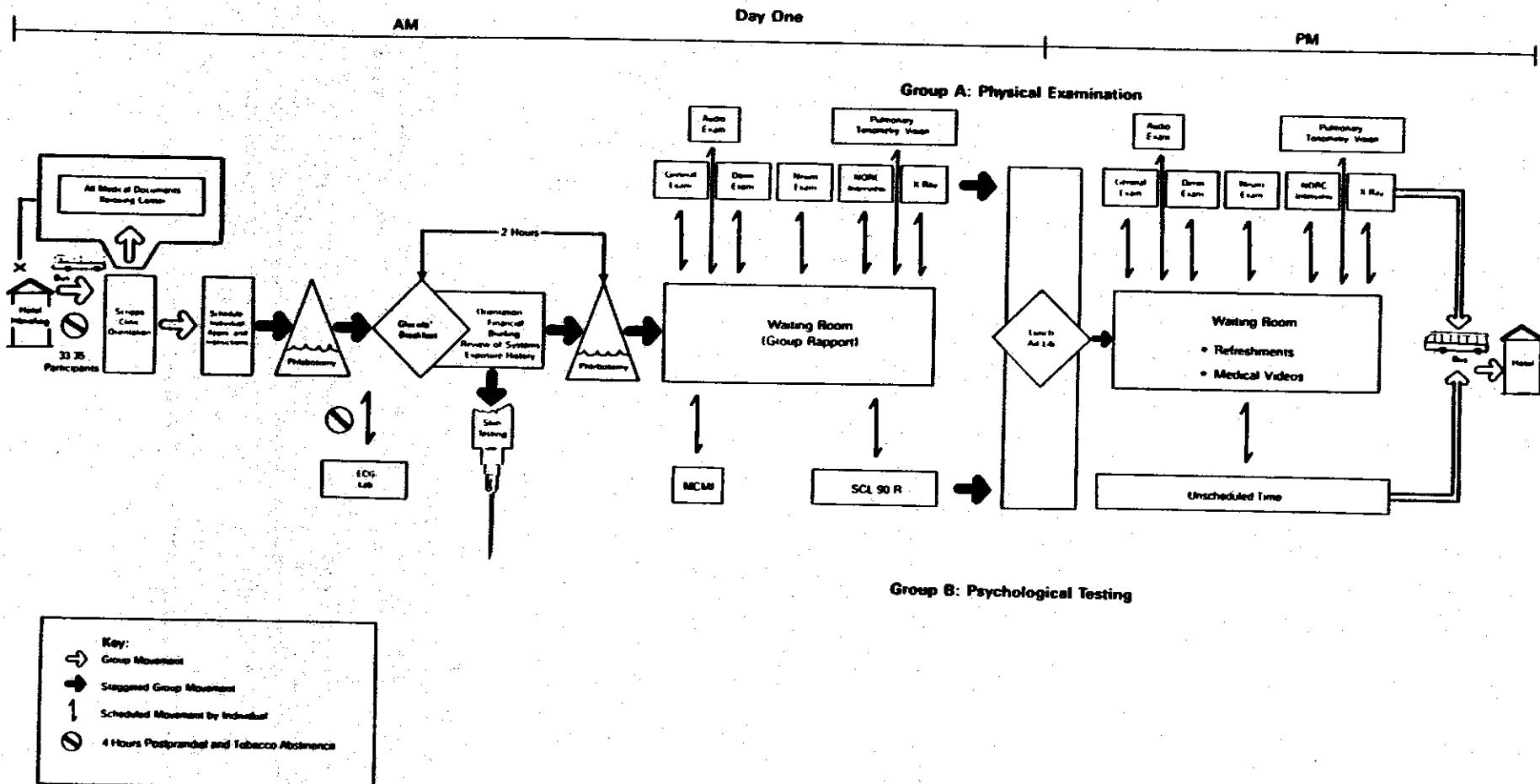


Figure 4-1.
Flow Diagram of Day One Followup Interview and Physical Examination

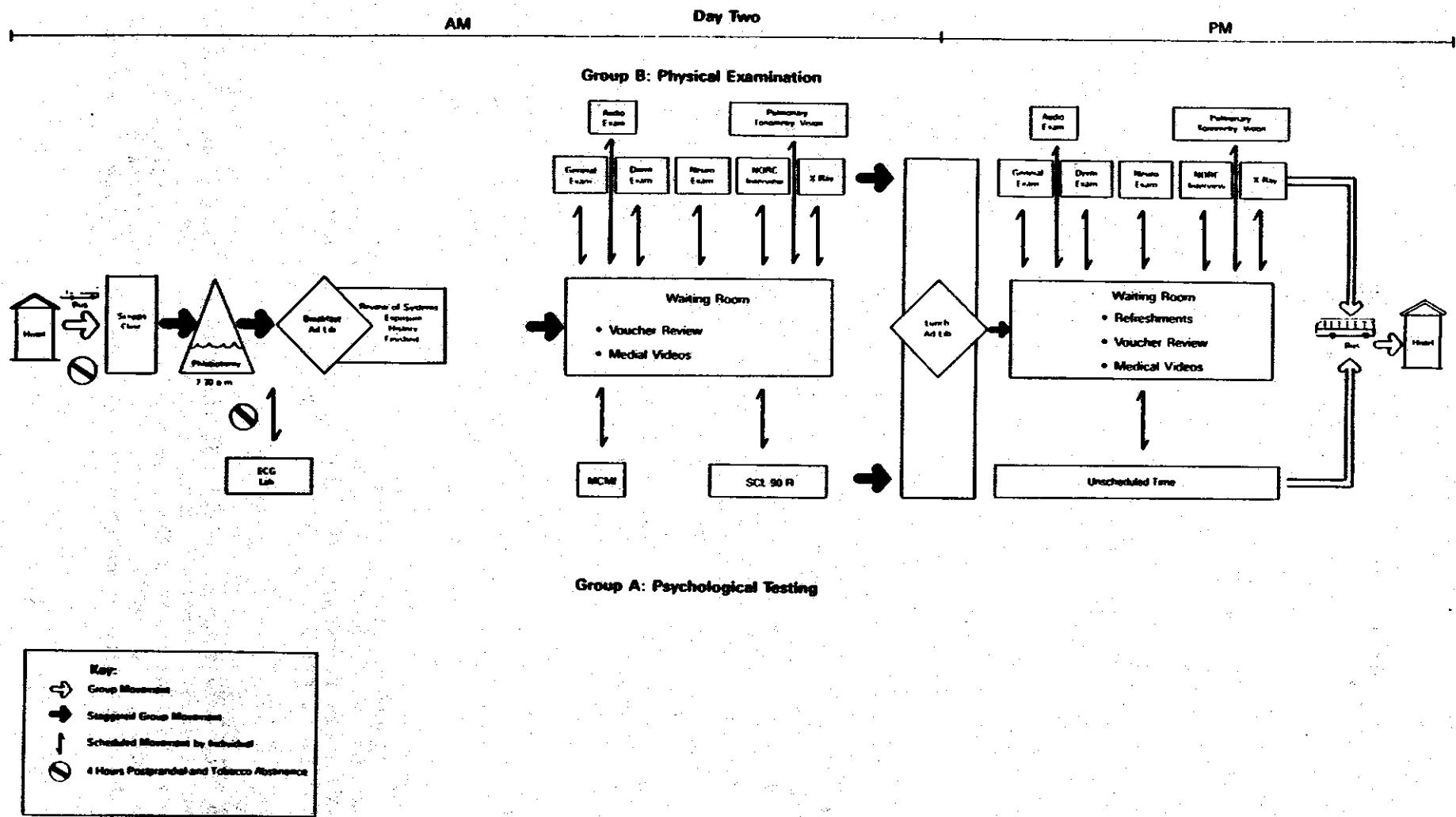


Figure 4-2.
**Flow Diagram of Day Two Followup Interviews
 and Physical Examination**

for generalized periods in relation to electrocardiograph testing). Each individual was reminded of the fact that all aspects of the examination were strictly voluntary, and that refusals would be honored without question. Both general and specific consent forms (e.g., skin biopsy), approved by the Air Force, were explained in detail.

As in the 1985 examination, great reliance was placed upon each individual to find the appropriate clinic area at his scheduled time. This approach had great appeal to this self-reliant population as evidenced by critique feedback. Throughout the examination day, generous time was provided for waiting-room activities, i.e., renewal of past friendships, discussions of experiences in SEA, consumption of refreshments when permitted, and completion of paperwork. Day 3 of the examination was largely spent in finishing up the specialty examinations and receiving the outbriefings from a psychologist and medical diagnostician. Only upon completion of these important debriefings were the participants paid their stipend, reimbursed for travel expenses, and transported to the airport.

As noted previously, the SCRF clinical team was hand-picked for participation in this project. In total, 15 board-certified physicians in internal medicine, neurology, and dermatology participated in the general, specialty, and diagnostic examination. Involved in the performance and interpretation of laboratory testing were 10 radiologists, 3 gastroenterologists, 3 allergists, 5 pulmonologists, and 2 cardiologists. To reduce observer variability, turnover in the clinical and paramedical staffs was minimized during the 10 months of examinations. One SCRF physician served as the Project Medical Director, responsible for the scheduling, conduct, and quality control of the examinations. All examining physicians were introduced to the mark-sense examination forms during the pretest examination. The layout of the form was designed to parallel the flow of the clinical examination so as to minimize recording errors. Because data transcription was not permitted, each physician was responsible for filling in the bubbled form. To a large extent, these mark-sense forms and subsequent quality control were the primary reason for a remarkably clean data set. A complete set of forms is provided in Appendix B.

For the 1987 followup, the special testing included delayed hypersensitivity skin tests and immunologic tests. Skin tests for four antigens were administered in a standardized manner: Candida (1:1,000 weight/volume, 0.1 ml intradermal), mumps (2 complement-fixing units), Trichophyton (1:1,000 weight/volume, 0.1 ml intradermal), and staph-phage lysate ($6-9 \times 10^6$ colony-forming units of S. aureus and $0.5-5 \times 10^7$ staphylococcus bacteriophage plaque-forming units). Allergy-immunology nurse specialists measured the indurations by the standard pen method* at 48 hours after injections. For unusual cases of anergy or severe local reactions, physician consultation was provided. Detailed immunologic testing (see Table 4-2) was conducted on approximately

*Starting 1 to 2 cm away from the margin of the skin test reaction, a medium ball point pen is used to trace a line toward the center of the skin test reaction. When the line reaches the margin of the area, resistance is incurred, and the line is stopped. A similar line is drawn from the opposite direction of the first line. The distance between the two lines is measured.

40 percent of the participants. By the use of the terminal digits of the study numbers that were used for previous testing, a longitudinal connection was established between examinations for these participants. Workload factors mandated blood draws on day 2 for one-half of the selected group. These individuals were excluded from skin testing to avoid interference with the immunologic results. The immunologic tests were subjected to highly structured quality control procedures set forth by the Air Force in an effort to ensure data quality. Every data point was extensively evaluated for validity and quality control.

Two other noteworthy examination features, which were implemented in 1985, were used in the 1987 followup. Because of the high proportion of adverse reactions at the first blood draw during the Baseline examination and their adverse effect upon the flying status of many of the participants, reclining blood-bank chairs were used for all phlebotomy procedures. Further, for the several serious illnesses diagnosed as a result of the examination, personal calls were made by the diagnostician to the participant's personal physician to convey accurately all of the medical findings. This consultation was followed by an immediate letter that included appropriate supporting medical data.

CHAPTER 4

REFERENCES

1. Patterson, D.G. Jr., L.L. Needham, and J.L. Pirkle. Correlation between serum and adipose levels of 2,3,7,8-tetrachlorodibenzo-p-dioxin in 50 persons from Missouri. Archives of Environmental Contamination and Toxicology 17:139-143.

CHAPTER 5

STUDY SELECTION AND PARTICIPATION

INTRODUCTION

During the design phase of the Air Force Health Study (AFHS), the authors of the Protocol anticipated that loss to followup would pose the greatest threat to study validity. In particular, they expected differential compliance with relatively more Ranch Hands self-selecting into the study than Comparisons and with health differences of unknown character between refusing Ranch Hands and refusing Comparisons. As a partial correction, the study design specified that refusing Comparisons would be replaced by Comparisons with the same values of the matching variables and the same health perception. In this way, the replacement Comparisons would serve as surrogates for those Comparisons who refused to participate. This would tend to reduce bias due to refusal in the Comparison group and would have the added advantage of maintaining group size. No corresponding strategy for the Ranch Hands was possible since all Ranch Hands had been identified and invited to participate.

The first Comparison in each randomized matched set asked to participate in the Baseline questionnaire and physical examination was identified as the Original Comparison for his respective Ranch Hand (in accordance with the Protocol). If the Original Comparison was noncompliant (i.e., he refused to participate, was partially compliant, or unlocatable), he was replaced by a "replacement" Comparison. Replacement Comparisons were identified in the data base to satisfy the Protocol requirement that they be contrasted with the refusing Original Comparisons (also called refusals). In the case of an unlocatable Original Comparison, this contrast is, of course, not possible. Deceased Original Comparisons were not replaced.

The statistical contrast of replacements and refusals was to be based on responses to a telephone questionnaire administered to refusals and to their potential replacements. This questionnaire assessed self-perception of health, days lost from work due to illness, and medication use, and was to serve as the basis for the health matching required by the Protocol. Although the Protocol was not explicit on this point, it implied that the decision to include or exclude the replacements from the study would be based only on this contrast. A telephone questionnaire was administered to refusals at Baseline and 1985 followup examinations. At the 1987 followup examination, refusals were simply asked during the scheduling process for their self-perception of health. Health-matching replacements was not implemented at Baseline but was implemented at the 1985 and 1987 followup examinations. Replacement Comparisons were matched to noncompliant (refusal, partially compliant, or unlocatable) Original Comparisons with respect to age, race, rank, and occupation at all examinations.

In this chapter, the cumulative study compliance is summarized and refusing Ranch Hands and Comparisons at the 1987 followup examination are contrasted with respect to reason for refusal and reported health status. All Ranch Hands and Comparisons were contrasted on reported health with adjustment for compliance (fully compliant, refusal). Scheduling patterns were compared by plotting cumulative compliance versus calendar time for Ranch Hands, Original Comparisons, and replacement Comparisons.

Adherence to the replacement algorithm for noncompliant Original Comparisons was investigated at the 1987 followup. Replacement Comparisons were contrasted with the Original Comparisons they replaced on reported health status. Ranch Hands and Comparisons at least partially compliant in the 1987 followup were descriptively contrasted on reported health, medication, and work loss, with adjustment for compliance status (full, partial); these data were too sparse for formal statistical analysis. Finally, Ranch Hands and Comparisons who passively refused the 1987 followup examination were contrasted with respect to reported health status.

FACTORS KNOWN OR SUSPECTED TO INFLUENCE STUDY PARTICIPATION

A multitude of factors influence self-selection. These may be broadly classified as health, logistic, operational, publicity, or demographic factors. For example, health factors are thought to include self-perception of health as well as demonstrable health indicators, such as medication use and work days lost due to illness or injury. Logistic factors include distance to the examination site, reluctance to spend time away from family or job, income, and occupation. Demographic factors include flying status, age, race, or military duty status (active, retired, separated). Operational factors include any aspect of study operation that may cause differential compliance, such as differential treatment of participants during scheduling, physical examination, interview, or debriefing procedures. Publicity factors are related to national attitudes and media presentations regarding the Agent Orange issue, the Vietnam war, veteran health care, or health care in general. Additionally, these considerations may affect people differently and, in particular, may influence Ranch Hands differently than Comparisons.

The decision to volunteer for this study or any study is admittedly complex, making statistical assessment of compliance bias difficult and necessarily crude in that many of the factors contributing to self-selection cannot be measured directly. Instead, compliance bias was investigated at the 1987 followup as in the 1985 followup and Baseline reports, with respect to self-perception of health, medication use, and days lost from work due to illness or injury.

1987 FOLLOWUP SCHEDULING AND REPLACEMENT OPERATION

Matching replacements to noncompliant Original Comparisons on the basis of reported health status, as well as the four matching variables (age, race, rank, and occupation), was continued at the 1987 followup scheduling operation. The telephone survey data base collected at the 1985 followup was utilized to obtain self-perception of health of refusals and all potential replacement candidates who had not been previously contacted. If the replacement or refusal was not represented in the telephone survey data, he was asked at scheduling for his health status. Examination group integrity was encouraged at the 1987 followup as during the 1985 followup (the 81 groups were randomly scheduled for an examination). However, study participants were given the option to remain with their group or to reschedule their examination at a more convenient time.

1987 FOLLOWUP COMPLIANCE

Eighty-four percent (995/1,188) of the eligible Ranch Hands and 77 percent (939/1,224) of the eligible Original Comparisons participated in the 1987 followup examination and questionnaire process. Of 494 replacement Comparisons invited for the 1987 followup, 360 (73%) chose to attend the examination. These and other counts are summarized in Tables 5-1 through 5-4. Table 5-1 provides counts for the Ranch Hands. Total Comparison group counts are shown in Table 5-2. Original Comparison counts are summarized in Table 5-3 and replacement Comparison counts are provided in Table 5-4. Undefined categories are indicated by dashes. For example, a partially compliant participant at Baseline (completed the Baseline questionnaire) could not be partially compliant at a later examination, since partial compliance only occurred when a participant agreed to the Baseline questionnaire but refused to attend the physical examination. Ninety-two percent of living Ranch Hands and 93 percent of living Comparisons who were fully compliant at the Baseline examination returned for the 1987 followup examination.

Fourteen Ranch Hands, 17 Original Comparisons, and 42 replacement Comparisons were examined for the first time at the 1987 followup examination. Table 5-5 describes these newly examined participants in terms of their compliance at the Baseline and 1985 followup studies. Nine of the 14 newly examined Ranch Hands were partially compliant at a previous study, and 2 refused both previous examinations. Three Ranch Hands were new to the study between the 1985 and 1987 followup.

Eleven Original Comparisons were partially compliant at a previous study, and two were new to the study between the 1985 and 1987 followups. Four Originals were refusals at previous studies. Eight (4+2+2) replacement Comparisons were partially compliant at Baseline or the 1985 followup, and 12 (9+3) had previously refused (Table 5-5). Twenty-eight replacements were new to the study between the two followups (Table 5-4). Twenty-two of these 28 replacements were newly examined at the 1987 followup (Table 5-5). Six of these 28 were partially compliant at the 1987 followup.

REFUSING RANCH HANDS VERSUS REFUSING COMPARISONS

Of the 1,188 Ranch Hands and 1,731 Comparisons eligible for the 1987 followup examination, 171 Ranch Hands and 360 Comparisons chose not to attend. Their reasons for refusal are summarized in Table 5-6.

A test of association between reason for refusal and group adjusted for age and rank was performed; the results are summarized in Table 5-7. Due to sparse data, reason for refusal was collapsed to three categories: logistic (job commitment, no time or interest, travel distance--family, confidentiality, financial hardship); passive (passive refusal); and other (fear of physical, dissatisfaction with the U.S. Air Force (USAF), health reasons, dissatisfaction with Baseline, other). The covariates age and rank were dichotomized for the analysis (born before 1942 and born in or after 1942; officer and enlisted, respectively). Twenty-eight Blacks (8 Ranch Hands and 20 Comparisons) were deleted from this analysis due to small cell counts.

The association between reason for refusal and group adjusted for age and rank was not significant ($p=0.238$). The adjusted association between reason

TABLE 5-1.

**Baseline Compliance and Followup Disposition of Ranch Hands
at the Baseline, 1985, and 1987 Examinations**

Time Period	Disposition	Baseline Compliance						Total
		FC	PC	R	UNL	NS		
Baseline		1,045	129	32	2	0	0	1,208
Between Baseline and 1985 Followup	New to Study	--	--	--	--	9	9	9
	Died	10	9	0	0	0	0	19
1985 Followup	Eligible for 1985 Followup	1,035	120	32	2	9	1	1,198
	Contact Not Attempted	0	0	0	0	0	0	0
	Contact Attempted	1,035	120	32	2	9	1	1,198
	Subject Unlocatable	28	12	0	0	0	0	40
	Subject Refused	36	69	29	1	0	0	135
	Subject Partial Compliant	--	--	3	0	4	7	
	Subject Fully Compliant	971	39	0	1	5	1	1,016
Between 1985 and 1987 Followup	New to Study	--	--	--	--	4	4	4
	Died	11	3	0	0	0	0	14
1987 Followup	Eligible for 1987 Followup	1,024	117	32	2	13	1	1,188
	Contact Not Attempted	0	0	0	0	0	0	0
	Contact Attempted	1,024	117	32	2	13	1	1,188
	Subject Unlocatable	9	10	2	0	0	0	21
	Subject Refused	71	70	26	1	3	1	171
	Subject Partial Compliant	--	--	1	0	0	0	1
	Subject Fully Compliant	944	37	3	1	10	1	995

Legend: FC = Fully Compliant at Baseline
 PC = Partially Compliant at Baseline
 R = Refusal at Baseline
 UNL = Unlocatable at Baseline
 NS = New to Study Since Baseline

TABLE 5-2.

Baseline Compliance and Followup Disposition of Comparisons
at the Baseline, 1985, and 1987 Examinations

Time Period	Disposition	Baseline Compliance						Total
		FC	PC	R	UNL	NS		
Baseline		1,224	307	128	9	0		1,668*
Between Baseline and 1985 Followup	New to Study	--	--	--	--	73		73**
	Died	16	9	1	0	0		26
1985 Followup	Eligible for 1985 Followup	1,208	298	127	9	73		1,715
	Contact Not Attempted	0	0	0	0	0		0
	Contact Attempted	1,208	298	127	9	73		1,715
	Subject Unlocatable	39	27	0	0	1		67
	Subject Refused	30	175	87	5	30		327
	Subject Partial Compliant	--	--	22	0	6		28
	Subject Fully Compliant	1,139	96	18	4	36		1,293
Between 1985 and 1987 Followup	New to Study	--	--	--	--	32		32
	Died	14	1	1	0	0		16
1987 Followup	Eligible for 1987 Followup	1,194	297	126	9	105		1,731
	Contact Not Attempted	0	0	0	0	2		2
	Contact Attempted	1,194	297	126	9	103		1,729
	Subject Unlocatable	8	21	8	3	3		43
	Subject Refused	73	180	87	3	17		360
	Subject Partial Compliant	--	--	13	0	14		27
	Subject Fully Compliant	1,113	96	18	3	69		1,299

*The Baseline Report total count of 1,669 listed in the Baseline Report should be 1,668 due to the inclusion of 1 ineligible Comparison.

**Twenty-one of these 73 were actually identified as eligible for the study during Baseline but the contract ended before they could be located by the contractor.

Legend: FC = Fully Compliant at Baseline
 PC = Partially Compliant at Baseline
 R = Refusal at Baseline
 UNL = Unlocatable at Baseline
 NS = New to Study Since Baseline

TABLE 5-3.

**Baseline Compliance and Followup Disposition of Original Comparisons
at the Baseline, 1985 and 1987 Examinations**

Time Period	Disposition	Baseline Compliance						Total
		FC	PC	R	UNL	NS		
Baseline		936	220	78	3	--		1,237
Between Baseline and 1985 Followup	New to Study	--	--	--	--	17		17
	Died	11	9	1	0	0		21
1985 Followup	Eligible for 1985 Followup	925	211	77	3	17		1,233
	Contact Not Attempted	0	0	0	0	0		0
	Contact Attempted	925	211	77	3	17		1,233
	Subject Unlocatable	29	20	0	0	1		50
	Subject Refused	24	129	61	2	4		220
	Subject Partial Compliant	--	--	7	0	1		8
	Subject Fully Compliant	872	62	9	1	11		955
Between 1985 and 1987 Followup	New to Study	--	--	--	--	4		4
	Died	12	1	0	0	0		13
1987 Followup	Eligible for 1987 Followup	913	210	77	3	21		1,224
	Contact Not Attempted	0	0	0	0	0		0
	Contact Attempted	913	210	77	3	21		1,224
	Subject Unlocatable	7	14	8	2	1		32
	Subject Refused	51	132	52	1	6		242
	Subject Partial Compliant	--	--	11	0	0		11
	Subject Fully Compliant	855	64	6	0	14		939

Legend: FC = Fully Compliant at Baseline
 PC = Partially Compliant at Baseline
 R = Refusal at Baseline
 UNL = Unlocatable at Baseline
 NS = New to Study Since Baseline

TABLE 5-4.

**Baseline Compliance and Followup Disposition of Replacement Comparisons
at the Baseline, 1985, and 1987 Examination**

Time Period	Disposition	Baseline Compliance						Total
		FC	PC	R	UNL	NS		
Baseline		288	87	50	6	--		431
Between Baseline and 1985 Followup	New to Study	--	--	--	--	56		56
	Died	5	0	0	0	0		5
1985 Followup	Eligible for 1985 Followup	283	87	50	6	56		482
	Contact Not Attempted	0	0	0	0	0		0
	Contact Attempted	283	87	50	6	56		482
	Subject Unlocatable	10	7	0	0	0		17
	Subject Refused	6	46	26	3	26		107
	Subject Partial Compliant	--	--	15	0	5		20
	Subject Fully Compliant	267	34	9	3	25		338
Between 1985 and 1987 Followup	New to Study	--	--	--	--	28		28
	Died	2	0	1	0	0		3
1987 Followup	Eligible for 1987 Followup	281	87	49	6	84		507
	Contact Not Attempted	0	0	0	0	2		2*
	Contact Attempted	281	87	49	6	82		505
	Subject Unlocatable	1	7	0	1	2		11
	Subject Refused	22	48	35	2	11		118
	Subject Partial Compliant	--	--	2	0	14		16
	Subject Fully Compliant	258	32	12	3	55		360

*Records indicate that the contractor failed to recognize these two individuals and consequently did not attempt to schedule them.

Legend: FC = Fully Compliant at Baseline
 PC = Partially Compliant at Baseline
 R = Refusal at Baseline
 UNL = Unlocatable at Baseline
 NS = New to Study Since Baseline

TABLE 5-5.

New Fully Compliant Participants at the 1987 Followup by Group and Previous Compliance

Baseline	Previous Compliance	1985 Followup	Group		
			Ranch Hand	Original Comparison	Replacement Comparison
Partially Compliant	Refusal	5	9	4	
	Unlocatable	1	2	0	
Refusal	Partially Compliant	1	0	2	
	Refusal	2	2	3	
New to Study	Partially Compliant	2	0	2	
	Refusal	0	2	9	
	New to Study	3	2	22	
Total		14	17	42	

for refusal and age was of borderline significance ($p=0.063$); a greater percentage of men born in or after 1942 were passive refusals (26%) than men born before 1942 (18%). There were no significant higher order interactions.

Of the 531 refusals, reported health status was available on 150 (88%) of 171 refusing Ranch Hands and 324 (90%) of 360 refusing Comparisons. Data sources included AFHS questionnaires at the 1985 followup and at Baseline, the telephone survey at the 1985 followup, and the noncompliant telephone questionnaire administered at Baseline. Their responses are presented in Table 5-8. Among the 474 refusals responding to the health status question, there was a borderline significant association between group (Ranch Hand, Comparison) and reported health ($p=0.080$); a greater percentage of refusing Comparisons (47%) reported excellent health than refusing Ranch Hands (40%), and a greater percentage of refusing Ranch Hands (11%) reported fair health than Comparisons (5%).

At the 1985 followup, the reported health status of 35 refusing Ranch Hands was not associated with that of 42 refusing Comparisons ($p=0.720$). The large difference in significance levels between these two analyses appears due to a much larger sample size at the 1987 followup. In addition, the direction and magnitude of the difference between the groups in the good and fair categories changed between the 1985 and 1987 followups.

Ideally, compliance bias between the groups should be assessed by comparing the health of refusing and fully compliant participants with adjustment for the matching variables. The only data available on the refusing participants, however, are their responses to the health status question at the 1987

TABLE 5-6.
Reason for Refusal by Group*

Reason	Ranch Hand		Comparison	
	Number	Percent	Number	Percent
Fear of Physical	1	0.6	4	1.1
Job Commitment	32	18.7	61	17.0
Dissatisfaction with USAF	10	5.8	11	3.1
No Time or Interest	28	16.4	79	22.1
Travel Distance, Family	5	2.9	17	4.7
Confidentiality	1	0.6	4	1.1
Health Reasons	11	6.4	16	4.5
Passive Refusal	40	23.4	78	21.8
Dissatisfaction With Baseline	0	0.0	1	0.3
Financial Hardship	1	0.6	1	0.3
Other (unspecified)	42	24.6	86	24.0
Total	171		358	

*Data on two Comparisons were missing.

followup and previous studies. A test of association between reported health status and group adjusted for compliance, age, and rank was performed. The results are summarized in Table 5-9. Due to sparse data, reported health status was collapsed to two categories: excellent/good and fair/poor. The covariates age and rank were dichotomized (born before 1942 and born in or after 1942; officer and enlisted, respectively). The covariate occupation (flying or ground duty) could not be accommodated. Blacks (n=166) were excluded from the analysis due to small cell counts.

The association between reported health status and group adjusted for compliance, age, and rank was not significant ($p=0.310$). The adjusted association between reported health status and compliance was statistically significant ($p<0.001$) for both groups combined. As can be seen in the

TABLE 5-7.

Reason for Refusal Versus Group Adjusted
for Age and Rank Among Nonblacks

Age	Rank	Group	Reason for Refusal						Total
			Logistic		Passive		Other		
Number	Percent	Number	Percent	Number	Percent	Number	Percent	Total	
<1942	Officer	RH	17	42.5	7	17.5	16	40.0	40
		Comp	36	45.6	13	16.4	30	38.0	79
	Enlisted	RH	18	36.7	9	18.4	22	44.9	49
		Comp	30	44.1	14	20.6	24	35.3	68
≤1942	Officer	RH	8	42.1	7	36.8	4	21.1	19
		Comp	24	33.3	19	26.4	29	40.3	72
	Enlisted	RH	20	36.4	15	27.3	20	36.4	55
		Comp	66	55.5	27	22.7	26	21.8	119

Abbreviations: RH = Ranch Hand
Comp = Comparison

TABLE 5-8.

Reported Health Status of Refusals at the 1987 Followup

Reported Health Status	Group					
	Ranch Hand		Comparison		Number	Percent
	Number	Percent	Number	Percent		
Excellent	60	40.0	153	47.2		
Good	65	43.3	143	44.1		
Fair	16	10.7	17	5.2		
Poor	9	6.0	11	3.4		
Total	150		324			

TABLE 5-9.
Reported Health Status Versus Group Adjusted
for Compliance, Age, and Rank Among Nonblacks

Compliance	Birth Year	Rank	Group	Reported Health Status				Total	
				Excellent/Good		Fair/Poor			
				Number	Percent	Number	Percent		
Fully Compliant	<1942	Officer	RH Comp	281	94.6	16	5.4	297	
				359	95.7	16	4.3	375	
		Enlisted	RH Comp	238	89.5	28	10.5	266	
				299	89.0	37	11.0	336	
	≥1942	Officer	RH Comp	73	97.3	2	2.7	75	
				110	98.2	2	1.8	112	
		Enlisted	RH Comp	282	94.3	17	5.7	299	
				369	93.4	26	6.6	395	
Refusal	<1942	Officer	RH Comp	31	88.6	4	11.4	35	
				63	94.0	4	6.0	67	
		Enlisted	RH Comp	37	80.4	9	19.6	46	
				54	81.8	12	18.2	66	
	≥1942	Officer	RH Comp	14	87.5	2	12.5	16	
				64	98.5	1	1.5	65	
		Enlisted	RH Comp	38	80.9	9	19.1	47	
				101	91.0	10	9.0	111	

Abbreviations: RH = Ranch Hand
Comp = Comparison

percentages in Table 5-9, refusing participants report poorer health more often than their fully compliant counterparts, except for officer Comparisons born in or after 1942. It is of interest that, among refusals, Ranch Hands consistently reported poorer health more often than Comparisons. The interaction of reported health status, group, and compliance was borderline significant ($p=0.084$).

SCHEDULING AT 1985 AND 1987 FOLLOWUP

During the 1985 followup scheduling period, the schedulers were required to find and schedule a willing health-matched replacement within 5 working days of a confirmed refusal to correct differences in the pattern of group scheduling experienced at Baseline. This constraint proved impractical to implement since Comparisons would often vacillate, forcing a series of repeated telephone calls. Rather than terminate the process at 5 days, as required by the contract, the Air Force directed the schedulers to continue their recruiting attempts, sometimes for several months. Hence, new health-matched replacements were brought into the study much later than other participants. At the 1987 followup, the Air Force required that schedulers attempt to schedule health-matched replacements within 15 working days of identifying a refusal.

At the 1987 followup, the 15-day scheduling constraint also proved impractical due to the Comparisons' hesitancy to schedule. The Air Force directed schedulers to extend their recruiting attempts in an effort to provide maximum opportunity for Comparisons to participate. The percent completing the physical examination by calendar date is plotted in Figure 5-1 for Ranch Hands, Original Comparisons, replacement Comparisons, and all Comparisons. These patterns are similar to those seen at 1985 followup. Cumulative participation by month for all three examinations is shown in Appendix C.

REPLACEMENT COMPARISONS VERSUS THE NONCOMPLIANT ORIGINAL COMPARISONS THEY REPLACED

A contrast of refusing Original Comparisons and their replacements based on reported health status was not accomplished at Baseline since the necessary data were not available at the time. At the 1985 followup, a short noncompliance questionnaire similar to the telephone survey questionnaire was used to elicit reported health status of refusing Comparisons.

Of 288 Comparisons replaced at Baseline, only 57 responded to the short noncompliance telephone questionnaire. These 57 comprised 38 Original Comparisons and 19 replacements. Replacements were statistically contrasted with the refusing Comparisons they replaced based on their reported health status. This contrast was summarized in Table 5-9 of the 1985 followup report. There was no statistical difference in reported health patterns between refusing Original Comparisons and their replacements. It is noteworthy that 53 percent of Original refusing Comparisons were matched, by chance, perfectly to their replacements, on reported health status.

In April 1985, all previously uncontacted living Comparisons were identified for telephone contact to assess their current health. This health status information was necessary for matching replacements to refusing Original Comparisons. From 9,982 available Comparisons, 7,963 (80%) were identified for the telephone survey. The remaining 2,019 Comparisons included 360 verified as being deceased and 1,659 who had been previously contacted. The group of 1,659 previously contacted Comparisons was comprised of Comparisons who were fully compliant, partially compliant, or refusals at Baseline. Of the 7,963 identified for the telephone survey, responses were obtained from 7,411 Comparisons. These counts correct corresponding figures cited on page 5-7 of the 1985 followup final report.

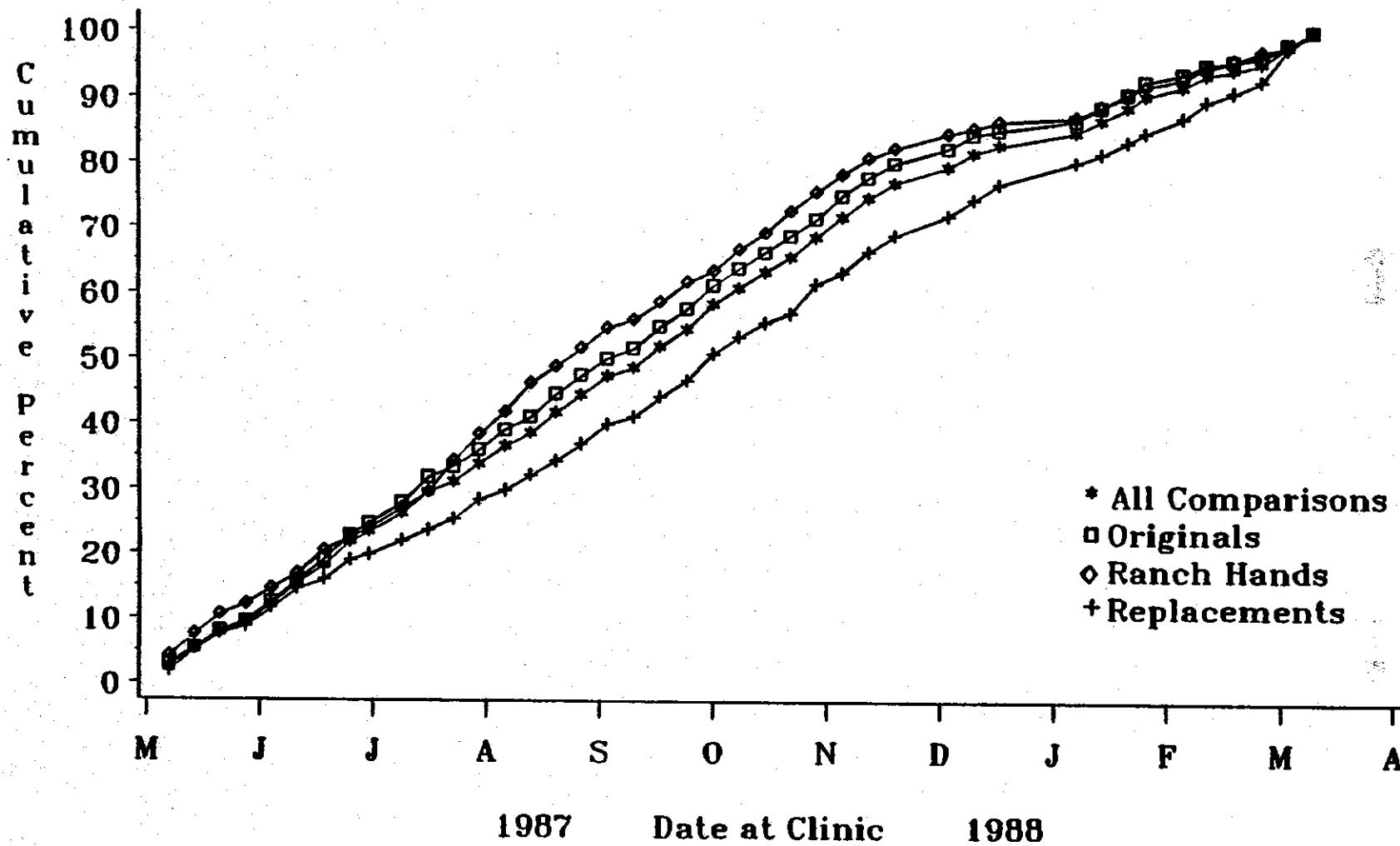


Figure 5-1.
Percent Completed Physical Examination by Calendar Date

The survey questionnaire asked the respondent for his self-perception of health, current prescribed medication use, work days lost due to illness or injury, special health care needs, and income.

As initiated at the 1985 followup, matching replacements to refusing Original Comparisons on the basis of health status as well as age, race, rank, and occupation was maintained at the 1987 followup. The reported health status of new replacements for refusing Original Comparisons was obtained from the telephone survey at the 1985 followup. If a potential replacement was not in the telephone survey data base, he was asked for his self-perception of health during scheduling.

In all, 28 new replacements were added to the study at the 1987 followup. Documentation of replacement actions was located on 24 of these individuals. Of these 24 replacements, only 13 were scheduled to replace refusing Original Comparisons; the remaining 11 mistakenly replaced refusing replacements. Records on health status could be located on 12 of these 13 replacements. Health-matching replacement strategy is summarized on these 12 replacement Comparisons in Table 5-10.

All but one Original reported good or excellent health. The other Original reported fair health. Of the 12 replacements, 1 reported poor health and all others reported good or excellent health. All of the 12 replacements were correctly matched to Originals on health status as required in the Protocol. The inclusion of health-matched replacements corrects possible compliance bias arising from refusal in the Comparison group. The relatively small number of health-matched replacements minimized the actual effect of this bias correction, however.

Two hundred and eighty-five Original Comparisons were noncompliant at the 1987 followup. It is of interest to determine whether these Originals were appropriately replaced at the 1987 followup by compliant replacements. The entire matched set of replacement candidates for each noncompliant Original was reviewed to determine if the appropriate replacement strategy had been followed; a compliant replacement Comparison is present in the Original's matched set. The results on these 285 noncompliant Originals are presented in Table 5-11.

As can be seen from Table 5-11, 230 noncompliant Original Comparisons have been appropriately replaced by compliant replacement Comparisons in their matched set.

There are two circumstances where replacement of noncompliant Original Comparisons has not been accomplished: (1) either the noncompliant Original Comparison belongs to a matched set in which all contacted replacement Comparisons are noncompliant and some Comparisons remain uncontacted, or (2) the noncompliant Original is a member of a matched set in which all replacement Comparisons are uncontacted. These two cases occur 22 and 33 times, respectively.

Health records on these 55 matched sets were reviewed to determine whether replacement action was precluded because of a health mismatch between the refusing Original and all uncontacted replacement Comparisons in the matched set. Health records could not be located on five of the refusing

TABLE 5-10.

Reported Health Status of Replaced Originals and Their Matched Replacements at the 1987 Followup

Replacement's Reported Health	Original Comparison's Reported Health					Total
	Excellent	Good	Fair	Poor		
Excellent	6	0	0	0		6
Good	1	4	0	0		5
Fair	0	0	0	0		0
Poor	0	0	1	0		1
Total	7	4	1	0		12

TABLE 5-11.

Matched Set Compliance of 285 Noncompliant Original Comparisons

Matched Set Compliance	Original's Compliance				Total
	Refusal	Unlocatable	Partial		
At Least One Compliant Replacement	193	26	11		230
All Contacted Replacements Noncompliant and Other Uncontacted Comparisons in the Matched Set	20	2	0		22
No Comparisons Contacted	29	4	0		33
Total	242	32	11		285

Originals. In two other cases, health records indicate that a health mismatch did in fact exist between the refusing Original and each uncontacted replacement Comparison in his matched set. In all of the remaining 48 matched sets, at least 1 uncontacted replacement Comparison matched the health status of the refusing Original Comparison and would have been eligible to participate in the study.

In conclusion, of 285 noncompliant Original Comparisons at the 1987 followup, all but 55 were members of matched sets having at least 1 other compliant replacement Comparison. Thirty-three of the 55 were noncompliant Original Comparisons whose replacements were never contacted, and 22 were members of matched sets in which all contacted replacements are noncompliant and at least 1 other replacement was uncontacted. Of these 55 noncompliant Original Comparisons, 48 belonged to matched sets containing at least 1 uncontacted replacement matched on health status to the refusing Original Comparison. Thus, 48 noncompliant Original Comparisons appeared not to have been replaced as required by the Protocol. The Air Force intended that additional replacements be contacted in a matched set until a health-matched compliant replacement is found. The effect of these oversights is considered negligible and these oversights will be corrected at the next examination.

PARTIALLY COMPLIANT VERSUS FULLY COMPLIANT PARTICIPANTS

In addition to the analyses summarized in Tables 5-8 and 5-9, a contrast of partially compliant versus fully compliant participants at the 1987 followup is presented. However, only 1 Ranch Hand and 27 Comparisons were partially compliant at the 1987 followup (Tables 5-1 and 5-2), precluding statistical analysis of these data for group differences. These individuals were administered the Baseline questionnaire in their homes but subsequently refused to attend the examination. The previous compliance of the 28 participants partially compliant at the 1987 followup is summarized in Table 5-12. Data on health status, medication use, and work loss of the 28 partially compliant and 2,294 fully compliant participants at 1987 followup are reported in Tables 5-13 through 5-15, respectively.

These data were sparse and were not considered supportive or nonsupportive of the compliance bias calculations presented in the Baseline report. The Baseline report conclusions regarding the potential effects of differential compliance should be regarded as conservative overestimates of bias but worthy of consideration until more data become available.

ANALYSIS OF PASSIVE REFUSALS

One of the reasons for refusal summarized in Table 5-16 was passive refusal. Passive refusal included failure to appear at a scheduled physical examination. There were 40 Ranch Hand, 53 Original Comparison, and 25 replacement Comparison passive refusals at the 1987 followup. Ranch Hand and Comparison passive refusals were contrasted with respect to reported health status. These data are summarized in Table 5-16.

TABLE 5-12.

Previous Compliance Status of 28 Partially Compliant Participants at the 1987 Followup

Previous Compliance	Group		
	Ranch Hand	Original Comparison	Replacement Comparison
Refusal at Baseline and 1985 Followup	1	11	2
New to Study at 1985 Followup and Refusal at 1985 Followup	0	0	8
New to Study at 1987 Followup	0	0	6
Total	1	11	16

TABLE 5-13.

Reported Health of Partially and Fully Compliant Participants at the 1987 Followup

1987 Followup Compliance	Reported Health	Group			Comparison	Total
		Ranch Hand	Number	Percent		
Full	Excellent	474	47.6	651	50.2	1,125
	Good	454	45.6	560	43.1	1,014
	Fair	51	5.1	75	5.8	126
	Poor	16	1.6	12	0.9	28
Total		995		1,298*		2,293
Partial	Excellent	0	0.0	17	63.0	17
	Good	1	100.0	10	37.0	11
	Fair	0	0.0	0	0.0	0
	Poor	0	0.0	0	0.0	0
Total		1		27		28

*One participant answered "Don't know."

TABLE 5-14.

**Reported Medication Use of Partially and Fully Compliant Participants
at the 1987 Followup**

1987 Followup Compliance	Medication Use	Group				
		Ranch Hand		Comparison		
		Number	Percent	Number	Percent	Total
Full	Yes	253	25.4	332	25.6	585
	No	742	74.6	967	74.4	1,709
Total		995		1,299		2,294
Partial	Yes	0	0.0	2	7.4	2
	No	1	100.0	25	92.6	26
Total		1		27		28

TABLE 5-15.

**Reported Work Loss of Partially and Fully Compliant Participants
at the 1987 Followup**

1987 Followup Compliance	Work Loss	Group				
		Ranch Hand		Comparison		
		Number	Percent	Number	Percent	Total
Full	Yes	136	16.7	190	18.0	326
	No	675	83.2	867	82.0	1,542
Total		811		1,057		1,868*
Partial	Yes	0	0.0	2	7.7	2
	No	1	100.0	24	92.3	25
Total		1		26		27*

*One partially compliant and 426 fully compliant participants skipped this question.

TABLE 5-16.
Reported Health Status of Passive Refusals

Reported Health Status			Group				
	Ranch Hand		Original Comparison		Replacement Comparison		
	Number	Percent	Number	Percent	Number	Percent	Total
Excellent	16	40.0	28	52.8	15	60.0	59
Good	21	52.5	24	45.3	9	36.0	54
Fair	3	7.5	1	1.9	0	0.0	4
Poor	0	0.0	0	0.0	1	4.0	1
Total	40		53		25		118

The data indicated no significant association between group and reported health status among passive refusals ($p=0.170$). Additionally, health status was collapsed to excellent/good and fair/poor, and group was collapsed to Ranch Hand and Comparison because of sparse data in the full table. Analysis of the data from the collapsed table revealed no significant association between group and reported health status ($p=0.220$).

CONCLUSIONS

These compliance analysis results suggested that there has been no change in the way replacements self-selected for entry into this study from the Baseline and 1985 followup examinations. As stated in the two previous reports, there appears to be little selection bias due to nonparticipation.

Forty-eight of 285 noncompliant (refusing, partially compliant, or unlocatable) Original Comparisons were not replaced as required in the Protocol. The biasing effect of this omission is not known but is considered negligible.

CHAPTER 5

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CHAPTER 6

QUALITY CONTROL

During the 1987 Air Force Health Study (AFHS) followup, stringent adherence to quality assurance (QA) was planned for and upheld throughout the study, from project initiation to final product delivery and acceptance by the Air Force. A quality program plan was developed for this study cycle, outlining all contract activities requiring periodic and/or systematic QA and quality control (QC) monitoring. The purpose of this chapter is to provide an overview of the specific QA measures developed and used by the project team, specifically in the areas of administrative QA; questionnaire, physical, and psychological examination QC; laboratory QC measures; data management QC; and statistical QC.

ADMINISTRATIVE QUALITY ASSURANCE

In recognition of the magnitude, complexity, and importance of the AFHS, a Quality Review Committee (QRC) was established, at the contractor's initiative, at the initiation of the 1985 followup and continued through the 1987 followup for the purpose of providing general oversight to the AFHS QA Program and advice on the appropriateness of program management and QC actions. The QRC was composed of senior corporate personnel from the prime contractor. These independent reviewers remained separate from the project management staff. The QRC met formally each quarter to review recent study progress and any issues that either had an impact on study quality or were perceived as a potential problem.

Assisting the QRC in day-to-day oversight responsibilities was a QA secretary. As part of the monitoring function, the QA secretary received exception reports from project task managers whenever an incident occurred that could affect study quality. Monthly reports were also prepared for the Air Force, documenting project compliance with project QA criteria and noting any instances of noncompliance.

The remainder of this chapter describes the specific QC procedures followed for the individual tasks.

QUESTIONNAIRE QUALITY CONTROL

The National Opinion Research Center (NORC) used both onsite and home-office QC procedures to produce a comprehensive data set. All AFHS questionnaires were pretested to evaluate their completion time and participant acceptability before they were used at the Scripps Clinic and Research Foundation (SCRF). Onsite QC procedures included observing and rating interviewers, review of every questionnaire at the completion of the interview, and monitoring participant evaluations. The Air Force also continuously conducted QA observations of all onsite activities. QC of data processing included manually editing each questionnaire, including verifying critical items (10% of total items) for each questionnaire, computerized cleaning (with both single item and interitem review for range and consistency), identifying values out of range, and reviewing the actual questionnaire copy to reconcile or correct detected errors.

NORC recruited and trained 12 interviewers according to the procedures described in Chapter 3. A minimum number of interviewers was selected to reduce interviewer variability. Additionally, these individuals were blinded to the participants' exposure status to avoid bias. Interviewers were required to ask questions exactly as recorded, and in the order in which they appeared. No personal interpretation was allowed.

An onsite field manager closely supervised each interviewer's work, observing individual interviews weekly during the examination schedule. The field manager reported directly to the NORC Project Director weekly, and was in turn evaluated by the Project Director during quarterly site visits, to ensure direct accountability by the home office and the field manager for promptly resolving any issues.

Specifically, interviewers were checked for accuracy in questionnaire skip patterns, probing, circling of the correct code, control of the interview, voice quality, reading, and use of associated documents. When called for, the onsite manager gave immediate retraining after each error and documented the content of this training. At weekly meetings, held with all interviewers, the field manager used generalizations from individual interviewer performance observations to train the entire group of interviewers.

The NORC field manager also monitored participant evaluations of the study closely and used the information gathered to plan and implement retraining. The manager and staff reviewed each completed questionnaire, attempting to retrieve missing data while the study participant was at the physical examination site. In addition, a second review of the questionnaires for completeness was conducted by a reviewer who was independent of the interviewing staff. Missing or ambiguous data were also retrieved by telephone when necessary.

Once the participant questionnaires were received for data processing, they were reviewed for completeness by a coding supervisor and staff dedicated to the AFHS for the entire project. Resolution of inconsistencies was accomplished by staff members, who coded all responses prior to keypunching. Questionnaires were then coded, and a 10-percent recode was done on open-ended items. When a batch failed the 10-percent recode, the entire batch was recoded and the coding staff was retrained.

During data entry, range validity checks were performed and 10 percent of the most important items in each questionnaire was verified. Data were then passed through a computer program that checked for inter- and intra-column errors. When errors were detected, the questionnaires were reviewed and the errors corrected. The process continued until no errors were detected by the cleaning program. Then, frequencies were reviewed and any anomalies or errors previously undetected were corrected by reviewing the questionnaires on a case-by-case basis. All corrections were documented and entered into the data base, but no changes were made to the original data recorded in the questionnaires. QA reports were generated monthly, detailing the summary statistics on the number of questionnaires reviewed, the number and types of transcriptions failing QC checks, and the average number of coding errors per batch processed. The data review process continued until no errors or discrepancies were discernible.