

Table 4-18

"At the present time, do you smoke cigarettes?"
 "Have you ever smoked cigarettes on a regular basis?"

CURRENT SMOKING STATUS

	MALES		FEMALES		TOTAL	
	No.	%	No.	%	No.	%
Current Smokers	75	35%	64	27%	139	31%
Former Smokers	42	20%	49	21%	91	20%
Never Smoked	98	45%	122	52%	220	49%
	215	100%	235	100%	450	100%

Table 4-20

FOR FORMER SMOKERS

"When you were smoking regularly, on the average how many cigarettes did you smoke per day?"

No. of cigarettes	MALES		FEMALES		TOTAL	
	No.	%	No.	%	No.	%
1-19	24	57%	32	65%	56	62%
20-39	16	38%	14	29%	30	33%
≥ 40	2	5%	1	2%	3	3%
Don't know	0	-	2	4%	2	2%
	42	100%	49	100%	91	100%

Table 4-19

FOR CURRENT SMOKERS

"What is the average number of cigarettes you smoke per day now?"

No. of Cigarettes	MALES		FEMALES		TOTAL	
	No.	%	No.	%	No.	%
1-19	29	39%	26	41%	55	40%
20-39	34	45%	32	50%	66	47%
≥ 40	12	16%	5	8%	17	12%
Don't Know	0	-	1	1%	1	1%
	75	100%	64	100%	139	100%

When current drinkers were asked the number of days per month they typically drink, they responded as shown in Table 4-23. Again there is a difference between males and females in the higher alcohol consumption categories.

Twenty-three percent of the male regular drinkers reported drinking 5 or more drinks on the days they did drink, while only 5% of the female drinkers reported this.

Table 4-24 shows the response to the question about heavy drinking. Again males responded to having three or more drinks per day regularly, and five or more drinks at a time, more frequently than females.

Table 4-25 gives the frequency of once-regular drinkers among current non-drinkers. More males among the non-drinkers than females have been regular drinkers in the past (30% to 13%). For former regular drinkers, the median age they began drinking was 20 years and the median age they stopped was 23 years (the same for males and females).

4.2.3 Drug Usage

The administration of the drug questionnaire included a methodological trial of two alternative ways of collecting the data. As described in Appendix C, some of the subjects received a self-administered drug questionnaire with their identification number (ID) on it, and some of the subjects were given a completely anonymous version. For face-to-face interviews, the ID-numbered version was handed back to the interviewer, while the anonymous version was to be mailed by the respondent back to the study office after the interview. For interviews conducted by telephone, both versions were mailed to the subjects after the interview, with instructions on how to complete it and mail it back to us.

While confidentiality was assured in both cases, subjects receiving the ID-numbered version knew that his or her responses were not anonymous. But we felt that subjects receiving the anonymous version would be convinced that their responses would be truly anonymous and not traceable back to them.

Table 4-21

FOR FORMER SMOKERS

"What was the main reason you stopped smoking?"

<u>REASON</u>	<u>No.</u>	<u>%</u>
Health related reason, but not on a doctor's suggestion.	26	28%
Health related reason, following a doctor's suggestion.	2	2%
Adverse publicity about smoking.	17	19%
Pregnancy	9	10%
Other (e.g. religious, changed friends, got tired of it, etc.)	37	41%
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	91	100%

Table 4-24

FOR CURRENT DRINKERS

"Have you ever regularly had three or more drinks per day, every day?"

	MALES		FEMALES		TOTAL	
	No.	%	No.	%	No.	%
YES	35	29%	10	12%	45	22%
NO	122	100%	84	100%	206	100%

"Have there been periods when you have had five or more drinks at a time, at least twice a month?"

	MALES		FEMALES		TOTAL	
	No.	%	No.	%	No.	%
YES	90	74%	39	46%	129	63%
NO	32	26%	45	54%	77	37%
	122	100%	84	100%	206	100%

Table 4-25 FOR CURRENT NON-DRINKERS

"In the past, has there ever been a time when you regularly drank alcoholic beverages?"

	MALES		FEMALES		TOTAL	
	No.	%	No.	%	No.	%
YES	28	30%	20	13%	48	20%
NO	65	70%	131	87%	196	80%
	93	100%	151	100%	244	100%

Table 4-22

ALCOHOL CONSUMPTION

"At the present time do you regularly drink alcoholic beverages?"

	MALES		FEMALES		TOTAL	
	<u>No.</u>	<u>%</u>	<u>No.</u>	<u>%</u>	<u>No.</u>	<u>%</u>
YES	122	57%	84	36%	206	46%
NO	93	43%	151	64%	244	54%
	215	100%	235	100%	450	100%

Table 4-23 FOR CURRENT DRINKERS

"During a typical month, about how many days do you drink alcoholic beverages?"

<u>No. of Days</u>	MALES		FEMALES		TOTAL	
	<u>No.</u>	<u>%</u>	<u>No.</u>	<u>%</u>	<u>No.</u>	<u>%</u>
1-9 days	62	51%	52	62%	114	55%
10-19 days	25	20%	22	26%	47	23%
<u>> 20 days</u>	35	29%	10	12%	45	22%
	122	100%	84	100%	206	100%

"On the days you do drink, about how many drinks do you have on an average day?"

<u>No. of Drinks</u>	MALES		FEMALES		TOTAL	
	<u>NO.</u>	<u>%</u>	<u>No.</u>	<u>%</u>	<u>No.</u>	<u>%</u>
1-2 per day	68	56%	56	67%	124	60%
3-4 per day	26	21%	24	28%	50	24%
<u>> 5 per day</u>	28	23%	4	5%	32	16%
	122	100%	84	100%	206	100%

Table 4-26

Refusal Rates for ID-Numbered and Anonymous Drug Questionnaires,
By Interview Type.

	<u>ID</u>	<u>ANONYMOUS</u>
Face to Face Interviews:		
Refused	1 (1%)	1 (1%)
Agreed to Complete	125 (99%)	101 (99%)
	<hr/>	<hr/>
	126 (100%)	102 (100%)
Telephone Interviews		
Refused	22(21%)	1 (1%)
Agreed to Complete	83(79%)	116 (99%)
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	105 (100%)	117 (100%)

Because the two versions were randomly allocated (using a table of random numbers at the time the subjects were assigned to interviewers), the drug use histories should tend to be equally distributed between the two groups of subjects. If the two questionnaire versions yielded different drug use histories, this could be because subjects did not trust the confidentiality of the ID-numbered version and so falsified answers or refused to answer. If the two questionnaire versions yielded similar results, we could infer that anonymous drug histories were not needed to elicit valid information and future questionnaire versions can have ID-numbers included.

Table 4-26 shows the rates of refusal for ID-numbered drug questionnaires and anonymous questionnaires according to whether the interview was administered face-to-face or by telephone. The "refusals" in this analysis are instances in which the study subject actually refused to accept the drug questionnaire from the interviewer and would not complete it. Table 4-26 indicates a higher refusal rate for ID-numbered questionnaires which are administered over the telephone (21% refusal rate, compared to 1% for anonymous questionnaires administered by telephone).

Besides refusing to complete the questionnaire at the time of the interview, it is also possible to tacitly "refuse" to complete a drug questionnaire administered by telephone by simply not mailing it back. Table 4-27 compares completion rates (i.e. rates that take into account both outright refusal to complete and failure to return the completed form). It appears as if, when the interviewer is not physically present with the subjects (perhaps reassuring them), the subjects are more reluctant to return the ID-numbered questionnaires.

Tables 4-28 and 4-29 compare the responses on the marijuana and other drug use questions between the ID-numbered and anonymous questionnaires. For those subjects responding, the responses are very similar on all questions. Where the results differ, however, is in the proportion of subjects refusing to respond to individual questions. (For the purpose of this analysis, questions left blank (tacit refusal) and "Don't wish to answer" responses have been combined). For the questions on marijuana use, the ID-numbered questionnaires have a slightly larger proportion of refusals.

Table 4-28

Comparison of Responses on Marijuana Use
Between ID-Numbered and Anonymous Questionnaires

	<u>ID</u>	<u>ANONYMOUS</u>
1. Ever Used Marijuana	<u>%</u>	<u>%</u>
% Responding Yes	56%	55%
% Refusing to Respond	5%	3%
2. Age of First Use		
Median of Responses	17 years	17 years
% Refusing to Respond	13%	7%
3. Years of Marijuana Use		
Median of Responses	5 years	4 years
% Refusing to Respond	12%	7%
4. Frequency of Marijuana Use (% of Responses)		
Every day or Nearly	9%	10%
3-4 times per week	12%	11%
1-2 times per week	12%	16%
1-3 times per month	20%	18%
Less than once a month	38%	43%
Don't wish to answer	9%	2%

Table 4-27

Overall Completion Rates for ID- Numbered and Anonymous
Drug Questionnaires Requiring Return to Study Office
By Mail

	<u>ID (by telephone)</u>	<u>ANONYMOUS</u>
Administred	105	219
Returned to office	66	179
Return Rate	66/105 = 63%	179/219 = 82%

Table 4-29

Comparison of Responses on Drug Use
Between ID-Numbers and Anonymous Questionnaires (Cont.)

	<u>ID</u>		<u>ANONYMOUS</u>	
	<u>No.</u>	<u>%</u>	<u>No.</u>	<u>%</u>
5. Heroin				
Regular User	0	0%	1	1%
Occasional User	3	2%	3	2%
Have Never Used	184	96%	164	91%
Refused to Answer	4	2%	11	6%
	<hr/>		<hr/>	
	191	100%	179	100%
6. Cocaine				
Regular User	2	1%	2	1%
Occasional User	32	17%	22	12%
Have Never Used	153	80%	142	80%
Refused to Answer	4	2%	13	7%
	<hr/>		<hr/>	
	191	100%	179	100%
7. Inhalants				
Regular User	0	0%	0	0%
Occasional User	0	0%	4	2%
Have Never Used	186	97%	162	91%
Refused to Answer	5	3%	13	7%
	<hr/>		<hr/>	
	191	100%	179	100%

Table 4-29

Comparison of Responses on Drug Use
Between ID-Numbers and Anonymous Questionnaires

	<u>ID</u>		<u>ANONYMOUS</u>	
	No.	%	No.	%
1. Barbituates				
Regular User	1	1%	1	1%
Occasional User	17	9%	21	12%
Have Never Used	167	87%	141	78%
Refused to Answer	6	3%	16	9%
	191	100%	179	100%
2. Amphetamines				
Regular User	2	1%	1	1%
Occasional User	40	21%	38	21%
Have Never Used	140	73%	124	69%
Refused to Answer	9	5%	16	9%
	191	100%	179	100%
3. Tranquilizers				
Regular User	1	1%	1	1%
Occasional User	24	12%	22	12%
Have Never Used	157	82%	139	78%
Refused to Answer	9	5%	17	9%
	191	100%	179	100%
4. Hallucinogens				
Regular User	1	1%	0	0%
Occasional User	28	15%	23	13%
Have Never Used	155	81%	140	78%
Refused to Answer	7	3%	16	9%
	191	100%	179	100%

Table 4-30

Drug Use of Subjects 25 Years of Age or Less
Compared to National Survey on Drug Abuse Data

	<u>Subjects *</u> <u>≤ 25 yrs.</u> <u>% Ever Used</u>	<u>NSDA Data</u> <u>18-25 years</u> <u>% Ever Used</u>
Marijuana	60%	68%
Stimulants (Amphetamines)	27%	18%
Tranquilizers	12%	16%
Hallucinogens	15%	25%
Heroin	2%	4%
Cocaine	23%	28%
Inhalants (glue)	0	17%

* Study subjects in this age group range from 21 to 25 years. N = 60

For the questions on other drug use, the anonymous questionnaires appear to have a higher refusal rate.

To see how the drug usage in our cohort compares to that of the general population, we have used data from the National Survey on Drug Abuse. This survey's findings are summarized for age groups 12 to 17 years, 18 to 25 years and adults 26 years and older. In order to compare similar age groups we restricted the comparison to study subjects less than 25 versus national data in young adults 18 to 25 years. These comparisons are presented in Table 4-30. Note, however, that there were no study subjects less than 21 at the time of the interview. So, in effect, Table 4-30 compares subjects 21 to 25 years of age to national survey data for persons 18 to 25 years of age.

Study subjects have about the same proportion of "ever used" as the national data for marijuana, heroin and cocaine; a smaller proportion than the national data for tranquilizers, hallucinogens, and inhalants; and a greater proportion of users of stimulants.

4.2.4 Occupational Exposures

The reported occupational exposures have been categorized and listed in Table 4-31. Up to three hazards could have been coded for each respondent. It is interesting to note that several of these exposures are substances with known carcinogenic potential, such as asbestos, various organic chemicals, and of course, vinyl chloride.

The number of reported hazardous exposures per subject is given in Table 4-32. Over half (55%) of the subjects did not report a hazardous exposure, while 22% reported 2 or more.

Table 4-31

"Do you know of any hazardous exposures in this job?
By that, I mean any exposures that might affect a
persons health. What hazards were you exposed to?"
(Continued)

<u>OCCUPATIONAL EXPOSURE</u>	<u>NO. OF SUBJECTS REPORTING</u>
Insecticides or Herbicides	
Insect sprays	14
Herbicides, week killers	5
Crop sprays, N.O.S.	7
Plastics or Resins	
Castin resins, epoxy resins, acrylic resin	5
Vinyl chloride, PVC	10
Plastics, N.O.S., N.E.C.	7
Anaesthetic gases	1
Radiologic Exposures	
Nuclear power plant worker	2
Radar technician	2
Nuclear medicine, laboratory work	2
X-ray machine operator	11
Radon (mining)	1
Radiologic N.O.S.	1
Petroleum Products, Fuels, Combustion Products	
Gasoline, automobile, service station	19
Diesel fuel, heavy equipment driver	3
Exhaust fumes, N.O.S.	19
Jet, airplane fuel, exhaust	1
Asphalt, road surfacing	1
Oil (Machinery lubrication)	1
Smoke, fire-fighting	4
Petroleum products, N.O.S., N.E.C.	3

Table 4-31

REPORTED OCCUPATIONAL HAZARDS

"Do you know of any hazardous exposures in this job?
By that, I mean any exposures that might affect a
persons health. What hazards were you exposed to?"

<u>OCCUPATIONAL EXPOSURE</u>	<u>NO. OF SUBJECTS REPORTING</u>
Organic Chemicals	
Cleaning chemicals, solvents	36
Wood glue, sawdust, preservatives	9
Aromatics (toluene, xylene, etc.)	6
Paints, thinner, turpentine	23
Dyes (textile, leather)	3
Hair dyes, sprays (cosmetologist)	10
Gases (methane, tear gas, toxic gases)	7
Organic chemicals, N.O.S.* or N.E.C.**	13
Inorganic Chemicals	
Inorganic acids	9
Amonia	3
Cement, sand dust, glass dust	9
H ₂ S gas	2
Sulphur (glass works)	2
Pool chemicals, water treatment chemicals	7
chlorine gas (not for water treatment)	3
Chemicals N.O.S.	16
Insulation Materials	
Brake, clutch dust (automobile work)	11
Asbestos (construction, pipes, welding)	8
Asbestos (hair dryer)	1
Fiberglass insulation	8
Insulation materials, N.O.S., N.E.C.	3

* N.O.S. : Not Otherwise Specified

** N.E.C. : Not Elsewhere Classified

Table 4-32

Number of Occupational Hazards Reported Per Subject

<u>Number of Hazards Reported</u>	<u>Number of Subjects</u>	<u>%</u>
None	248	55%
1	105	23%
2	61	14%
3	23	5%
4	8	2%
5	3	1%
6	<u>2</u>	<u><1%</u>
	450	100%

Table 4-31

"Do you know of any hazardous exposures in this job?
 By that, I mean any exposures that might affect a
 persons health. What hazards were you exposed to?
 (Continued)

<u>OCCUPATIONAL EXPOSURE</u>	<u>NO. OF SUBJECTS REPORTING</u>
Metal Fumes, Dust	
Lead fumes	1
Aluminum forging, dust	1
Heavy Metals (e.g. Hg, Mn)	3
Welding fumes	8
Soldering fumes, flux	6
Coke over gases	1

Table 4-33
Reported Diseases

"Have you ever been told by a doctor
that you had any of the following?"

	Males Reporting (N = 215)		Females Reporting (N = 235)	
	No.	%	No.	%
<u>Respiratory Diseases</u>				
Asthma	24	11%	26	11%
Bronchitis	40	19%	54	23%
Pneumonia	31	14%	50	21%
Emphysema	1	<1%	2	1%
<u>Heart or Circulatory Diseases</u>				
Hypertension	21	10%	23	10%
Buerger's Disease	0	--	1	<1%
Raynaud's Disease	0	--	4	2%
Thrombophlebitis	0	--	5	2%
Rheumatic Fever	4	2%	5	2%
Varicose Veins	5	2%	13	5%
<u>Blood Diseases</u>				
Anemia	10	5%	69	29%
Aplastic Anemia	0	--	1	<1%
Sickle Cell Anemia	0	--	0	--
Thalassemia	0	--	0	--
Leukopenia	0	--	0	--
Thrombocytopenia	1	<1%	0	--
Leukemia	0	--	1	<1%
Polycythemia	0	--	0	--
Lymphoma	0	--	0	--
<u>Digestive System Diseases</u>				
Hepatomegaly	0	--	5	2%
Splenomegaly	0	--	2	1%
Cirrhosis of the Liver	0	--	1	<1%
Gall Stones	0	--	11	5%
Pancreatitis	2	1%	1	1%
Colitis	3	1%	6	3%
Diverticulitis	0	--	0	--

4.2.5 Reported Diseases

The numbers (and percentages) of subjects reporting that they have had the specific diseases listed in the questionnaire are given in Table 4-33. These data were collected as incidence data, not as prevalence. The questions ask, "Have you ever been told by a doctor that you had . . ." a given disease, and the specific year of the diagnosis. After follow-up has been completed and the entire study and control groups interviewed, it will be possible to compute year by year incidence rates or use a life table analysis for these diseases. In the present analysis the incidences tabulated here represent the proportion of study subjects reporting that they have had a given disease during their lifetime.

These incidences have been presented for males and females separately, since several diseases have had a much higher incidence among females (e.g. anemia, bladder infections, eczema). In fact, females had a higher reported incidence of diseases overall. The 235 women interviewed have reported a total of 556 diseases; for an average of 2.4 diseases per woman. The men reported 260 diseases, for an average of 1.2 diseases per man.

The list of diseases in Table 4-33 includes many that have been associated with vinyl chloride exposure, as well as diseases with no known VC association. These non-VC diseases have been added to serve as distractors, to prevent subjects from knowing which specific conditions we were studying.

Tables 4-34 and 4-35 presents the proportions of females and males who have ever had these diseases, stratified by length of exposure (10 months vs. greater than 10 months). Furthermore, we have separated the diseases in these tables into those which have possible VC association (whose proportions we might expect to be elevated in the high exposure group) and those diseases without a VC association (whose proportions we would expect to be about the same between the high and low exposure groups).

In Table 4-34, which shows data for the 235 females, nine of the VC related diseases are elevated in the high exposure group. These are asthma, emphysema, Raynaud's disease, hepatomegaly, splenomegaly, ulcers, hepatitis (all forms combined), pyelonephritis, and other kidney diseases.

Table 4-34

Proportion of Females Reporting Diseases
With 10 Months Exposure and Greater than 10 Months Exposure

Diseases with Possible Association to VC Exposure:	10 Mos. Exposure	> 10 Mos. Exposure
	(N = 68) %	(N = 167) %
Asthma	4%	14%
Bronchitis	25%	22%
Emphysema	7%	11%
Raynaud's Disease	1%	2%
Leukopenia	0	0
Thrombocytopenia	0	0
Leukemia	0	<1%
Lymphoma	0	0
Hepatomegaly	1%	2%
Splenomegaly	0	1%
Cirrhosis of the Liver	0	<1%
Ulcers	3%	11%
Hepatitis (all forms)	6%	7%
Other Digestive or Liver Diseases	6%	2%
Glomerulonephritis	0	<1%
Pyelonephritis	0	1%
Other Kidney Diseases	4%	10%
Osteoarthritis	4%	4%
Acroosteolysis	0	0
Finger clubbing	0	0
Scleroderma	0	<1%

Table 4-33

Reported Diseases (Cont.)

"Have you ever been told by a doctor
that you had any of the following?"

	<u>Males Reporting</u>		<u>Females Reporting</u>	
	(N = 215)		(N = 235)	
	<u>No.</u>	<u>%</u>	<u>No.</u>	<u>%</u>
<u>Digestive System Diseases (Cont.)</u>				
Ulcers	24	11%	21	9%
Appendicitis	17	8%	27	11%
Infectious Hepatitis	2	1%	1	<1%
Serum Hepatitis	0	--	1	<1%
Viral Hepatitis, N.O.S.*	0	--	3	1%
Chemical Hepatitis	0	--	0	--
Hepatitis, N.O.S.	10	5%	11	5%
Other Digestive or Liver Diseases	8	4%	8	3%
<u>Kidney or Urologic Diseases</u>				
Bright's Disease	0	--	1	<1%
Glomerulonephritis	0	--	1	<1%
Pyelonephritis	0	--	2	1%
Kidney Stones	2	1%	3	1%
Bladder Infection	15	7%	105	47%
Other Kidney Problems	9	4%	19	8%
<u>Bone, Joint, or Skin Diseases</u>				
Osteoarthritis	7	3%	10	4%
Rheumatoid Arthritis	7	3%	3	1%
Gout	4	2%	1	<1%
Fibrositis	0	--	0	--
Acroosteolysis	0	--	0	--
Clubbing of the Fingers	1	<1%	0	--
Psoriasis	3	1%	0	--
Eczema	4	2%	27	11%
Scleroderma	0	--	1	<1%
Cold Sores	12	6%	23	10%
Shingles	3	1%	3	1%

* N.O.S. -- Not otherwise specified

Table 4-35

Proportion of Males Reporting Diseases
With 10 Months Exposure and Greater than 10 Months Exposure

<u>Diseases with Possible Association to VC Exposure:</u>	<u>10 Mos. Exposure</u>	<u>>10 Mos. Exposure</u>
	(N = 51) %	(N = 164) %
Asthma	8%	12%
Bronchitis	8%	22%
Emphysema	0	< 1%
Raynaud's Disease	0	0
Leukopenia	0	0
Thrombocytopenia	0	< 1%
Leukemia	0	0
Lymphoma	0	0
Hepatomegaly	0	0
Splenomegaly	0	0
Cirrhosis of the Liver	0	0
Ulcers	14%	10%
Hepatitis (all forms)	6%	5%
Other Digestive or Liver Diseases	2%	4%
Glomerulonephritis	0	0
Pyelonephritis	0	0
Other Kidney Diseases	4%	4%
Osteoarthritis	4%	3%
Acroosteolysis	0	0
Finger Clubbing	0	<1%
Scleroderma	0	0

Table 4-34 (cont.)

Proportions of Females Reporting Diseases
With 10 Months Exposure and Greater than 10 Months Exposure

	10 Mos. Exposure (N = 68)	>10 Mos. Exposure (N = 167)
	<u>%</u>	<u>%</u>
<u>Diseases Not Associated With VC Exposure:</u>		
Pneumonia	12%	25%
Hypertension	7%	11%
Buerger's Disease	0	<1%
Thrombophlebitis	0	3%
Rheumatic Fever	1%	2%
Varicose Veins	9%	4%
Anemia	21%	33%
Aplastic Anemia	0	<1%
Sickle Cell Anemia	0	0
Thalassemia	0	0
Polycythemia	0	0
Gall Stones	6%	4%
Pancreatitis	0	<1%
Colitis	6%	4%
Diverticulitis	0	0
Appendicitis	10%	12%
Bright's Disease	1%	0
Kidney Stones	0	2%
Bladder Infection	50%	43%
Rheumatoid Arthritis	1%	1%
Gout	0	<1%
Fibrositis	0	0
Psoriasis	0	3%
Eczema	13%	11%
Cold Sores	12%	11%
Shingles	1%	1%

Only two of the VC associated disease incidences are elevated in the low (10 month exposure) group: bronchitis, and other digestive and liver diseases. The remaining 10 VC related diseases have approximately equal incidences within the two groups.

The non-VC associated diseases, however, are divided more evenly. Eight are elevated in the high exposure group, 7 are elevated in the low exposure group, and 11 are approximately equal.

Table 4-35 presents the same analysis for males. Three VC associated diseases (asthma, bronchitis, and other digestive and liver diseases) were elevated in the group with greater than 10 months exposure, while three diseases (ulcers, hepatitis and osteoarthritis) were elevated in the low exposure group. The remaining VC related diseases were about equal between the two groups.

For non-VC related illnesses, 7 were elevated in the high exposure group, 6 were elevated in the low exposure group, and 13 diseases had about the proportions in both groups.

Unfortunately, no other comparisons can be adequately performed at this time. For most of the diseases in Table 4-33 no general population incidence data are available. A control group responding to the same questions would be necessary to generate non-exposed comparison data.

Table 4-35 (Cont.)

Proportion of Males Reporting Diseases
With 10 Months Exposure and Greater than 10 Months Exposure

Diseases Not Associated with VC Exposure:	10 Mos. Exposure	>10 Mos. Exposure
	(N = 51) %	(N = 164) %
Pneumonia	8%	16%
Hypertension	6%	11%
Buerger's Disease	0	0
Thrombophlebitis	0	0
Rheumatic Fever	2%	2%
Varicose Veins	0	3%
Anemia	8%	4%
Aplastic Anemia	0	0
Sickle Cell Anemia	0	0
Thalessemia	0	0
Polycythemia	0	0
Gall Stones	0	0
Pancreatitis	0	1%
Colitis	2%	1%
Diverticulitis	0	0
Appendicitis	8%	8%
Bright's Disease	0	0
Kidney Stones	2%	0
Bladder Infection	12%	5%
Rheumatoid Arthritis	2%	3%
Gout	2%	2%
Fibrositis	0	0
Psoriasis	0	2%
Eczema	0	2%
Cold Sores	8%	5%
Shingles	2%	1%

Table 4-36 REPORTED CANCERS

"Have you ever had any form of cancer?"

	<u>No.</u>	<u>%</u>
YES	7	2%
NO	442	98%
DON'T KNOW	1	<1%
	<u>450</u>	<u>100%</u>

4.2.6 Chronic Conditions, Limitations, and Hospitalizations

Cancer

Seven of the 450 interviewed subjects ($\approx 2\%$) responded that they had ever had some form of cancer (Table 4-36). One person was reported to be currently undergoing diagnostic procedures, and so was listed in the "Don't Know" category.

The 7 reported cancers were grouped into the following categories:

- 4- Uterine, cervix, or other female genito-urinary
- 2- Skin
- 1- Leukemia

Ninety-eight (22%) of the subjects reported that a member of their family had had cancer (Table 4-37). The distribution of these cancers is given below.

- 32-Skin
- 17-Uterine, cervix, other female genito-urinary organs
- 13-Digestive organs and peritoneum
- 6-Breast
- 4-Lymphatic and hematopoietic
- 3-Bladder
- 3-Thyroid
- 3-Malignant melanoma
- 3-Respiratory system
- 2-Bone
- 1-Pharynx
- 11-Site unknown

Please bear in mind, however, that family histories are vulnerable to the biasing effect of large family size, as discussed in Section 4.1.5.

Other Medical Problems

Forty-nine percent (222 subjects) reported that they have had other medical problems as shown in Table 4-38 . The numbers of the various first-reported problems (grouped according to ICD classifications) are given in Table 4-38:

The median age of onset for their first reported condition was 19 years.

Table 4-38 OTHER MEDICAL PROBLEMS

"Have you ever had any other medical problems that were serious enough to require 3 or more visits to a doctor for one attack or episode of the problem? This refers to outpatient or office treatment?" "What was the problem?"

MEDICAL PROBLEM	<u>NO. OF SUBJECTS REPORTING</u>	<u>%</u>
None Reported	228	51%
Infective and Parasitic Diseases	25	6%
Neoplasms (all benign)	6	1%
Endocrine, Nutritional and Metabolic Diseases	6	1%
Diseases of Blood and Blood-Forming Organs	4	1%
Diseases of the Nervous System and Sense Organs	19	4%
Diseases of the Circulatory System	5	1%
Diseases of the Respiratory System	33	7%
Diseases of the Digestive System	9	2%
Diseases of the Genito-Urinary System	18	4%
Complications of Pregnancy and Childbirth	2	<1%
Diseases of the Skin and Subcutaneous Tissue	12	3%
Diseases of the Musculoskeletal System	14	3%
Congenital Abnormalities	2	<1%
Symptoms and Ill-Defined Conditions	28	6%
Accidents, Poisoning, Violence	38	8%
Don't Know	1	<1%
	<hr/> 450	<hr/> 100%

Table 4-37 REPORTED FAMILY CANCERS

"Has anyone in your family (father, mother, brother, or sister) ever had any form of cancer?"

	<u>No.</u>	<u>%</u>
YES	98	22%
NO	351	78%
DON'T KNOW	1	<1%
	<hr/> 450	<hr/> 100%

Table 4-39 Number of Reported "Other Medical Problems" per Subject

<u>Number of Problems</u>	<u>Number of Subjects Reporting</u>	<u>%</u>
None Reported	228	51%
1	124	28%
2	72	16%
3	18	4%
4	5	1%
5	3	<1%
	<hr/>	<hr/>
	450	100%

Table 4-39 gives the number of subjects reporting zero, one or more other medical problems. Twenty-eight percent reported one problem while 21% reported more than one.

Chronic Health Problems

One third (150) of the subjects reported that they have other chronic health problems, not already discussed. Table 4-40 shows the distribution of these responses. As in the other tables, for respondents reporting more than one problem, only the first is categorized in Table 4-40 .

The distribution of conditions in Table 4-40 reveals that almost three-fourths of the reported conditions are problems of the respiratory tissue, skin and subcutaneous tissue and symptoms and ill-defined conditions. This differs from the responses summarized in Table 4-38 for other medical problems, which sought information on serious, acute conditions that required medical treatment. There the categories of infective and parasitic diseases, genito-urinary diseases, and accidents and violence were also well represented.

The median age of onset for their first reported chronic condition was 16 years.

The number of chronic conditions reported per person is given in Table 4-41. Twenty-five percent of the subjects reported one chronic condition, 8% reported more than one.

Medications

Table 4-42 displays the medications the subjects reported taking for a period of three months or more. For respondents who have taken more than one medication for this length of time, only the first is shown in Table 4-42 . Almost half (223) of the respondents reported no medications. Of those that have taken medications, oral contraceptives is the largest single category, although analgesics, antihistamines, and antibiotics also account for a large number. Together, these four classifications make up 62% of the medications reported.

The number of medications reported per subject is given in Table 4-43 .

Table 4-41 Number of Reported Chronic Health Problems Per Subject

<u>Number of Chronic Health Problems</u>	<u>Number of Subjects Reporting</u>	<u>%</u>
None reported	300	67%
1	112	25%
2	33	7%
3	2	<1%
4	3	1%
	450	100%

Table 4-40 CHRONIC HEALTH PROBLEMS

"Do you have any chronic health problems we have not already discussed? By that, I mean problems which keep coming back, even if they do not bother you all the time?" What kinds of conditions are these?"

<u>CHRONIC PROBLEM</u>	<u>NUMBER OF SUBJECTS REPORTING</u>	<u>%</u>
None Reported	300	67%
Infective and Parasitic Diseases	6	1%
Endocrine, Nutritional and Metabolic Diseases	3	1%
Disease of the Nervous System and Sense Organs	9	2%
Diseases of the Circulatory System	7	1%
Diseases of the Respiratory System	31	7%
Diseases of the Digestive System	6	1%
Diseases of the Genito-Urinary System	8	2%
Disease of the Skin and Subcutaneous Tissue	12	3%
Diseases of the Musculoskeletal System and Connective Tissue	25	6%
Congenital Abnormalities	1	<1%
Symptoms and Ill-Defined Conditions	40	9%
Accidents, Poisonings, Violence	2	<1%
	<hr/> 450	<hr/> 100%

Table 4-43

Number of Medications Reported Per Subject

<u>Number of Medications</u>	<u>Number of Subjects Reporting</u>	<u>%</u>
None Reported	223	50%
1	148	33%
2	55	12%
3	14	3%
4	7	2%
≥5	3	<1%
	<hr/> 450	<hr/> 100%

Table 4-42

REPORTED MEDICATIONS

"Please tell me about all the medicines or prescriptions you have taken regularly for a period of three months or more."

<u>MEDICATION TYPE</u>	<u>NO.</u>	<u>%</u>
No medications reported	223	50%
Analgesics	24	5%
Anorexics	7	2%
Antiarthritics	4	1%
Antiasthma	6	1%
Antibacterials	28	6%
Anticonvulsants	2	<1%
Antidiabetic	2	<1%
Antihistamines	17	4%
Antiinflammatory agents	2	<1%
Antinauseants	2	<1%
Antispasmodics	5	1%
Bronchial dilators	4	1%
Antihypertensives	6	1%
Oral Contraceptives	72	16%
Dermatologicals	2	<1%
Diuretics	2	<1%
Hormones	3	1%
Muscle relaxants	6	1%
Sedatives	2	<1%
Thyroid Preparations	6	1%
Tranquilizers	7	2%
Other Medication Types	14	3%
Unable to Classify	4	1%
	<hr/>	<hr/>
	450	100%

Table 4-44

REPORTED HOSPITALIZATIONS

"Have you ever been admitted to the hospital and stayed at
at least two nights for a nonsurgical illness or injury?"
"What was the problem?"

<u>CAUSE OF HOSPITALIZATION</u>	<u>NUMBER OF SUBJECTS REPORTING</u>	<u>%</u>
None Reported	336	75%
Infective and Parasitic Diseases	7	2%
Benign Neoplasms	3	1%
Endocrine, Nutritional and Metabolic Diseases	2	<1%
Diseases of Blood and Blood Forming Organs	1	<1%
Mental Disorders	2	<1%
Diseases of the Nervous System and Sense Organs	4	1%
Diseases of the Circulatory System	3	1%
Diseases of the Respiratory System	29	6%
Diseases of the Digestive System	12	3%
Diseases of the Genito-Urinary System	6	1%
Complications of Pregnancy and Childbirth	3	1%
Diseases of the Skin and Subcutaneous Tissue	1	<1%
Diseases of the Musculoskeletal System and Conective Tissue	3	1%
Symptoms and Ill-Defined Conditions	19	4%
Accidents, Poisonings, and Violence	18	4%
Don't Know	1	<1%
	450	100%

Hospitalization

Twenty-five percent (114) of the subjects reported having been hospitalized for a nonsurgical illness. Table 4-44 lists the causes of hospitalization for the 114 subjects. The median age of hospitalization for this group was 18 years. For subjects who have had multiple hospitalizations, only the first reported one is listed in Table 4-44. Table 4-45 shows the number of persons reporting multiple hospitalization.

Limitations and Disabilities

The questions on limitations, disabilities and doctor visits were taken from the instrument used in the National Health Survey (see Vital and Health Statistics, Series 10, National Center for Health Statistics). Thus we are able to make comparisons with NHS data for these questions.

Seventy-one (15.7%) of the subjects reported that they were limited in activity because of disability or health, with the proportion of females with a limitation slightly greater than the proportion of males (17% to 14% respectively).

Thirty-one (6.9%) reported a limitation that was classified as a limitation of the major activity of the subjects. As used by the NCHS, major activity refers to "the ability to work, keep house or engage in school activities", (Vital and Health Statistics, Series 10, No. 130, 1979).

Table 4-46 compares the proportions of subject with limitations to data from the National Health Survey from 1978 (the most recent available). Note that NHS data is published for age range 17 to 44 years, whereas study subjects spanned 21 to 33 years, at the time of the interview. The proportion of study subjects with a limitation in their major activity is similar to national data (6.9% to 5.2%, respectively). However, study subjects have a greater proportion of persons reporting any activity limitation. This may be because of the different age ranges being compared, or because of a reporting bias. It may be that subjects who know they have been exposed to a hazardous environmental agent are inclined to exaggerate minor activity limitation.

Table 4-46

DISTRIBUTION OF SUBJECTS BY LIMITATION CATEGORY AND
COMPARISON WITH 1978 NATIONAL HEALTH SURVEY DATA

SEX	AGE RANGE	<u>PROPORTION OF SUBJECTS REPORTING</u>		
		WITH ACTIVITY LIMITATION	WITH LIMITATIONS IN MAJOR ACTIVITY	WITH NO ACTIVITY LIMITATION
Both Sexes:				
Subjects	21-33	15.7%	6.9%	84.3%
NHS Data	17-44	8.5%	5.2%	91.5%
Males:				
Subjects	21-33	14.0%	6.1%	86.0%
NHS Data	17-44	9.1%	5.5%	90.9%
Females:				
Subjects	21-33	17.0%	7.7%	83.0%
NHS Data	17-44	7.9%	4.9%	92.1%

Table 4-45

NUMBER OF HOSPITALIZATIONS REPORTED PER SUBJECT

<u>Number of Hospitalizations</u>	<u>Number of Subjects</u>	<u>%</u>
None Reported	336	75%
1	92	20%
2	16	4%
3	4	1%
4	1	<1%
<u>≥ 5</u>	1	<1%
	<hr/>	<hr/>
	450	100%

Table 4-47

CONDITIONS CAUSING ACTIVITY LIMITATION

"What conditions cause this limitation?"

<u>CONDITION REPORTED</u>	<u>NUMBER OF SUBJECTS REPORTING</u>	<u>%</u>
None Reported	379	84%
Infective and Parasitic Diseases	1	<1%
Endocrine, Nutritional and Metabolic Diseases	1	<1%
Diseases of the Nervous System and Sense Organs	5	1%
Diseases of the Circulatory System	2	<1%
Diseases of the Respiratory System	7	2%
Diseases of the Digestive System	1	<1%
Diseases of the Genito-Urinary System	1	<1%
Diseases of the Skin and Subcutaneous Tissue	2	<1%
Diseases of the Musculoskeletal System and Connective Tissue	19	4%
Symptoms and Ill-Defined Conditions	14	3%
Accidents and Violence	16	4%
Don't Know	2	<1%
	<hr/> 450	<hr/> 100%

The median age that subjects with a limitation reported they first became limited was 22 years, although the range extended from 1 year to 31 years of age.

The reported conditions are categorized in Table 4-47, again according to ICD classifications. Diseases of the musculoskeletal system, accidents and violence, and symptoms and ill-defined conditions account for more than two-thirds of the reported limiting conditions.

The number of reported days of bed disability are distributed as shown in Table 4-48. Males and females are shown separately since it appears as if the females have a slightly higher proportion reporting 10 or more bed-days.

When the mean numbers of bed disability days are calculated for males, females, and both sexes combined, they are found to be very similar to 1978 NHS data (Table 4-49). The NHS data cover a different age range than the study subjects, and so may not be strictly comparable. However, there does not appear to be a great difference in reported bed disability days.

The number of doctor visits within the last 12 months are distributed for males and females as shown in Table 4-50. Here the distribution of doctor visits for females is definitely skewed toward the high end. One-third of the females reported 5 or more visits, while only 14% of males reported 5 or more.

When the number of reported physician visits per year are compared with NHS data (Table 4-51), they are found to be almost identical for males, females and both sexes combined.

Table 4-49

MEAN DAYS OF BED DISABILITY AND COMPARISON WITH
1978 NATIONAL HEALTH SURVEY DATA

<u>SEX</u>	<u>SUBJECTS (AGE 21 TO 33 YRS)</u>	<u>NHS DATA (AGE 17 TO 44 YRS)</u>
Both Sexes	446 days/100 persons per yr	423 days/100 persons per yr
Males	357 days/100 persons per yr	319 days/100 persons per yr
Females	524 days/100 persons per yr	520 days/100 persons per yr

Table 4-48

REPORTED DAYS OF BED DISABILITY

"During the past 12 months, about how many days did illness or injury keep you in bed all or most of the day?"

<u>No. of Days Reported</u>	SUBJECTS REPORTING					
	<u>Male</u>		<u>Female</u>		<u>Total</u>	
	<u>No.</u>	<u>%</u>	<u>No.</u>	<u>%</u>	<u>No.</u>	<u>%</u>
None reported	91	42%	92	39%	183	41%
1-4	84	39%	79	34%	163	36%
5-9	27	13%	31	13%	58	13%
10-14	8	4%	16	7%	24	5%
≥ 15	5	2%	17	7%	22	5%
	<u>215</u>	<u>100%</u>	<u>235</u>	<u>100%</u>	<u>450</u>	<u>100%</u>

Table 4-51

NUMBER OF PHYSICIAN VISITS PER PERSON PER YEAR AND
COMPARISON WITH 1978 NATIONAL HEALTH SURVEY DATA

<u>Sex</u>	NUMBER OF VISITS PER PERSON PER YEAR		
	Subjects (21 to 33 yrs)	NHS Data (17 to 24 yrs)	NHS Data (25 to 44 yrs)
Both Sexes	4.2	4.3	4.7
Males	2.8	3.0	3.4
Females	5.4	5.5	5.8

Table 4-50

NUMBER OF REPORTED PHYSICIAN VISITS

"During the past 12 months, about how many times did you see or talk to a medical doctor? (Do not include doctors seen while you were a patient in a hospital)."

SUBJECTS REPORTING

<u>No. of Times Reported</u>	<u>Male</u>		<u>Female</u>		<u>Total</u>	
	<u>No.</u>	<u>%</u>	<u>No.</u>	<u>%</u>	<u>No.</u>	<u>%</u>
None Reported	75	35%	35	15%	110	24%
1-4	109	51%	123	52%	232	52%
5-9	10	4%	31	13%	41	9%
10-14	15	7%	25	11%	40	9%
<u>≥ 15</u>	<u>6</u>	<u>3%</u>	<u>21</u>	<u>9%</u>	<u>27</u>	<u>6%</u>
	215	100%	235	100%	450	100%

In order to consider whether the two exposure groups might differ in their willingness to respond to questions about diseases and symptoms, we examined the association between months of exposure and interview method. The proportion of subjects in the two exposure groups receiving face to face and telephone interviews is given below, separately for males and females.

<u>Males</u>	10 months Exposure (n=51)	>10 months Exposure (n=164)
Face to Face Interview	41%	51%
Telephone Interview	59%	49%
	<hr/>	<hr/>
χ^2_1 d.f.= 1.46, p = 0.22	100%	100%

<u>Females</u>	10 months Exposure (n=68)	>10 months Exposure (n=167)
Face to Face Interview	38%	55%
Telephone Interview	62%	45%
	<hr/>	<hr/>
χ^2_1 d.f.= 5.12, p= 0.02	100%	100%

Among the interviews conducted so far, therefore, cohort members who fall into the high exposure group were more likely to be interviewed face to face than members of the low exposure group.

This did not occur by design. The choice of face to face verses telephone interview was based strictly upon the availability of an interviewer in the area of the subjects' home. Length of exposure was unknown to both the persons tracing and contacting subjects. However, one might easily imagine that students who completed several years at Saugus Elementary School would tend to be long term residents of the Los Angeles area, and hence more likely to be available today for a face to face interview by one of our interviewers in the field. On the other hand, students who completed only a few months at the Saugus school before moving with their families to another district might be

4.2.7 Reported Symptoms

The numbers (and percentages) of subjects reporting that they have experienced the specific symptoms listed in the questionnaire are given in Table 4-52. As in section 4.2.5 which presented data for diagnosed diseases, we have presented data for males and females separately. Table 4-52 shows, however, that the proportions of males and females reporting these symptoms are for the most part very similar.

In Tables 4-53 and 4-54, the symptoms are grouped according to whether they are associated with VC exposure, for males and females respectively. Table 4-53 compares the reported symptoms for males with 10 months exposure and greater than 10 months exposure. Table 4-54 displays the same statistics for females. There appears to be no obvious relationship between months of exposure and proportion of subjects reporting symptoms. There are no good general population data for these symptoms, so that comparison with an unexposed population will require the incorporation of a control group.

Tables 4-55 and 4-56 show the symptoms recalled while the subjects were attending elementary school. We have shown both the proportion of students recalling these symptoms at any elementary school they attended, and those recalling them while attending the Saugus school.

Table 4-58 compares the proportions of women who recall being sent home from school, for women with 10 months exposure and greater than 10 months exposure. For this table, we have presented the proportions of subjects recalling being sent home from any school. We presented the data in this way, because being sent home from the Saugus school is partly a function of the length of attendance. Therefore examining episodes at the Saugus school for those with shorter or longer periods of attendance would not be a fair comparison.

Table 4-58 shows that most symptoms (even those not associated with VC exposure) were more commonly recalled for women with more than 10 months exposure.

Table 4-57 gives the same comparisons for males. For males, however, more non-VC related symptoms are elevated in the higher exposure group, while the VC associated symptoms were more frequently reported in the low exposure group.

Table 4-52

SYMPTOMS: "Do you remember a time when any of the following bothered you enough to limit your activities or cause you to see a doctor?"

SYMPTOMS	MALES REPORTING (n = 215)		FEMALES REPORTING (n = 235)	
	<u>No.</u>	<u>%</u>	<u>No.</u>	<u>%</u>
Dizziness or light headedness	47	22%	65	28%
Headaches	55	26%	98	42%
Pain in Upper Abdomen or Stomach	42	20%	50	21%
Lower Back Pain	72	33%	77	33%
Insomnia	15	7%	33	14%
Ringing or Buzzing in Ears	17	8%	14	6%
Pain in Joints of Your Legs or Arms	40	19%	34	14%
Loss of Feeling or Numbness in Your Hands or Feet	16	7%	31	13%
Tingling in Hands or Feet	9	4%	19	8%
Trouble breathing, short of breath	33	15%	46	20%
Diarrhea	18	8%	26	11%
Have you been bothered by problems in your arms, legs, hands, or feet, such as:				
Coldness or Numbness	19	9%	30	13%
Tingling sensations in your joints	9	4%	14	6%
Pain in the joints of your fingers or hands	8	4%	10	4%
Redness or flushing in your hands or feet	7	3%	3	1%
Whiteness or loss of color in your hands or feet	8	4%	4	2%
Cracking and peeling of the skin of your hands or feet	23	11%	22	9%

more likely to be living today outside the range of face to face interviews, and would have to be interviewed by telephone.

It is possible that different proportions of interview types between the two exposure groups would bias the result. It is not known, however, in which direction this bias might operate. Studies summarized by Selltitz et al (1976) and Sudman and Bradburn (1974) indicate that telephone interviews may be better than face to face interviews in eliciting responses on sensitive issues. The study by Henson et al (1977) on this subject was inconclusive.

If telephone interviews (because of their more impersonal nature) were better at eliciting sensitive and personal information, this might be expected to bias the results towards finding more diseases and symptoms among the low-exposure group. This would therefore be a conservative bias.

At this state of the follow-up, we have elected not to stratify the analysis by interview type because of the small numbers involved. Several of the disease frequencies would have to be derived from cells containing less than 30 subjects.

In the next phase of the study, all interviews will be conducted in a standard form, namely by telephone. This will prevent any possible bias that might be due to different interview techniques.

Table 4-54

PROPORTION OF FEMALES REPORTING SYMPTOMS WITH 10 MONTHS EXPOSURE
AND GREATER THAN 10 MONTHS EXPOSURE

<u>Symptoms Associated with VC Exposure:</u>	10 mos exposure (n = 68) %	>10 mos exposure (n = 167) %
Dizziness	26%	28%
Headaches	50%	38%
Stomach Pain	22%	21%
Pain in Joints	19%	13%
Numbness in Hands or Feet	10%	14%
Tingling in Hands or Feet	10%	7%
Coldness, Numbness in Arms, Legs, Hands, Feet	13%	13%
Tingling Sensations in Fingers or Toes	4%	7%
Pain in Fingers or Hands	4%	4%
Whiteness, Loss of Color in Hands or Feet	0%	2%
Cracking, Peeling of Skin	12%	8%
<u>Symptoms Not Associated with VC Exposure</u>		
Lower Back Pain	34%	32%
Insomnia	26%	9%
Ringling in the Ears	4%	7%
Short of Breath	12%	23%
Diarrhea	7%	13%
Redness, flushing in Hands or Feet	0%	2%

Table 4-53

PROPORTION OF MALES REPORTING SYMPTOMS WITH 10 MONTHS
EXPOSURE AND GREATER THAN 10 MONTHS EXPOSURE

<u>Symptoms Associated with VC Exposure</u>	10 mos. exposure (n = 51) %	>10 mos. exposure (n = 164) %
Dizziness	22%	22%
Headaches	27%	25%
Stomach Pain	20%	20%
Pain in Joints	18%	19%
Numbness in Hands or Feet	8%	7%
Tingling in Hands or Feet	6%	4%
Coldness or Numbness in Arms, Legs, Hands, Feet	6%	10%
Tingling Sensation in Fingers or Toes	4%	4%
Pain in Fingers or Hands	0%	5%
Whiteness, Loss of Color in Hands or Feet	8%	2%
Cracking, Peeling of Skin	14%	10%
<u>Symptoms Not Associated with VC Exposure</u>		
Lower Back Pain	41%	31%
Insomnia	4%	8%
Ringing in the Ears	4%	9%
Short of Breath	12%	16%
Diarrhea	16%	6%
Redness, Flushing in Hands or Feet	2%	4%

Table 4-56

SYMPTOMS RECALLED IN SCHOOL BY FEMALES

Symptoms: "Thinking back to when you were in elementary school, do you remember being sent home from school because of any of the following conditions?" If yes, "Do you remember what school you were attending?"

<u>Symptoms Associated With VC Exposure</u>	FEMALES (n=235)			
	Sent Home from Any School		Sent Home from Saugus	
	<u>No.</u>	<u>%</u>	<u>No.</u>	<u>%</u>
Dizziness	10	4%	7	3%
Headaches	11	5%	9	4%
Pain in Joints	2	1%	1	<1%
Numbness in Hands, Feet	2	1%	1	<1%
Tingling in Hands, Feet	0	-	0	-
Stomach Pain	17	7%	8	3%
<u>Symptoms Not Associated With VC Exposure</u>				
Ringling in Ears	3	1%	2	1%
Short of Breath	7	3%	5	2%
Bad Cough	26	11%	11	5%
Fever	40	17%	25	11%
Diarrhea	2	1%	1	<1%
Vomiting	27	11%	17	7%

Table 4-55

SYMPTOMS RECALLED IN SCHOOL BY MALES

"Thinking back to when you were in elementary school, do you remember being sent home from school because of any of the following conditions?" If yes, "Do you remember the school you were attending?"

<u>Symptoms Associated with VC Exposure</u>	MALES (n = 215)		Sent Home from Saugus	
	Sent Home from Any School		No.	%
	<u>No.</u>	<u>%</u>	<u>No.</u>	<u>%</u>
Dizziness	8	4%	3	1%
Headache	18	8%	12	6%
Pain in Joints	1	<1%	1	<1%
Numbness in Hands, Feet	0	-	0	-
Tingling in Hands, Feet	0	-	0	-
Stomach Pain	21	10%	10	5%
<u>Symptoms Not Associated With VC Exposure</u>				
Ringing in ears	3	1%	2	1%
Short of Breath	8	4%	5	2%
Bad Cough	21	10%	11	5%
Fever	41	19%	27	13%
Diarrhea	1	<1%	1	<1%
Vomiting	24	11%	13	6%

Table 4-58

PROPORTION OF FEMALES REPORTING SYMPTOMS AT SCHOOL WITH
10 MONTHS EXPOSURE AND GREATER THAN 10 MONTHS EXPOSURE

<u>Symptoms Associated with VC Exposure</u>	Subjects Reporting Being Sent Home From Any School	
	10 Mos. Exposure (n = 68)	>10 Mos. Exposure (n = 167)
	<u>%</u>	<u>%</u>
Dizziness	3%	5%
Headaches	1%	6%
Pain in Joints	0%	1%
Numbness in Hands, Feet	0%	1%
Tingling in Hands, Feet	0%	0%
Stomach Pain	1%	8%
<u>Symptoms Not Associated with VC Exposure</u>		
Ringing in Ears	1%	1%
Short of Breath	1%	4%
Bad Cough	9%	12%
Fever	15%	18%
Diarrhea	0%	1%
Vomiting	10%	12%

Table 4-57

PROPORTION OF MALES REPORTING SYMPTOMS AT SCHOOL WITH
10 MONTHS EXPOSURE AND GREATER THAN 10 MONTHS EXPOSURE

<u>Symptoms Associated with VC Exposure</u>	Subjects Reporting Being Sent Home From Any School	
	10 Mos. Exposure (n = 51)	>10 Mos. Exposure (n = 164)
	<u>%</u>	<u>%</u>
Dizziness	8%	2%
Headaches	10%	8%
Pain in Joints	2%	0%
Numbness in Hands, Feet	0%	0%
Tingling in Hands, Feet	0%	0%
Stomach	12%	9%
<u>Symptoms Not Associated With VC Exposure</u>		
Ringing in Ears	0%	2%
Short of Breath	2%	4%
Bad Cough	6%	11%
Fever	10%	22%
Diarrhea	0%	<1%
Vomiting	4%	13%

Table 4-59

MENSTRUAL PROBLEMS

"Has there ever been anything unusual about your periods,
or anything that concerned you or your doctor?"

PROBLEM	WOMEN REPORTING	
	No.	%
No problem reported	141	60%
Started late	2	1%
Cramps and/or pain	22	9%
Heavy flow and/or clots	12	5%
Irregular Periods	29	12%
Very long Periods	4	2%
More than one Problem	21	9%
Other Problem, N.E.C.*	4	2
	<hr/> 235	<hr/> 100%

* Not elsewhere classified

4.2.8 Reproductive History

Two-hundred thirty five of the study subjects were female. All of these women were asked several questions about their menstrual history. In addition, the women who had been married were asked a detailed series of questions about their reproductive histories.

Age at Menarche

The median age at menarche of the 235 women was 12 years, with the extremes of 8 and 18 years.

Menstrual Problems

Ninty-four of the women (40%) reported that they had had something unusual about their periods. The reported problems were categorized and given in Table 4-59. When asked if their periods have usually been regular, 76% responded yes, 24% responded no.

Reproductive History

Of the 235 interviewed female subjects, 189 (80%) had been married and of these 189, 159 (84% of the married women) had been pregnant at least once. The number of pregnancies per woman is given in Table 4-60 .

Pregnancy Outcome

The lack of a control group hampers our ability to make meaningful comparisons of observed pregnancy outcomes. Published vital statistics generally do not include miscarriages (spontaneous abortions) occurring before 20 weeks of gestational age. Also, the denominators of these statistics are live births, rather than number of pregnancies.

Published studies that have examined fetal deaths have produced rates of between 6 fetal deaths per 100 pregnancies and 15 per 100 pregnancies (Infante, et al,(1976), Monson (1979), Shapiro et al, (1962), Warburton and Fraser (1964)). The variation in the so-called general population or "control" rates is probably accounted for by:

- o Differences in the population studied (e.g., women enrolled in a HMO, wives of chemical workers)
- o Differences in the source of information (e.g., clinic records, husband's recollections), and
- o Differences in data collection (e.g., personal reporting, retrospective interview).

In short, there is no good single source of comparison data, and so without a control group, we have relied on internal comparisons in this initial, exploratory analysis.

One source of internal comparison for the exposed women is the experience of the (unexposed) wives of exposed males. Vinyl chloride monomer has been suggested to cause mutagenic effects in offspring of male VCM workers (Infante, et al, 1976). But since male germ cells have a continual turnover, it is unlikely that offspring of male members of our cohort would be affected by their father's VC exposure in elementary school.

Table 4-61 compares pregnancy outcome among exposed women and non-exposed spouses. For these comparisons, we have calculated statistics of four pregnancy outcomes.

- o The proportion of pregnancies that terminated in fetal deaths (miscarriages and still births).
- o The proportion of pregnancies that terminated in induced abortions.
- o The proportion of live births that women reported were born with a congenital malformation.
- o The proportion of live births that women reported had had a major illness.

We point out, however, that none of these outcomes has been verified by medical records. They are based strictly upon each woman's own recollection.

Fetal deaths, congenital malformations, and major illnesses might be associated with VC exposure. Induced abortions are unlikely to be

Table 4-60

Number of Pregnancies Reported Per Woman

No. of Reported Pregnancies	Women Reporting	
	<u>No.</u>	<u>%</u>
None	76	32%
1	39	17%
2	64	27%
3	42	18%
4	5	2%
5	7	3%
6	2	1%
	<hr/>	
	235	100%

Table 4-61

Pregnancy Outcome Among Exposed Women and Non-Exposed Wives
of Exposed Men

	Fetal Deaths <u>per 100 pregnancies</u>	Abortions <u>per 100 pregnancies</u>	Congenital Abnormalities <u>per 100 live births</u>	Major Illnesses <u>per 100 live births</u>
Exposed Women (n = 235)	36/360 = 10%	47/360 = 13%	23/277 = 8%	87/277 = 31%
Non-Exposed Wives (n = 122)	12/219 = 5%	18/219 = 8%	15/189 = 8%	21/189 = 11%
	RR = 1.8	RR = 1.6	RR = 1.0	RR = 2.8
	(p = 0.07)	(p = 0.10)	(p = 1.0)	(p < 0.001)

associated and are included as a dummy variable.

The risk ratios (RR=the risk in the exposed group relative to the unexposed are also given in Table 4-61, as well as p values*. It should be stressed, however, that the purpose of these analyses is not to accept or reject statistical hypotheses, but to explore associations.

Table 4-61 suggests that the risks of three of these pregnancy outcomes are elevated among exposed women- fetal deaths, induced abortion, and major illnesses in children.

There are unaccounted-for factors that might confound these results. One possible confounder is age -- these risk ratios have not been age-adjusted. However, the age distribution in these two groups appears to be very similar. The exposed women range in age from 21 to 33 years, the unexposed spouses range from 21 to 35 years. The data presented by Warburton and Fraser (1964) indicate that spontaneous abortion rates over the maternal age range 20 to 34 year increases by only 1-2 fetal deaths/100 pregnancies. The rates do not appreciably increase with maternal age until past the age of 40. Therefore, we do not feel that differences in maternal age are likely to be accounting for the higher rates observed among exposed women.

Alcohol consumption or smoking might differ between the groups, however, we did not include questions on these subjects in the original version of the spouse questionnaire. The revised version of the spouse questionnaire (to be used in the next phase of the study) will ask about smoking and drinking.

*Statistical significance has been evaluated under the null hypothesis that the difference in proportions is zero. The probability that the observed difference in proportion occurred under the null hypothesis has been calculated with the method given by Fleiss (1973), p. 18. This method uses Yates' Correction for Continuity, and is more conservative than similar methods that do not (for example, the equation in Dixon and Massey (1969) p. 249).

Table 4-62

Pregnancy Outcome Among Exposed Women, by Marital Status,
(at time of interview)

	Fetal Deaths <u>per 100 pregnancies</u>	Abortions <u>per 100 pregnancies</u>	Congenital Abnormalities <u>per 100 live births</u>	Major Illnesses <u>per 100 live births</u>
182 Currently Married (n = 147)	29/292 = 10%	31/292 = 11%	22/232 = 9%	72/232 = 31%
Single, Divorced, Separated, Widowed (n = 88)	7/68 = 10%	16/68 = 24%	1/45 = 2%	15/45 = 33%

One possible confounder that can be examined is current marital status. All unexposed wives of exposed males are by definition currently married, while the exposed women may be married, divorced, separated or widowed*. This might explain the higher proportion of induced abortions among exposed women -- an outcome thought to be unrelated to VC exposure.

Table 4-62 presents the same outcome measures for currently married exposed women and for exposed women who were divorced, separated or widowed at the time of the interview. As expected, a greater proportion of induced abortions occurred in the divorced, separated group, but the proportion of pregnancies ending in fetal deaths remained constant.

Table 4-63 gives the risk ratios for the four outcome measures among the currently married exposed women and the (currently married) unexposed wives. Again, these ratios show the trend of increased fetal death ratios, as well as congenital abnormalities and major illnesses.

Another internal control can be examined. Table 4-64 displays the four outcome measures for exposed women who attended Saugus Elementary School for only one school term (10 calendar months) and for women who attended for more than one term (11 calendar months or more). Ten months represents the minimum exposure period in this cohort, and we can look at risk in women with more exposure relative to these women.

Here the trend toward increasing fetal death risk is supported, although the congenital abnormalities and major illnesses have reversed their trend in proportion. The age distribution of these groups of women are very similar; both range from 21 to 33, and have a median age of 26 years. Smoking and drinking habits of these groups are summarized in Tables 4-65 and 4-66 and are seen to be similar. The association of fetal death with current marital status was not examined. However, among the entire group of exposed

* Note -- All information on pregnancy outcome was derived from women who had been married. The questions were not asked of women who had never been married because of our expectation that responses on this subject might be unreliable.

Table 4-64

Pregnancy Outcome Among Women with Greater than 10 Months Exposure
and Women With 10 Months Exposure Only

	Fetal Deaths <u>per 100 pregnancies</u>	Abortions <u>per 100 pregnancies</u>	Congenital Abnormalities <u>per 100 live births</u>	Major Illnesses <u>per 100 live births</u>
Women with > 10 months Exposure (n = 167)	32/278 = 12%	39/278 = 14%	14/208 = 7%	54/208 = 26%
Women with 10 months Exposure (n = 68)	4/82 = 5%	8/82 = 10%	9/69 = 13%	33/69 = 48%
184	RR = 2.4 (p = 0.12)	RR = 1.4 (p = 0.41)	RR = 0.5	RR = 0.5

Table 4-63

Risk Ratios for Currently Married Exposed Women Relative to Non-Exposed Wives of Exposed Men

	<u>Fetal Deaths per 100 pregnancies</u>	<u>Abortions per 100 pregnancies</u>	<u>Congenital Abnormalities per 100 live births</u>	<u>Major Illnesses per 100 live births</u>
Currently Married Exposed Women (n=147)	29/292 = 10%	31/292 = 11%	22/232 = 9%	72/232 = 31%
Non-Exposed Wives (n=122)	12/219 = 5%	18/219 = 8%	15/189 = 8%	21/189 = 11%
	RR = 1.8 (p=0.09)	RR = 1.3 (p=0.45)	RR = 1.2 (p=0.70)	RR = 2.8 (p<0.001)

Table 4-66

Drinking Habits of Women With 10 Months
and Greater Than 10 Months Exposure

	Women with 10 months Exposure (n = 68)	Women with > 10 months Exposure (n = 167)
Current Regular Drinkers	32%	37%
Former Regular Drinkers	12%	7%
Never Regular Drinkers	56%	56%
	<u>100%</u>	<u>100%</u>
 CURRENT REGULAR DRINKERS		
Median Age Began Drinking	19 yrs	21 yrs
Median number of drinking days per month	4 days	5 days
Median number of drinks per drinking day	2 drinks	2 drinks

Table 4-65

Smoking Habits of Women With 10 Months
And Greater Than 10 Months Exposure

	Women with 10 months of Exposure (n = 68)	Women with > 10 months of Exposure (n = 167)
Current Regular Smokers	25%	28%
Former Regular Smokers	16%	23%
Never Regularly Smoked	59%	49%
	100%	100%
CURRENT SMOKERS		
Median number of cigarettes per day currently	20/day	20/day
Median age began smoking	17 yrs	17 yrs
Median number of cigarettes per day since started smoking	16/day	15/day
FORMER SMOKERS		
Median number of cigarettes per day	10/day	10/day
Median age began smoking	18 yrs	18 yrs
Median age quit smoking	22 yrs	23 yrs

4.2.9 Mortality

During our efforts to trace the cohort members, we were informed that 11 former students were deceased. Many of these deaths came to our attention through the Department of Motor Vehicles records, a few deaths we heard about from family members.

We were able to examine death certificates for 9 of the eleven deaths, and the cause of death, age, sex and months of exposure at the Saugus school are given in Table 4-67. Six of the death certificates related the cause as due to trauma or accident, and the two deaths for which we did not see the death certificates were said to have been accidents.

Three of the deaths, however, were of causes unusual for this age group. Two were malignancies (malignant lymphoma and malignant melanoma) and the third death was attributed to erythema multiforme. Erythema multiforme is a dermatological manifestation of many disease processes, and is unlikely to be a true underlying cause of death. So the etiology of this death is uncertain.

To show the unusual nature of these deaths, we have provided the age distribution of deaths for the year each of these occurred, from the California Vital Statistics. For the malignant lymphoma death (ICD No. 200.2, 7th Rev.) and the erythema multiforme death (ICD No. 705.1, 7th Rev.), the two deceased study subjects represented the only deaths in the state, for their respective age groups, for their respective years of death (Tables 4-68 and 4-69). For malignant melanoma, (ICD No. 172.7, 8th Rev.) the death of a study subject at age 23 is not unique, but given the age distribution on Table 4-70, it is unusual.

women, marital status showed no association with fetal death risk (Table 4-62). Extensive and detailed stratified analyses were not performed with these data because the numbers were too small.

In studying Table 4-64, it should be noted that all women in this table were exposed. More than half of the "greater than 10 month exposure" group were exposed only 20 months or less. Less than one-fourth of this group were exposed for more than 30 months. Therefore, in Table 4-64, the exposure of the "high exposure" group is not that much greater than the "reference" group.

To repeat, these data are crude. None have been verified by medical records. Also, there are several potential confounding factors that would have been difficult to examine, such as family size and number of previous miscarriages, which appear to be related to fetal death risk (Warburton and Fraser, 1964).

However, we feel that the above results (especially the consistent elevation of fetal death risk) are sufficiently suggestive to warrant completing the interviews of the exposed women, and most importantly the formation of a control group so that meaningful comparisons can be made.

Table 4-68
DEATHS FROM EACH CAUSE BY SEX AND AGE
CALIFORNIA, 1964

(By place of residence)

Index Case is Male, Age 13, Cause = 200.2

SEVENTH REVISION NUMBER	CAUSE OF DEATH	SEX	TOTAL ALL AGES	UNDER ONE YEAR	AGE																	100 AND OVER	AGE NOT STATED				
					1-4	5-9	10-14	15-19	20-24	25-29	30-34	35-39	40-44	45-49	50-54	55-59	60-64	65-69	70-74	75-79	80-84			85-89	90-94	95-99	
200-205	Neoplasms of lymphatic and hematopoietic tissues	T	2,571	8	69	86	60	76	44	54	65	87	99	125	175	211	243	316	300	272	166	82	10	2	1	-	
		M	1,457	5	52	50	32	51	20	27	38	51	62	76	99	131	152	173	173	143	75	43	2	-	1	-	-
		F	1,114	3	37	36	28	25	24	27	27	36	37	49	76	80	91	143	127	129	91	39	8	1	-	-	-
200.0	Lymphosarcoma and reticulosarcoma Reticulum-cell sarcoma	T	210	-	2	1	3	4	3	5	4	10	13	16	17	25	22	28	26	15	10	6	-	-	-	-	
		M	126	-	1	1	2	4	2	4	3	8	7	13	6	17	16	16	12	8	3	3	-	-	-	-	
200.1	Lymphosarcoma	F	84	-	1	-	1	-	1	1	1	2	6	3	11	8	6	12	14	7	7	3	-	-	-	-	
		T	377	1	4	3	4	8	5	6	1	8	17	21	27	37	46	59	49	44	25	8	3	-	1	-	
200.2	Other primary malignant neoplasms of lymphoid tissue	M	204	1	2	3	2	6	2	5	-	4	11	15	11	21	30	27	29	20	8	6	1	-	1	-	
		F	173	-	2	-	2	2	3	1	1	4	6	6	16	16	16	32	21	24	17	2	2	-	-	-	
201	Hodgkin's disease	T	113	-	-	2	1	2	-	1	1	1	6	5	14	7	6	18	16	20	9	2	-	-	-	-	
		M	59	-	-	1	1	-	-	1	1	1	4	4	7	3	4	9	11	9	3	-	-	-	-	-	
		F	54	-	-	1	-	2	-	-	-	-	2	1	7	4	4	9	5	11	6	2	-	-	-	-	
202	Other forms of lymphoma (reticulosis) Giant follicular lymphoma (Brill-Symmers' disease)	T	281	-	-	3	2	2	14	15	18	27	18	21	23	20	33	25	14	14	11	3	-	-	-	-	
		M	163	-	-	2	1	10	3	9	12	14	11	8	17	15	25	12	7	10	5	2	-	-	-	-	
		F	118	-	-	1	1	10	11	6	6	13	7	13	6	5	8	13	7	4	6	1	-	-	-	-	
202.0	Other	T	15	-	-	-	-	-	-	-	-	1	4	-	2	2	1	1	1	2	-	-	-	-	-	-	
		M	11	-	-	-	-	-	-	-	-	-	4	-	2	1	1	1	1	1	1	-	-	-	-	-	
		F	4	-	-	-	-	-	-	-	-	-	1	-	-	2	-	-	-	-	1	-	-	-	-	-	
202.1	Multiple myeloma (plasmocytoma)	T	67	2	3	1	1	1	2	-	3	1	1	2	3	6	5	8	7	15	5	1	-	-	-	-	
		M	35	1	1	-	1	1	2	-	2	-	1	2	3	3	2	5	3	6	2	-	-	-	-	-	
		F	32	1	2	1	-	-	-	-	-	1	-	-	-	3	3	3	4	9	3	1	-	-	-	-	
203	Leukemia and aleukemia	T	301	-	-	-	-	-	-	-	-	5	9	16	25	34	44	52	47	37	15	11	2	1	-	-	
		M	184	-	-	-	-	-	-	-	-	5	2	12	19	22	25	31	33	18	8	8	1	-	-	-	
		F	117	-	-	-	-	-	-	-	-	-	7	4	9	12	19	21	14	19	7	3	2	-	-	-	
204.0	Lymphatic	T	236	-	3	7	3	1	2	2	-	1	3	3	15	16	19	34	39	39	30	16	2	1	-	-	
		M	135	-	1	3	1	-	-	-	-	-	2	1	9	10	13	22	24	24	16	8	1	-	-		
		F	101	-	2	4	2	1	2	2	-	1	1	2	6	6	6	12	15	15	14	8	1	1	-	-	
204.1	Myeloid	T	182	-	4	1	1	3	1	8	11	8	8	8	9	14	12	19	28	15	18	11	3	-	-	-	
		M	101	-	4	1	-	2	1	1	8	6	4	4	5	9	9	9	19	8	11	6	-	-	-	-	
		F	81	-	1	1	1	1	1	7	3	2	4	4	4	9	3	10	9	7	7	5	3	-	-	-	
204.2	Monocytic	T	122	-	1	2	3	2	4	4	7	5	3	6	8	13	18	13	13	12	4	4	-	-	-	-	
		M	61	-	-	-	2	1	3	2	3	-	3	3	5	9	10	9	3	7	1	-	-	-	-	-	
		F	61	-	-	1	2	1	1	1	2	4	5	-	3	3	4	8	4	10	5	3	4	-	-	-	
204.3	Acute	T	573	4	62	59	39	32	12	13	19	18	15	25	25	31	32	47	53	44	24	19	-	-	-	-	
		M	321	2	37	37	19	24	7	5	8	12	11	12	12	21	16	27	28	23	10	10	-	-	-	-	
		F	252	2	25	22	20	8	5	8	11	6	4	13	13	10	16	20	25	21	14	9	-	-	-	-	
204.4	Other and unspecified	T	83	1	10	7	3	3	1	1	2	1	4	6	3	8	7	14	11	1	-	-	-	-	-	-	
		M	49	1	6	3	3	3	1	-	1	1	-	1	3	5	1	3	4	8	5	-	-	-	-	-	
		F	34	-	4	4	-	-	-	-	-	-	-	-	1	1	2	5	3	6	6	1	-	-	-	-	
205	Mycosis fungoides	T	11	-	-	-	-	-	-	-	-	-	2	1	-	-	-	4	-	2	-	-	-	-	-		
		M	8	-	-	-	-	-	-	-	-	-	-	1	-	-	-	-	-	1	2	-	-	-	-	-	
		F	3	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	2	-	-	-	-	-	-	-	
210-229	Benign neoplasm	T	239	3	6	7	3	4	4	7	9	8	10	25	25	23	24	28	16	11	11	6	1	-	-	-	
		M	134	3	3	4	3	1	2	4	3	1	6	12	12	13	12	15	8	5	3	3	1	-	-	-	
		F	125	-	3	3	-	3	2	3	6	7	12	13	13	10	12	13	8	6	8	3	-	-	-	-	
210	Buccal cavity and pharynx	T	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
		F	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
211	Other parts of digestive system	T	20	-	-	1	-	-	-	-	-	-	1	-	2	-	1	4	3	3	4	1	-	-	-	-	
		M	11	-	-	-	-	-	-	-	-	-	-	1	-	1	-	3	3	1	1	1	-	-	-	-	
212	Respiratory system	F	9	-	-	1	-	-	-	-	-	-	-	-	1	-	1	1	1	2	3	-	-	-	-	-	
		T	13	-	1	-	-	-	-	-	-	-	-	1	-	1	1	3	3	2	-	-	-	-	-	-	
213	Breast	M	11	-	-	-	-	-	-	-	-	-	1	-	1	1	3	2	2	-	-	-	-	-	-	-	
		F	2	-	1	-	-	-	-	-	-	-	-	-	-	-	1	1	-	-	-	-	-	-	-	-	
214	Uterine fibromyoma	T	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
		F	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
215	Uterus, other	T	11	-	-	-	-	-	-	-	-	1	-	3	4	2	1	-	-	-	-	-	-	-	-	-	
		F	11	-	-	-	-	-	-	-	-	-	-	3	4	2	1	-	-	-	-	-	-	-	-	-	

Table 4-67

KNOWN DEATHS AMONG COHORT

<u>Cause of Death</u>	<u>Sex</u>	<u>Age</u>	<u>Months of Exposure</u>
Vehicle Accident	Male	23	17
Vehicle Accident	Male	19	48
Homicide	Male	25	20
Vehicle Accident	Male	21	19
Vehicle Accident	Male	28	10
Vehicle Accident	Male	23	10
Malignant Melanoma	Male	23	15
Erythema Multiforme	Male	11	33
Malignant Lymphoma	Male	13	40

Table 4-70
DEATHS FROM EACH CAUSE BY SEX AND AGE
CALIFORNIA, 1975

(By place of residence)

EIGHTH REVISION NUMBER	CAUSE OF DEATH	SEX	TOTAL UNDER ALL AGES	ONE YEAR	AGE																			AGE AND OVER	AGE NOT STATED
					1-4	5-9	10-14	15-19	20-24	25-29	30-34	35-39	40-44	45-49	50-54	55-59	60-64	65-69	70-74	75-79	80-84	85-89	90-94		
170-174	MALIGNANT NEOPLASM OF BONE, CONNECTIVE TISSUE, SKIN, AND BREAST	M	4,096	31	51	143	271	301	321	691	761	2021	3061	4351	4941	5141	5161	4671	3591	2821	1661	711	221	11	-
		F	3,546	11	31	61	101	101	161	521	741	1811	2711	4241	4391	4591	4591	3321	3091	2521	1491	611	191	11	-
170.0	MALIGNANT NEOPLASM OF BONE BONES OF SKULL AND FACE	M	181	-	-	-	-	-	-	11	-	-	-	-	-	21	21	41	31	21	11	21	11	-	-
		F	71	-	-	-	-	-	-	11	-	-	-	-	-	21	21	41	11	21	11	21	11	-	-
170.1	LOWER JAW BONE	M	181	-	-	-	-	-	-	-	-	-	-	-	41	11	41	21	51	-	11	11	-	-	-
		F	71	-	-	-	-	-	-	-	-	-	-	-	31	11	31	11	21	-	11	11	-	-	-
170.2	VERTEBRAL COLUMN (EXCLUDING SACRUM AND COCCYX)	M	161	-	-	-	-	11	-	-	-	-	-	-	11	21	41	21	31	11	11	11	-	-	-
		F	61	-	-	-	-	-	-	-	-	-	-	-	11	41	21	11	41	21	11	11	11	-	-
170.3	RIBS, STERNUM, AND CLAVICLE	M	11	-	-	-	-	-	-	-	-	-	-	-	11	-	-	-	-	-	-	-	-	-	-
		F	11	-	-	-	-	-	-	-	-	-	-	-	11	-	-	-	-	-	-	-	-	-	-
170.4	LONG BONES OF UPPER LIMB AND SCAPULA	M	31	-	-	-	-	-	-	-	-	-	-	-	11	-	11	-	-	-	-	-	-	-	-
		F	11	-	-	-	-	-	-	-	-	-	-	-	11	-	11	-	-	-	-	-	-	-	-
170.6	PELVIC BONES, SACRUM, COCCYX	M	141	-	21	21	11	-	-	-	-	-	-	-	11	21	-	-	-	11	21	11	11	-	-
		F	61	-	21	11	11	-	-	-	-	-	-	-	11	21	-	-	-	11	11	11	11	-	-
170.7	LOWER LIMB, LONG BONES	M	261	-	11	31	81	11	11	21	-	21	11	-	11	-	-	-	11	21	11	11	-	-	-
		F	121	-	11	11	41	11	-	21	-	11	11	-	11	-	-	-	11	11	11	11	-	-	-
170.9	SITE UNSPECIFIED	M	141	-	-	11	31	41	-	11	-	11	11	-	11	21	71	11	11	11	21	11	11	-	-
		F	551	-	-	11	21	31	11	-	-	11	11	-	11	21	31	41	11	31	21	11	11	-	-
	MALIGNANT NEOPLASM OF CONNECTIVE AND OTHER SOFT TISSUE	M	201	-	-	11	11	31	-	11	-	11	-	-	21	-	41	21	-	11	21	11	-	-	-
		F	201	-	-	11	11	31	-	11	-	11	-	-	21	-	41	21	-	11	21	11	-	-	-
171.0	MALIGNANT NEOPLASM OF HEAD, FACE, AND NECK	M	41	-	-	-	11	-	-	-	-	-	-	-	11	-	-	-	11	-	-	-	-	-	-
		F	21	-	-	-	11	-	-	-	-	-	-	-	11	-	-	-	11	-	-	-	-	-	-
171.1	TRUNK	M	341	-	-	-	21	-	-	21	-	11	31	21	61	41	41	71	11	-	11	11	-	-	-
		F	161	-	-	-	11	-	-	11	-	11	21	-	31	31	11	21	-	-	11	11	-	-	-
171.2	UPPER LIMB (INCLUDING SHOULDER)	M	51	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	11	11	11	-	-	-	-
		F	21	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	11	11	11	-	-	-	-
171.3	LOWER LIMB (INCLUDING HIP)	M	141	-	-	11	-	-	-	-	-	-	11	21	11	31	-	11	31	11	11	11	-	-	-
		F	91	-	-	11	-	-	-	-	-	-	11	11	11	21	-	11	11	11	11	11	-	-	-
171.9	SITE UNSPECIFIED	M	961	-	11	21	51	31	41	11	61	31	11	51	71	101	111	111	81	91	61	11	-	-	-
		F	431	-	-	11	41	11	31	-	41	11	-	41	31	71	21	41	31	41	21	21	11	-	-
	MALIGNANT MELANOMA OF SKIN LIPS	M	11	-	-	-	-	-	-	-	-	-	-	-	-	11	-	-	-	-	-	-	-	-	-
		F	11	-	-	-	-	-	-	-	-	-	-	-	-	11	-	-	-	-	-	-	-	-	-
172.1	EYELIDS, INCLUDING CANTHI	M	11	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	11	-	-	-	-	-
		F	11	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	11	-	-	-	-	-
172.2	EAR AND EXTERNAL AURICULAR CANAL	M	31	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	11	11	-	-	-	-
		F	31	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	11	11	-	-	-	-
172.3	OTHER AND UNSPECIFIED PARTS OF FACE	M	101	-	-	-	-	-	-	-	-	-	-	21	-	-	11	-	21	21	11	21	-	-	-
		F	51	-	-	-	-	-	-	-	-	-	-	21	-	-	11	-	11	11	11	21	-	-	-
172.4	SCALP AND NECK	M	111	-	-	-	-	11	-	21	11	11	-	-	11	-	11	-	11	21	-	-	-	-	-
		F	101	-	-	-	-	11	-	21	11	11	-	-	11	-	11	-	11	21	-	-	-	-	-
172.6	TRUNK, EXCEPT SCROTUM	M	451	-	-	11	-	21	41	11	21	61	11	71	51	61	41	41	-	-	21	41	-	-	-
		F	371	-	-	11	-	21	31	-	21	51	11	61	51	51	31	31	-	-	11	41	-	-	-
172.7	UPPER LIMB	M	231	-	-	-	-	21	21	-	21	11	31	21	-	31	21	61	11	-	11	11	-	-	-
		F	191	-	-	-	-	21	21	-	21	11	31	21	-	21	21	31	11	-	11	11	-	-	-
172.8	LOWER LIMB	M	331	-	-	-	-	21	-	41	11	41	31	11	41	51	41	31	21	-	11	11	-	-	-
		F	171	-	-	-	-	11	-	31	11	21	21	11	11	11	31	21	11	-	11	11	-	-	-
		F	161	-	-	-	-	11	-	11	-	11	-	21	11	-	31	21	21	21	21	21	-	-	-

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Index Case is Male, Age 23, Cause of Death = 172.7

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APPENDIX A

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Card No.

0 3

1-2

ID No.

[][][][][][]

3-7

CONFIDENTIAL

Date of Interview

[][]
Month

[][]
Day

[][]
Year

8-13

Time of Interview-Beginning

(24-hour clock)

[][]
hour

[][]
min.

14-17

-Ending

[][]
hour

[][]
min.

18-21

Name of Interviewer

(PLEASE PRINT)

Interviewer Number

[][]

22-23

ID No. _____

CONFIDENTIAL

HEALTH EFFECTS SURVEY OF VINYL CHLORIDE EXPOSURE

Name _____

LAST

MAIDEN (if applicable)

FIRST

MIDDLE

Address _____

NUMBER AND STREET

CITY

STATE

ZIP CODE

Telephone Number _____

AREA CODE

NUMBER

STATEMENT OF CONFIDENTIALITY

THE PURPOSE OF THIS SURVEY IS TO OBTAIN INFORMATION WHICH WILL BE USED SOLELY FOR MEDICAL RESEARCH INTO THE EFFECTS OF ENVIRONMENTAL FACTORS ON PUBLIC HEALTH. THIS WORK IS BEING CONDUCTED FOR THE U.S. ENVIRONMENTAL PROTECTION AGENCY.

THE INFORMATION RECEIVED FROM YOU WILL BE HELD IN STRICT CONFIDENCE. ALL RESULTS WILL BE SUMMARIZED FOR GROUPS OF PEOPLE. NO INFORMATION ABOUT INDIVIDUAL PERSONS WILL BE RELEASED.

THE QUESTIONNAIRES USED IN THIS SURVEY ARE AUTHORIZED BY LAW (42 U.S.C. 7401 AS AMENDED). WHILE YOU ARE NOT REQUIRED TO RESPOND, YOUR COOPERATION IS NEEDED TO MAKE THE RESULTS OF THIS SURVEY COMPREHENSIVE, ACCURATE, AND TIMELY. FAILURE TO PARTICIPATE OR FAILURE TO COMPLETE THE STUDY ONCE ENROLLED WILL CARRY NO PENALTY.

I HAVE READ AND UNDERSTAND THE STATEMENT ABOVE.

Date

Signature of Respondent

CONFIDENTIAL

This is an important medical survey of possible health effects of exposure to vinyl chloride gas, which is being conducted by Science Applications, Inc., for the U.S. Environmental Protection Agency.

You should have received a letter explaining the importance of this survey. Elevated levels of vinyl chloride (which might effect health) were present around the area of the Saugus Elementary School. This school is located near a factory that uses vinyl chloride to make plastic. We are giving survey questionnaires to persons who may have been exposed while attending this school, as well as to persons from other schools who were not exposed, for comparison.

HAND R STATEMENT OF CONFIDENTIALITY AND PEN

This form is a statement of confidentiality prepared by the Environmental Protection Agency.

This is to assure you that this questionnaire is for health research only and that all of your answers will be strictly confidential and will never be connected with your name.

Please read it, sign and date the bottom to show that you understand, and return it to me.

1. STATEMENT HAS BEEN SIGNED AND RETURNED.

2. OTHER, SPECIFY _____

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4. How many sisters and brothers did you have in your family?

(RECORD) Sisters _____ 34-35

Brothers _____ 36-36

5. Did you live with your natural parents during your childhood, or with step parents or guardians?

(RECORD) _____ 38
MALE FEMALE

IF R DID NOT HAVE A FATHER OR MALE GUARDIAN DURING CHILDHOOD, GO TO 7

6A. What was your father's (OR _____) major occupation during your childhood? (Be specific) 39-40

(RECORD) _____

6B. What is his present occupation? 41-42

(RECORD) _____

WRITE "DECEASED" OR "RETIRED" IF APPROPRIATE

6C. What was the highest grade in school he completed? 43-44

(CIRCLE ONE)

- | | | | | | |
|-------------------|----------------------|---|--------------------------|------------------------|-----------|
| <u>5, 6, 7, 8</u> | <u>9, 10, 11, 12</u> | <u>13, 14, 15, 16,</u> | <u>17</u> | <u>18</u> | <u>19</u> |
| Grade School | High School | Years of College
or post high
school training | Some
post-
college | Masters | Doctorate |
| | | | | Graduate school | |
| | | | | Post college education | |

CONFIDENTIAL

Now, let's begin.

I need to first ask you a few general questions about you and your family. This information is important for statistical purposes, to see how people in this survey compare with the rest of the population.

1. What is your birthdate? 24-29

(RECORD) _____

2. What was the highest grade in school you completed? 30-31

(CIRCLE ONE)

<u>5,6,7,8</u>	<u>9,10,11,12</u>	<u>13,14,15,16</u>	<u>17</u>	<u>18</u>	<u>19</u>
Grade School	High School	Years of College or post high school training	Some post-college	Masters	Doctorate
				Graduate School	
				Post college education	

3. Are you currently enrolled in a school or college? 32

1. NO →

2. YES
↓

3A. What is the name and location of the school? 33

(RECORD) _____

NAME

CITY

STATE

CONFIDENTIAL

	8A	8B	8C
	What is (was) your job title?	What are (were) your major duties in this job?	What kind of company is (was) this?
Current (or most recent)			
Before that?			
Before that?			

52-53

54-55

RECORD ADDITIONAL JOBS ON LAST PAGE

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IF R DID NOT HAVE A MOTHER OR FEMALE GUARDIAN DURING CHILDHOOD, GO TO 8

7A. What was your mother's (OR _____) major occupation during your childhood? 45-46

(RECORD) _____

7B. What is her present occupation? 47-48

(RECORD) _____

WRITE "DECEASED" OR "RETIRED", IF APPROPRIATE

7C. What was the highest grade in school she completed? 49-50

(CIRCLE ONE)

<u>5, 6, 7, 8</u>	<u>9, 10, 11, 12</u>	<u>13, 14, 15, 16</u>	<u>17</u>	<u>18</u>	<u>19</u>
Grade School	High School	Years of College or post high school training	Some post-college	Masters	Doctorate
				Graduate school	
				Post College Education	

8 The next part of this questionnaire concerns jobs that you have held.

I am interested in all the different kinds of work you have done for a period of one month or more. Please include summer jobs or part-time jobs you may have held while you were going to school.

First, are you currently employed, either full or part-time? 51

- 1. NO
- 2. YES

IF NO → I would like to start with your most recent job and work backward. (IF R HAS NEVER HAD A JOB, EVEN VOLUNTEER WORK, SKIP TO 10.)

IF YES → I would like to start with your current job and work backward.

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8D	8E	8F		8G	
Do you know of any hazardous exposures in this job? By that I mean any exposures that might affect a person's health.	What hazards were you exposed to? (RECORD SPECIFICS)	When did you start this job?		When did this job end?	
		MONTH	YEAR	MONTH	YEAR
NO → GO TO 8F YES → GO TO 8E DK → GO TO 8F					
NO → GO TO 8F YES → GO TO 8E DK → GO TO 8F					
NO → GO TO 8F YES → GO TO 8E DK → GO TO 8F					
NO → GO TO 8F YES → GO TO 8E DK → GO TO 8F					
NO → GO TO 8F YES → GO TO 8E DK → GO TO 8F					
NO → GO TO 8F YES → GO TO 8E DK → GO TO 8F					

HAZARD

YEAR
STARTED

56-59

60-63

64-67

TOTAL NUMBER OF HAZARDOUS EXPOSURES

68

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9. I'm now going to read through a list of things you might have had contact with, either in a job or a hobby. Please tell me if you have worked with or been exposed to any of these things at least once a week for more than one month.

READ LIST BELOW, ASK FOR SPECIFICS IF YES TO ANY

- | | |
|--|--|
| <ul style="list-style-type: none"> 1. Chemicals, cleaning fluids or solvents (specify) 2. Asbestos, insulation material 3. Insecticides or plant sprays 4. Plastics or resins (specify) 5. X-rays | <ul style="list-style-type: none"> 6. Anaesthetic gases 7. Radioactivity, isotopes 8. Petroleum products, fuels, benzene (specify) 9. Lead or metal smelting fumes (specify) |
|--|--|

9A.	9B.	9C.
Exposure (RECORD SPECIFICS)	When were you first exposed to this? (YEAR)	When was the last time you were exposed to this? (YEAR)
<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>

69-73

RECORD NUMBER YES

74

ID No. _____

CONFIDENTIAL

FOR EACH DISEASE OR CONDITION, ASK R FOR THE NAME AND ADDRESS OF HIS/HER PHYSICIAN. ASK ONLY ABOUT DISEASES IN R, NOT IN FAMILY.

Disease/Condition (Name or number)	Name of Treating Physician or Clinic	Address of Treating Physician or Clinic

CONFIDENTIAL

10. The next section of the questionnaire will be a health history. I am going to read through a list of health problems. As we go through this list, please tell me if you have ever been told by a doctor that you had the disease mentioned. Then I will ask you if anyone in your family has ever had any of these diseases. By your family, I mean the people you were raised with, parents or step-parents, brothers and sisters. Any questions?

		RESPONDENT		FAMILY
		No, Yes, Don't Know	Date of First Diagnosis (YEAR)	M, F, S, B
Have you ever been told by a doctor that you had any of the following <u>Respiratory Diseases</u> ?				
10A. Asthma	01	N Y DK		
B. Bronchitis	02	N Y DK		
C. Pneumonia	03	N Y DK		
D. Emphysema	04	N Y DK		
E. Has any member of your family ever had any of these diseases? (REPEAT LIST IF NECESSARY, RECORD INITIALS OPPOSITE DISEASE)			(RECORD Doctor's name and address)	
11. Have you ever been told that you had any of the following <u>Heart or Circulatory Diseases</u> ?				
A. Hypertension (high blood pressure)	05	N Y DK		
B. Buerger's Disease (inflammation of veins of the legs)	06	N Y DK		
C. Raynaud's Disease (poor circulation in hands or feet)	07	N Y DK		
D. Thrombophlebitis (blood clot in a vein)	08	N Y DK		
E. Rheumatic Fever	09	N Y DK		
F. Varicose Veins	10	N Y • DK		
G. Has any member of your family ever had any of these diseases? (REPEAT LIST)				

CONFIDENTIAL

		RESPONDENT		FAMILY
		No, Yes, Don't Know	Date of First Diagnosis (YEAR)	M, F, S, B
13. Have you ever been told by a doctor that you had any of the following <u>Diseases of the Digestive System?</u>		N Y		
13A. Hepatomegaly (enlarged liver)	20	DK		
B. Splenomegaly (enlarged spleen)	21	N Y DK		
C. Cirrhosis of the liver	22	N Y DK		
D. Gall stones	23	N Y DK		
E. Pancreatitis (inflammation of the pancreas)	24	N Y DK		
F. Colitis (inflammation of the colon)	25	N Y DK		
G. Diverticulitis	26	N Y DK		
H. Ulcers	27	N Y DK		
I. Appendicitis	28	N Y DK		

(RECORD Doctor's name and address)

CONFIDENTIAL

		RESPONDENT		FAMILY
12. Have you ever been told that you had any of the following <u>Blood Diseases</u> ?		No, Yes, Don't Know	Date of First Diagnosis (YEAR)	M, F, S, B
		N Y DK		
12A. Anemia (low blood)	11	N Y DK		
B. Aplastic anemia	12	N Y DK		
C. Sickle cell anemia	13	N Y DK		
D. Thalassemia	14	N Y DK		
E. Leukopenia (low white blood cell count)	15	N Y DK		
F. Thrombocytopenia (low platelet count)	16	N Y DK		
G. Leukemia	17	N Y DK		
H. Polycythemia	18	N Y DK		
I. Lymphoma	19	N Y DK		
J. Has any member of your family ever had any of these diseases? (REPEAT LIST) (Remember to record Doctor's Name and Address)				

I.D. No. _____

CONFIDENTIAL

14. Have you ever been told by a doctor that you had any of the following Kidney or Urologic Problems?

		RESPONDENT		FAMILY
		No, Yes, Don't Know	Date of First Diagnosis (YEAR)	M, F, S, B
14A. Bright's Disease	36	N Y DK		
B. Glomerulonephritis	37	N Y DK		
C. Pyelonephritis	38	N Y DK		
D. Kidney stones	39	N Y DK		
E. Bladder infection	40	N Y DK		
F. Any other kidney problems? (SPECIFY) _____	41	N Y DK		

G. Has anyone in your family ever had any of these kidney problems?
(REPEAT LIST)

(RECORD Doctor's name and address)

CONFIDENTIAL

	RESPONDENT		FAMILY
	No, Yes, Don't Know	Date of First Diagnosis (YEAR)	M, F, S, B
13J. Hepatitis (yellow jaundice) FOR R ONLY, IF N OR DK, GO TO 13K FOR R ONLY, IF Y	N Y DK		
↓ Ji Did the doctor tell you what kind of hepatitis it was? (RECORD)			X
Jii Did the doctor tell you how or why you got it? (RECORD)			X
13K. Any other Digestive or Liver Diseases? Specify _____	N Y DK		

29

(RECORD Doctor's name and address)

13L. Has any member of your family ever had any of these diseases?
 (REPEAT LIST, RECORD INITIALS OF FAMILY MEMBERS)

Card No.

ID No.

				0	4

1-2

3-7

CONFIDENTIAL

16. Have you ever had any form of cancer? 8

1. NO ———→ GO TO 17

2. YES

16A. What form of cancer was it?
In what part of the body?

16B. When was it first diagnosed?
(YEAR)

<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>

9-12

(RECORD Doctor's Name and Address)

17. Has anyone in your family (father, mother, brothers, or sisters) ever had any form of cancer? 13

1. NO ———→ GO TO 18

2. YES

17A. Who had it? (M, F, S, B)

17B. What form of cancer was it?
In what part of the body?

<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>

14-16

TOTAL NUMBER OF CANCERS
IN FAMILY

17

CONFIDENTIAL

15. Have you ever been told by a doctor that you had any of the following Bone, Joint, or Skin Problems?	RESPONDENT		FAMILY
	No, Yes, Don't Know	Date of First Diagnosis (YEAR)	M, F, S, B
15A. Osteoarthritis 42	N Y DK		
B. Rheumatoid Arthritis 43	N Y DK		
C. Gout 44	N Y DK		
D. Fibrositis 45	N Y DK		
E. Acroosteolysis (changes in finger bones) 46	N Y DK		
F. Clubbing of the fingers 47	N Y DK		
G. Psoriasis 48	N Y DK		
H. Eczema 49	N Y DK		
I. Scleroderma (thickening or scaling skin) 50	N Y DK		
J. Cold Sores (Herpes simplex) 51	N Y DK		
K. Shingles 52	N Y DK		
L. Has anyone in your family ever had any of these Bone, joint or skin problems? (REPEAT LIST)	(RECORD Doctor's name and address)		

CONFIDENTIAL

19. Do you have any chronic health problems we have not already discussed?
By that I mean problems which keep coming back, even if they do not
bother you all the time. 28

1. NO → GO TO 20

2. YES

19A. What kinds of conditions are these, and how old were you when
you first got them?

KIND OF CONDITION	AGE
_____ <input type="checkbox"/> <input type="checkbox"/>	_____ <input type="checkbox"/> <input type="checkbox"/> 29 - 32
_____ <input type="checkbox"/> <input type="checkbox"/>	_____ <input type="checkbox"/> <input type="checkbox"/> 33 - 36
_____	_____

RECORD ADDITIONAL CHRONIC CONDITIONS ON LAST PAGE.

TOTAL NUMBER OF CHRONIC CONDITIONS 37

CONFIDENTIAL

22. Are you limited in the kind of work you can do because of your health? 53

1. NO → GO TO 23

2. YES → GO TO 24A

23. Are you limited in your activity in any way because of disability or health? 54

1. NO → GO TO 25

2. YES

24A. In what way are you limited? 55-56

(RECORD LIMITATION, NOT CONDITION) _____

24B. When did you first become limited like this? (YEAR) _____ 57-58

24C. What conditions cause this limitation? 59-60

(RECORD) _____

25. During the past 12 months, about how many days did illness or injury keep you in bed all or most of the day? (RECORD) _____ 61-62

26. During the past 12 months, about how many times did you see or talk to a medical doctor? (Do not count doctors seen while you were a patient in a hospital) 63-64

CONFIDENTIAL

20. Please tell me about all the medicines or prescriptions you have taken regularly for a period of three months or more. Include all medicines prescribed by your doctor, and ones you buy at the drugstore without a prescription. Please tell me first about medicines your doctor has prescribed. (Do not include vitamins.)

	Name of Medicine	What did you take it for?	How often did you take it?	When was the first time you took it? (YEAR)	When did most recently take it?	
20A.	<input type="text"/>					38-39
20B.	<input type="text"/>					40-41

RECORD ADDITIONAL MEDICINES ON LAST PAGE

TOTAL NUMBER OF MEDICINES, RECORD "0" IF NONE

42

21. Have you ever been admitted to the hospital and stayed at least two nights for a nonsurgical illness or injury?

43

1. NO →

2. YES

	Hospitalization No. 1		Hospitalization No. 2		
21A. What was the problem? (RECORD)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	44-47
21B. When were you admitted?	Mo. <input type="text"/>	Year <input type="text"/>	Mo. <input type="text"/>	Year <input type="text"/>	48-51
21C. What hospital?	<input type="text"/>		<input type="text"/>		
21D. What City and State?	<input type="text"/>		<input type="text"/>		

RECORD ADDITIONAL HOSPITALIZATIONS ON LAST PAGE

TOTAL NUMBER OF HOSPITALIZATIONS
A-20

52

ID No. _____

CONFIDENTIAL

FOR EACH DISEASE OR CONDITION, ASK R FOR THE NAME AND ADDRESS OF HIS/HER PHYSICIAN. ASK ONLY ABOUT DISEASES IN R, NOT IN FAMILY.

Disease/Condition (Name or number)	Name of Treating Physician or Clinic	Address of Treating Physician or Clinic

Card No.

0 5

1-2

ID No.

[] [] [] [] [] [] [] []

3-7

CONFIDENTIAL

27. Now, I am going to read through a list of symptoms or conditions that you may have noticed in yourself.

Do you remember a time when any of the following bothered you enough to limit your activities, or cause you to see a doctor?

	No, Yes Dont' Know	IF YES, When were you first bothered enough to limit your activities or see a doctor? (YEAR)	
27A. Have you ever been bothered by dizziness or light headedness? 53	N Y DK		[] [] 8-9
B. Headaches? 54	N Y DK		[] [] 10-11
C. Pain in your upper abdomen or stomach? 55	N Y DK		[] [] 12-13
D. Lower back pain? 56	N Y DK		[] [] 14-15
E. Insomnia? 57	N Y DK		[] [] 16-17
F. Ringing or buzzing in the ears? 58	N Y DK		[] [] 18-19
G. Pain in the joints of your legs or arms? 59	N Y DK		[] [] 20-21
H. Loss of feeling or numbness in your hands or feet? 60	N Y DK		[] [] 22-23
	A-22	(RECORD Doctor's name and address, if any)	

CONFIDENTIAL

28. Thinking back to when you were in elementary school, do you remember being sent home from school because of any of the following conditions?

		No, Yes Dont' Know	IF YES, Do you remember what grade you were in, and what school you were attending? (RECORD)	
28.A. Dizziness	70	N Y DK		<input type="checkbox"/> 42
B. Headaches	71	N Y DK		<input type="checkbox"/> 43
C. Ringing or Buzzing in the ears	72	N Y DK		<input type="checkbox"/> 44
D. Trouble breathing, short of breath	73	N Y DK		<input type="checkbox"/> 45
E. Bad cough	74	N Y DK		<input type="checkbox"/> 46
F. Pain in the joints of your arms and legs	75	N Y DK		<input type="checkbox"/> 47
G. Loss of feeling or numb- ness in your hands or feet	76	N Y DK		<input type="checkbox"/> 48
H. Tingling in hands or feet	77	N Y DK		<input type="checkbox"/> 49
I. Fever	78	N Y DK		<input type="checkbox"/> 50

CONFIDENTIAL

		No, Yes Dont' Know	IF YES, When were you first bothered enough to limit your activities or see a doctor? (YEAR)	
		N Y DK		
27.I.	Tingling in hands or feet? 61			<input type="text"/> <input type="text"/> 24-25
J.	Trouble breathing, short of breath? 62			<input type="text"/> <input type="text"/> 26-27
K.	Diarrhea? 63			<input type="text"/> <input type="text"/> 28-29
27L.	Have you been bothered by problems in your arms, legs, hands, or feet, such as: Coldness or numbness? 64			<input type="text"/> <input type="text"/> 30-31
M.	Tingling sensations in your fingers or toes? 65			<input type="text"/> <input type="text"/> 32-33
N.	Pain in the joints of your fingers or hands 66			<input type="text"/> <input type="text"/> 34-35
O.	Redness or flushing in your hands or feet 67			<input type="text"/> <input type="text"/> 36-37
P.	Whiteness or loss of color in your hands or feet? 68			<input type="text"/> <input type="text"/> 38-39
Q.	Cracking and peeling of the skin of your hands or feet? 69			<input type="text"/> <input type="text"/> 40-41
		A-23	(RECORD Doctor's Name and address, if any)	

CONFIDENTIAL

R IS MALE, SKIP 29 THROUGH 34, GO TO 35

R IS FEMALE, PROCEED WITH 29

29. Next, I'm going to ask you some questions about your menstrual periods.

How old were you when your periods started?

8-9

30. Has there ever been anything unusual about your periods, or anything that concerned you or your doctor?

10

1. NO → GO TO 31

2. YES

30A. Can you tell me what this was?

11-12

(RECORD) _____

31. Since your periods started, have they usually been regular? For this question please ignore any time you might have been taking birth control pills. 1. NO 2. YES

13

R HAS NEVER BEEN MARRIED, SKIP 32 THROUGH 34, GO TO 35

R HAS BEEN MARRIED, PROCEED WITH 32

ID No. _____

CONFIDENTIAL

		No, Yes Dont' Know	IF YES, Do you remember what grade you were in, and what school you were attending? (RECORD)	
28 J. Diarrhea	79	N Y DK		<input type="checkbox"/> 51
K. Stomach pain	80	N Y DK		<input type="checkbox"/> 52
L. Vomiting	81	N Y DK		<input type="checkbox"/> 53

CONFIDENTIAL

	First	Second	Third	
	Current=88 88			
34A. When did your (first, second, third) pregnancy end? (MONTH, YEAR)	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	20-31
34B. How many months did this pregnancy last?	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	32-37
34C. Did this pregnancy end with the birth of a live baby that lived at least one month? If not, how did it end?	1. LB ≥ 1 mo. 2. LB < 1 mo. 3. Stillborn 4. Miscarriage 5. Abortion 6. Ectopic <input type="checkbox"/>	1. 2. 3. 4. 5. 6. <input type="checkbox"/>	1. 2. 3. 4. 5. 6. <input type="checkbox"/>	38-40
IF 4, 5, or 6, SKIP D THROUGH J, GO BACK TO 34 A				
34D. Was this a boy or girl?	1. Girl 2. Boy <input type="checkbox"/>	1. 2. <input type="checkbox"/>	1. 2. <input type="checkbox"/>	41-43
34E. How much did he/she weigh at birth?	lbs. oz. <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	lbs. oz. <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	lbs. oz. <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	44-55
34F. Were there any congenital abnormalities, or birth defects in the baby?	1. No. 2. Yes, Specify <input type="checkbox"/>	1. 2. <input type="checkbox"/>	1. 2. <input type="checkbox"/>	56-58
IF STILLBORN, SKIP G THROUGH J, GO BACK TO 34A.				
34G. Has this child had any major illnesses during its lifetime?	1. No. 2. Yes, Specify <input type="text"/> <input type="text"/>	1. 2. <input type="text"/> <input type="text"/>	1. 2. <input type="text"/> <input type="text"/>	59-64
34H. Is the child alive at present?	1. No 2. Yes <input type="checkbox"/>	1. 2. <input type="checkbox"/>	1. 2. <input type="checkbox"/>	65-67
IF CHILD IS ALIVE, SKIP I THROUGH J, GO BACK TO 34A.				
34I. What was the date of the child's death? (MO, YEAR)	_____ <input type="text"/> <input type="text"/>	_____ <input type="text"/> <input type="text"/>	_____ <input type="text"/> <input type="text"/>	68-73
34J. What was the <u>cause</u> of death? (RECORD)	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	74-79

TOTAL NUMBER OF PREGNANCIES 80

RECORD ADDITIONAL PREGNANCIES ON LAST PAGE

CONFIDENTIAL

32. Have you ever been pregnant? 14

2. YES

1. NO

32B. Was there ever a time when you were trying to become pregnant and could not do so? 15

1. NO

2. YES

GO TO 35

32A. How many times have you been pregnant? 16

(RECORD) _____

33. Was there ever a period of time when you were trying to become pregnant, and either could not do so, or it took more than six months to do so? 17

1. NO → **GO TO 34**

2. YES

33A. What is the most number of months or years at one stretch that you tried to become pregnant? 18-19

(RECORD) _____

34. Next, I am going to ask you a few questions about (each of) your pregnancy (ies).

CONFIDENTIAL

36C. How old were you when you stopped smoking cigarettes regularly? 20-21

36D. What was the main reason you stopped smoking? 22

(RECORD) _____

- 1. HEALTH REASON
- 2. HEALTH REASON, DOCTOR'S SUGGESTION
- 3. ADVERSE PUBLICITY
- 4. OTHER

37. Do you smoke pipes or cigars now? 23

1. NO → GO TO 38

2. YES

37A. Which do you smoke? 1. Pipe 2. Cigar 3. Both . . . 24

37B. How many pipefuls or cigars do you usually smoke each day? 25-26

37C. How old were you when you first smoked pipes or cigars? 27-28

GO TO 39

38. Have you ever smoked pipes or cigars regularly? 29

1. NO → GO TO 39

2. YES

38A. Which did you smoke? 1. Pipe 2. Cigar 3. Both 30
(Circle)

Card No.

0 7

1-2

CONFIDENTIAL

I.D. No.

[] [] [] [] []

3-7

35. At the present time, do you smoke cigarettes? Please include little cigars, or brown cigarettes.

[] 8

1. NO → GO TO 36

2. YES

35A. What is the average number of cigarettes you smoke per day now?

[] [] 9-10

(RECORD) _____

35B. How old were you when you began smoking cigarettes regularly?

[] [] 11-12

35C. Thinking back over the time since you first started smoking, what is the average number of cigarettes you've smoked per day? Please give your best estimate.

[] [] 13-14

(RECORD) _____

GO TO 37

36. Have you ever smoked cigarettes, on a regular basis?

[] 15

1. NO → GO TO 37

2. YES

36A. When you were smoking regularly, on the average how many cigarettes did you smoke per day?

[] [] 16-17

(RECORD) _____

36B. How old were you when you began smoking cigarettes regularly?

[] [] 18-19

CONFIDENTIAL

39. At the present time, do you regularly drink alcoholic beverages? . . . 38

1. NO -----> GO TO 40

2. YES
↓

39A. About how old were you when you began drinking regularly? 39-40

39B. During a typical month, on about how many days do you drink alcoholic beverages? 41-42

39C. On the days you do drink, about how many drinks do you have on the average day? By a drink, I mean a can of beer, a glass of wine, or one shot glass of hard liquor. 43

(RECORD) _____

39D. Have you ever regularly had three or more drinks per day every day? 44

- 1. NO
- 2. YES

39E. Have there been periods when you've had five or more drinks at one time, at least twice a month? 45

- 1. NO
- 2. YES

GO TO 41

ID No. _____

CONFIDENTIAL

- 38B. How many pipefuls or cigars did you usually smoke each day? 31-32
- 38C. How old were you when you first smoked pipes or cigars regularly? 33-34
- 38D. How old were you when you stopped smoking pipes or cigars? 35-36
- 38E. What was the main reason you stopped? 37
(RECORD) _____

- 1. HEALTH REASON
- 2. HEALTH REASON, DOCTOR'S SUGGESTION
- 3. ADVERSE PUBLICITY
- 4. OTHER

CONFIDENTIAL

41. This next section of the questionnaire will ask you about marijuana and other drugs. In order to keep your answers to these important questions strictly confidential, you will fill out this short section yourself, and seal it in an envelope before you give it back to me.

HAND IN THE SUPPLEMENTAL DRUG QUESTIONNAIRE (WITH I.D. NUMBER)
AND ENVELOPE

Please read the instructions in the box at the top of the page. (PAUSE)

Each question has an answer choice that requires the same amount of writing. Even if a question does not apply to you, or you'd rather not answer it, there is a choice that fits this, too. I will not be able to tell how you are answering any question.

As with the rest of the questionnaire, this section is confidential, and your name will not be connected with your answer. We need this important information for statistical purposes only.

Do you have any questions?

R COMPLETED SUPPLEMENTAL QUESTIONNAIRE? . . .

57

- I.D. NUMBER: 1. NO
2. YES
3. YES, RELUCTANTLY
ANONYMOUS: 4. NO
5. YES
6. YES, RELUCTANTLY

CONFIDENTIAL

40. In the past, has there ever been a time when you regularly drank alcoholic beverages? 46

1. NO → GO TO 41

2. YES

40A. About how old were you when you began drinking regularly? . . . 47 48

40B. During a typical month when you were drinking, on about how many days per month did you drink alcoholic beverages? 49 50

40C. On the days when you did drink, about how many drinks did you have on the average day? By a drink, I mean a can of beer, a glass of wine, or one shot glass of hard liquor. 51

(RECORD) _____

40D. Have you ever regularly had three or more drinks per day every day? 52

- 1. NO
- 2. YES

40E. Have there been periods when you've had five or more drinks at one time, at least twice a month? 53

- 1. NO
- 2. YES

40F. How old were you when you stopped drinking regularly? 54 55

40G. What was the main reason you stopped drinking regularly? 56

(RECORD) _____

RELEASE OF MEDICAL RECORDS

I have agreed to participate in a study being conducted by Science Applications, Inc. for the Environmental Protection Agency. This study is investigating possible health effects of exposure to vinyl chloride.

I authorize the release of my medical records to:

Program Physician
Vinyl Chloride Health Survey
Science Applications, Inc.
1801 Avenue of the Stars, #1205
Los Angeles, California 90067

so that they may be reviewed for information pertinent to the study. This authorization is valid for a period of 6 months from this date.

Subject

Date

Witness (Interviewer)

Date

42. That concludes the medical portion of the questionnaire. There are just a few more general questions.

How old were you on your last birthday?

71-72

43. In what city and state were you born?

73

(RECORD) _____
(CITY) (STATE)

44. What is your religious preference?

74

(RECORD) _____

45. Before we finish, there are two more consent forms that you must read.

HAND R RELEASE OF MEDICAL RECORDS FORM AND PEN

Your signature on this form will allow doctors working with our study to have access to your medical records, if they feel this is necessary.

Please read it, sign and date the bottom to show that you agree, and return the form to me.

1. RELEASE OF RECORDS FORM HAS BEEN SIGNED AND RETURNED.

75

2. FORM NOT SIGNED. REASON: _____

SIGN YOUR NAME AND DATE THE FORM AS THE WITNESS.

CONSENT FOR FOLLOW-UP

I have agreed to participate in a study being conducted by Science Applications, Inc. for the Environmental Protection Agency. This study is investigating possible health effects of exposure to vinyl chloride.

I also agree to allow Science Applications, Inc. to keep my name and address in a confidential file, which may be used to contact me again. I understand that any future contact will only be for the purposes of gathering information pertinent to the study, and that I am not agreeing to any actual participation.

Subject

Date

Witness (Interviewer)

Date

CONFIDENTIAL

46. This last form is a consent for follow up.

HAND R CONSENT FOR FOLLOW UP FORM AND PEN

This is to allow us to contact you in the future, if necessary, in order to update the information needed for this study or contact you about any findings which might be important to you.

Please read it, sign and date the bottom to show that you agree, and return it to me.

1. CONSENT FOR FOLLOW UP HAS BEEN SIGNED AND RETURNED.

76

2. FORM NOT SIGNED. REASON: _____

SIGN YOUR NAME AND DATE THE FORM AS THE WITNESS.

47. To help us keep in touch with you, could you please give me the names and addresses of two people who will always know how to reach you?

1. YES

2. RESPONDENT REFUSES

77

1. _____

2. _____

CONFIDENTIAL

48. That finishes the questionnaire. Thank you very much for your cooperation in this study. Would you like to make any comments about this interview?

78

1. NO

2. YES (RECORD)

49. RECORD THE TIME THE INTERVIEW ENDED.

(RECORD)

CONFIDENTIAL

FILL IN THE FOLLOWING ITEMS IMMEDIATELY AFTER LEAVING RESPONDENT'S HOME

Interview was conducted	1. In person, face to face <input type="checkbox"/> 2. By telephone 3. Other, Specify _____	8
Location of respondent during interview	1. respondent's home <input type="checkbox"/> 2. respondent's workplace 3. survey office 4. other, Specify: _____	9
Housing Type (If interview conducted at home)	1. single family residence <input type="checkbox"/> 2. duplex 3. apt. bldg (under 20 units) 4. apt. bldg. (20 units or more) 5. mobile home 6. other, Specify: _____	10
Respondent was:	1. White <input type="checkbox"/> 2. Black 3. <i>chicano, Hispanic</i> 4. Oriental 5. Other, Specify: _____	11
Interest of Respondent during Interview	1. very interested <input type="checkbox"/> 2. somewhat interested 3. uninterested	12
Language of Interview	1. English <input type="checkbox"/> 2. Spanish 3. Other, Specify: _____	13
Was there any other person present during the interview?	1. Yes, part of the time, spouse <input type="checkbox"/> 2. Yes, most of the time, spouse 3. Yes, part of the time, parents 4. Yes, most of the time, parents 5. Yes, part of the time, other 6. Yes, most of the time, other 7. No	14

ID No. _____

CONFIDENTIAL

ID No. _____

CONFIDENTIAL

Card No./I.D.

0	9					
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1-7

Disease Code	R Date	P	S
<input type="text"/> 19	<input type="text"/> 21	<input type="text"/> 23	<input type="text"/> 24
<input type="text"/> 20	<input type="text"/> 22		
<input type="text"/> 25	<input type="text"/> 27	<input type="text"/> 29	<input type="text"/> 30
<input type="text"/> 26	<input type="text"/> 28		
<input type="text"/> 31	<input type="text"/> 33	<input type="text"/> 35	<input type="text"/> 36
<input type="text"/> 32	<input type="text"/> 34		
<input type="text"/> 37	<input type="text"/> 39	<input type="text"/> 41	<input type="text"/> 42
<input type="text"/> 38	<input type="text"/> 40		
<input type="text"/> 43	<input type="text"/> 45	<input type="text"/> 47	<input type="text"/> 48
<input type="text"/> 44	<input type="text"/> 46		
<input type="text"/> 49	<input type="text"/> 51	<input type="text"/> 53	<input type="text"/> 54
<input type="text"/> 50	<input type="text"/> 52		
<input type="text"/> 55	<input type="text"/> 57	<input type="text"/> 59	<input type="text"/> 60
<input type="text"/> 56	<input type="text"/> 58		
<input type="text"/> 61	<input type="text"/> 63	<input type="text"/> 65	<input type="text"/> 66
<input type="text"/> 62	<input type="text"/> 64		
<input type="text"/> 67	<input type="text"/> 69	<input type="text"/> 71	<input type="text"/> 72
<input type="text"/> 68	<input type="text"/> 70		

Disease Code	R Date	P	S
<input type="text"/> 8	<input type="text"/> 10	<input type="text"/> 12	<input type="text"/> 13
<input type="text"/> 9	<input type="text"/> 11		
<input type="text"/> 14	<input type="text"/> 16	<input type="text"/> 18	<input type="text"/> 19
<input type="text"/> 15	<input type="text"/> 17		
<input type="text"/> 20	<input type="text"/> 22	<input type="text"/> 24	<input type="text"/> 25
<input type="text"/> 21	<input type="text"/> 23		
<input type="text"/> 26	<input type="text"/> 28	<input type="text"/> 30	<input type="text"/> 31
<input type="text"/> 27	<input type="text"/> 29		
<input type="text"/> 32	<input type="text"/> 34	<input type="text"/> 36	<input type="text"/> 37
<input type="text"/> 33	<input type="text"/> 35		
<input type="text"/> 38	<input type="text"/> 40	<input type="text"/> 42	<input type="text"/> 43
<input type="text"/> 39	<input type="text"/> 41		
<input type="text"/> 44	<input type="text"/> 46	<input type="text"/> 48	<input type="text"/> 49
<input type="text"/> 45	<input type="text"/> 47		
<input type="text"/> 50	<input type="text"/> 52	<input type="text"/> 54	<input type="text"/> 55
<input type="text"/> 51	<input type="text"/> 53		
<input type="text"/> 56	<input type="text"/> 58	<input type="text"/> 60	<input type="text"/> 61
<input type="text"/> 57	<input type="text"/> 59		

Number of Diseases in Respondent

<input type="text"/>	<input type="text"/>
----------------------	----------------------

62 63

Number of Diseases in Family Members

<input type="text"/>	<input type="text"/>
----------------------	----------------------

64 65

CONFIDENTIAL

How much influence did that person(s) exert on the Respondent? 15

1. great
2. moderate
3. little or none
4. no one else present, does not apply

Did the Respondent receive help or prompting during: 16

a. Occupational Section:

1. Parents
2. Spouse
3. Other, Specify _____
4. None

b. Medical Section? 17

1. Parents
2. Spouse
3. Other, Specify _____
4. None

How honest do you feel the Respondent's answers were? 18

1. very honest
2. somewhat honest
3. not very honest

CONFIDENTIAL

Show your answers by circling the number next to the answer that fits.
 Example: Do you usually eat breakfast?
 ①. YES 2. NO

Or, some questions ask you to write in a number.
 Example: How old were you when you learned to drive a car?
 _____ 16 _____ (estimated age)
 (If you have never learned to drive, write in 99)

41A. Have you ever used marijuana (grass, pot)?

58

- 1. YES
- 2. NO
- 3. DON'T WISH TO ANSWER

41B. How old were you when you first started to use marijuana?

59 - 60

_____ (estimated age)

(If you have never used marijuana, write in 99)

41C. Altogether, about how many years have you used marijuana?

61 - 62

_____ (estimated number of years)

(If you have never used marijuana, write in 99)

41D. During the time you used marijuana about how often have you used it, on the average?

63

(Circle the number)

- 1. EVERYDAY, OR NEARLY EVERYDAY
- 2. THREE TO FOUR TIMES PER WEEK
- 3. ONE TO TWO TIMES PER WEEK
- 4. ONE TO THREE TIMES PER MONTH
- 5. LESS OFTEN THAN ONCE PER MONTH
- 6. DON'T WISH TO ANSWER
- 7. DOES NOT APPLY/HAVE NEVER USED

CONFIDENTIAL

41. This next section of the questionnaire will ask you about marijuana and other drugs. In order to keep your answers to these important questions strictly confidential, you will fill out this short section yourself, and seal it in an envelope before you give it back to me.

HAND IN THE SUPPLEMENTAL DRUG QUESTIONNAIRE (WITH I.D. NUMBER)
AND ENVELOPE

Please read the instructions in the box at the top of the page. (PAUSE)

Each question has an answer choice that requires the same amount of writing. Even if a question does not apply to you, or you'd rather not answer it, there is a choice that fits this, too. I will not be able to tell how you are answering any question.

As with the rest of the questionnaire, this section is confidential, and your name will not be connected with your answer. We need this important information for statistical purposes only.

Do you have any questions?

HAVE YOU COMPLETED SUPPLEMENTAL QUESTIONNAIRE? . . .

57

- I.D. NUMBER: 1. NO
2. YES
3. YES, RELUCTANTLY
ANONYMOUS: 4. NO
5. YES
6. YES, RELUCTANTLY

CONFIDENTIAL

Heroin or Morphine

68

1. REGULAR USER
2. OCCASIONAL USER
3. HAVE NEVER USED
4. DON'T WISH TO ANSWER

Cocaine (Coke)

69

1. REGULAR USER
2. OCCASIONAL USER
3. HAVE NEVER USED
4. DON'T WISH TO ANSWER

Glue Sniffing (or other inhalants)

70

1. REGULAR USER
2. OCCASIONAL USER
3. HAVE NEVER USED
4. DON'T WISH TO ANSWER

THAT FINISHES THIS SECTION OF THE QUESTIONNAIRE. THANK YOU FOR YOUR COOPERATION. PLEASE SEAL THESE PAGES IN THE ENVELOPE AND RETURN IT TO THE INTERVIEWER.

CONFIDENTIAL

41 E. The substances listed below are some of the more commonly used drugs. For each one, please circle the number that best describes your non-medical use, now or in the past.

Barbiturates (downers, Quaaludes)

64

- 1. REGULAR USER
- 2. OCCASIONAL USER
- 3. HAVE NEVER USED
- 4. DON'T WISH TO ANSWER

Amphetamines (Dexedrine, Benzedrine, uppers, speed)

65

- 1. REGULAR USER
- 2. OCCASIONAL USER
- 3. HAVE NEVER USED
- 4. DON'T WISH TO ANSWER

Tranquilizers (Valium, Librium)

66

- 1. REGULAR USER
- 2. OCCASIONAL USER
- 3. HAVE NEVER USED
- 4. DON'T WISH TO ANSWER

Hallucinogens (LSD, Mescaline, PCP, Angel Dust)

67

- 1. REGULAR USER
- 2. OCCASIONAL USER
- 3. HAVE NEVER USED
- 4. DON'T WISH TO ANSWER

PLEASE CONTINUE ON NEXT PAGE

ID No. _____

CONFIDENTIAL

QUESTIONNAIRE FOR SPOUSE

HEALTH EFFECTS SURVEY OF VINYL CHLORIDE EXPOSURE

NAME

LAST

MAIDEN (if applicable)

FIRST

MIDDLE

ADDRESS

NUMBER AND STREET

CITY

STATE

ZIP CODE

TELEPHONE NUMBER

AREA CODE

NUMBER

APPENDIX B

Card No.

1 0

1-2

ID No.

[][][][][]

3-7

CONFIDENTIAL

Date of Interview

[][]

Month

[][]

Day

[][]

Year

8-13

Time of Interview-Beginning

(24-hour clock)

[][]

hour

[][]

min.

14-17

-Ending

[][]

hour

[][]

min.

18-21

Name of Interviewer

(PLEASE PRINT)

Interviewer Number

[][]

22-23

CONFIDENTIAL

This is an important medical survey of the possible health effects of exposure to vinyl chloride gas, which is being conducted by Science Applications, Inc., for the U.S. Environmental Protection Agency.

Elevated levels of vinyl chloride (which might affect health) were present around the area of the Saugus Elementary School. This school is located near a factory that uses vinyl chloride to make plastic. We are giving survey questionnaires to persons who may have been exposed while attending this school, as well as to persons who were not exposed.

One part of this survey deals with pregnancies and births, which are, of course, influenced by both husband and wife. Therefore it is necessary to ask you a few questions.

HAND R STATEMENT OF CONFIDENTIALITY AND PEN

This form is a statement of confidentiality prepared by the Environmental Protection Agency.

This is to assure you that this questionnaire is for health research only and that all of your answers will be strictly confidential and will never be connected with your name.

Please read it, sign and date the bottom to show that you understand, and return it to me.

1. STATEMENT HAS BEEN SIGNED AND RETURNED.

2. OTHER, SPECIFY _____

Now, let's begin.

I need to first ask you a few general questions. This information is important for statistical purposes, to see how people in this survey compare with the rest of the population.

1. What is your birthdate? 24-29

(RECORD) _____

2. What was the highest grade in school you completed? 30-31

(CIRCLE ONE)

<u>5,6,7,8</u>	<u>9,10,11,12</u>	<u>13,14,15,16</u>	<u>17</u>	<u>18</u>	<u>19</u>
Grade School	High School	Years of College or post high school training	Some post-college	Masters Graduate School	Doctorate Post college education

3. Are you currently enrolled in a school or college? 32

1. NO ——— GO TO 4

2. YES
↓

3A. What is the name and location of the school? 33

(RECORD) _____

NAME

CITY STATE

ID No. _____

STATEMENT OF CONFIDENTIALITY

THE PURPOSE OF THIS SURVEY IS TO OBTAIN INFORMATION WHICH WILL BE USED SOLELY FOR MEDICAL RESEARCH INTO THE EFFECTS OF ENVIRONMENTAL FACTORS ON PUBLIC HEALTH. THIS WORK IS BEING CONDUCTED FOR THE U.S. ENVIRONMENTAL PROTECTION AGENCY.

THE INFORMATION RECEIVED FROM YOU WILL BE HELD IN STRICT CONFIDENCE. ALL RESULTS WILL BE SUMMARIZED FOR GROUPS OF PEOPLE. NO INFORMATION ABOUT INDIVIDUAL PERSONS WILL BE RELEASED.

THE QUESTIONNAIRES USED IN THIS SURVEY ARE AUTHORIZED BY LAW (42 U.S.C. 7401 AS AMENDED). WHILE YOU ARE NOT REQUIRED TO RESPOND, YOUR COOPERATION IS NEEDED TO MAKE THE RESULTS OF THIS SURVEY COMPREHENSIVE, ACCURATE, AND TIMELY. FAILURE TO PARTICIPATE OR FAILURE TO COMPLETE THE STUDY ONCE ENROLLED WILL CARRY NO PENALTY.

I HAVE READ AND UNDERSTAND THE STATEMENT ABOVE.

Date

Signature of Respondent

CONFIDENTIAL

	5A	5B	5C	
	What is (was) your job title?	What are (were) your major duties in this job?	What kind of company is (was) this?	
				35-36
Current (or most recent)				
				37-38
Before that?				
Before that?				

RECORD ADDITIONAL JOBS ON LAST PAGE

CONFIDENTIAL

4. The next part of this questionnaire concerns jobs that you have held.

I am interested in all the different kinds of work you have done for a period of one month or more. Please include summer jobs or part-time jobs you may have held while you were going to school.

First, are you currently employed, either full or part-time?

34

1. NO

2. YES

IF NO → I would like to start with your most recent job and work backward. (IF SPOUSE HAS NEVER WORKED, EVEN VOLUNTEER WORK, SKIP TO 7.)

IF YES → I would like to start with your current job and work backward.

CONFIDENTIAL

6. I'm now going to read through a list of things you might have had contact with, either in a job or a hobby. Please tell me if you have worked with or been exposed to any of these things at least once a week for more than one month.

READ LIST BELOW, ASK FOR SPECIFICS IF YES TO ANY

- | | |
|---|---|
| 1. Chemicals, cleaning fluids or solvents (specify) | 6. Anaesthetic gases |
| 2. Asbestos, insulation material | 7. Radioactivity, isotopes |
| 3. Insecticides or plant sprays | 8. Petroleum products, fuels, benzene (specify) |
| 4. Plastics or resins (specify) | 9. Lead or metal smelting fumes (specify) |
| 5. X-rays | |

6A.	6B.	6C.
Exposure (RECORD SPECIFICS)	When were you first exposed to this? (YEAR)	When was the last time you were exposed to this? (YEAR)
<input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>

52-56

RECORD NUMBER YES

57

CONFIDENTIAL

5D	5E	5F		5G	
Do you know of any hazardous exposures in this job? By that I mean any exposures that might affect a person's health.	What hazards were you exposed to? (RECORD SPECIFICS)	When did you start this job?		When did this job end?	
		MONTH	YEAR	MONTH	YEAR
NO → GO TO 5F YES → GO TO 5E DK → GO TO 5F					
NO → GO TO 5F YES → GO TO 5E DK → GO TO 5F					
NO → GO TO 5F YES → GO TO 5E DK → GO TO 5F					
NO → GO TO 5F YES → GO TO 5E DK → GO TO 5F					
NO → GO TO 5F YES → GO TO 5E DK → GO TO 5F					
NO → GO TO 5F YES → GO TO 5E DK → GO TO 5F					

HAZARD

<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>

YEAR
STARTED

<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>
<input type="text"/>	

39-42

43-46

47-50

51

TOTAL NUMBER OF HAZARDOUS EXPOSURES

CONFIDENTIAL

10. Have you ever been pregnant? 14

2. YES

1. NO

10B. Was there ever a time when you were trying to become pregnant and could not do so? 15

1. NO

2. YES

GO TO 13

10A. How many times have you been pregnant? 16

(RECORD) _____

11. Was there ever a period of time when you were trying to become pregnant, and either could not do so, or it took more than six months to do so? 17

1. NO → **GO TO 12**

2. YES

11 A. What is the most number of months or years at one stretch that you tried to become pregnant? 18-19

(RECORD) _____

12. Next, I am going to ask you a few questions about (each of) your pregnancy (ies).

Card No.

111

1-2

ID No.

[] [] [] [] [] [] [] []

3-7

CONFIDENTIAL

SPOUSE IS MALE, SKIP 7 THROUGH 12, GO TO 13

SPOUSE IS FEMALE, PROCEED WITH 7

7. Next, I'm going to ask you some questions about your menstrual periods.

How old were you when your periods started?

8-9

8. Has there ever been anything unusual about your periods, or anything that concerned you or your doctor?

10

1. NO → GO TO 9

2. YES



8A. Can you tell me what this was?

11-12

(RECORD) _____

9. Since your periods started, have they usually been regular? For this question please ignore any time you might have been taking birth control pills. 1. NO 2. YES

13

CONFIDENTIAL

13. That finishes the questionnaire. Thank you very much for your cooperation in this study.

RECORD THE TIME THE INTERVIEW ENDED.

(RECORD)

CONFIDENTIAL

	First	Second	Third		
12A. When did your (first, second, third) pregnancy end? (MONTH, YEAR)	Current=88 88 <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	20-31
12B. How many months did this pregnancy last?					32-37
12C. Did this pregnancy end with the birth of a live baby that lived at least one month? If not, how did it end?	1. LB ≥ 1 mo. 2. LB < 1 mo. 3. Stillborn 4. Miscarriage 5. Abortion 6. Ectopic <input type="checkbox"/>	1. 2. 3. 4. 5. 6. <input type="checkbox"/>	1. 2. 3. 4. 5. 6. <input type="checkbox"/>	<input type="checkbox"/>	38-40
IF 4, 5, or 6, SKIP D THROUGH J, GO BACK TO 12 A					
12D. Was this a boy or girl?	1. Girl 2. Boy <input type="checkbox"/>	1. 2. <input type="checkbox"/>	1. 2. <input type="checkbox"/>	<input type="checkbox"/>	41-43
12E. How much did he/she weigh at birth?	lbs. oz. <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	lbs. oz. <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	lbs. oz. <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	44-55
12F. Were there any congenital abnormalities, or birth defects, in the baby?	1. No. 2. Yes, Specify <input type="checkbox"/>	1. 2. <input type="checkbox"/>	1. 2. <input type="checkbox"/>	<input type="checkbox"/>	56-58
IF STILLBORN, SKIP G THROUGH J, GO BACK TO 12A.					
12G. Has this child had any major illnesses during its lifetime?	1. No. 2. Yes, Specify <input type="checkbox"/>	1. 2. <input type="checkbox"/>	1. 2. <input type="checkbox"/>	<input type="checkbox"/>	59-64
12H. Is the child alive at present?	1. No 2. Yes <input type="checkbox"/>	1. 2. <input type="checkbox"/>	1. 2. <input type="checkbox"/>	<input type="checkbox"/>	65-67
IF CHILD IS ALIVE, SKIP I THROUGH J, GO BACK TO 12 A.					
12I. What was the date of the child's death? (MO, YEAR)	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	68-73
12J. What was the <u>cause</u> of death? (RECORD)					74-79
TOTAL NUMBER OF PREGNANCIES				<input type="checkbox"/>	80
RECORD ADDITIONAL PREGNANCIES ON LAST PAGE					

CONFIDENTIAL

FILL IN THE FOLLOWING ITEMS IMMEDIATELY AFTER LEAVING RESPONDENT'S HOME

Spouse Questionnaire was Administered:

- 1. At the same session as the Study-Subject Questionnaire 8
- 2. At a different session

Respondent for Spouse Questionnaire was:

- 1. Spouse 9
- 2. Study Subject
- 3. Other, Specify _____

If not spouse, explain why:

- 1. Spouse is deceased. 10
- 2. Spouse is otherwise unable to be interviewed. Specify reason _____

Interview was conducted

- 1. In person, face to face 11
- 2. By telephone
- 3. Other, Specify _____

Location of respondent during interview

- 1. respondent's home 12
- 2. respondent's workplace
- 3. survey office
- 4. other, Specify: _____

Housing Type (If interview conducted at home)

- 1. single family residence 13
- 2. duplex
- 3. apt. bldg (under 20 units)
- 4. apt. bldg. (20 units or more)
- 5. mobile home
- 6. other, Specify: _____

Respondent was:

- 1. White 14
- 2. Black
- 3. Chicano, Hispanic
- 4. Oriental
- 5. Other, Specify: _____

Interest of Respondent during Interview

- 1. very interested 15
- 2. somewhat interested
- 3. uninterested

APPENDIX C

ID No. _____

CONFIDENTIAL

The funding for the study began in October 1978 for a two year pilot segment with a subsequent one year option period. The first several months of the program have involved identifying the student population, developing the questionnaire and the detailed study protocol and establishing the models and information base to support the calculation of plant emissions and cohort exposure. This questionnaire has been thoroughly reviewed by Dr. G. Wilkinson, Senior Epidemiologist with the Epidemiology Branch of the EPA Health Effects Research Laboratory. The questionnaire has been revised by the performing contractor in response to these reviews. It is considered to be appropriate toward accomplishing the objectives of this program. Prompt further review and clearance are deemed to be vital in order that the study proceed in a timely manner to bring about efficient use of contract funds and allow for sufficient time for data reduction and analysis.

In summary, for this research program, Health Effects in Children Exposed to Vinyl Chloride (EPA Contract No. 68-02-2986), the performing contractor, Science Applications, Inc. (SAI), will survey the health status of the exposed cohort. In order to accomplish this objective a comprehensive health survey questionnaire administered by personal interview will be utilized. Comparison with concomitant health statistics data for unexposed populations will be made. Survey by questionnaire is the only appropriate procedure for developing the necessary data base for analysis. No existing data base contains information which can answer the study questions.

1.2 Data Utilization

Although a considerable body of occupational and laboratory toxicological data have demonstrated the carcinogenic action of vinyl chloride monomer, there appears to be no epidemiological literature uniquely detailing significant exposure to children. The administration and analysis of the questionnaire is a necessary component of the program which will: determine whether any statistically significant elevation of health effects exists in the cohort; evaluate their dose/effects relationship; provide a contrast with respect to latency period - pathology type observed - dose sensitivity, etc.

SUPPORTING STATEMENT - VINYL CHLORIDE HEALTH EFFECTS SURVEY QUESTIONNAIRE

1.0 JUSTIFICATION

1.1 Information Requirement

In the spring of 1978 the Saugus Elementary School was permanently closed because of concern about the hazards of vinyl chloride monomer (VCM) emissions from an adjacent polyvinyl chloride (PVC) fabrication and product manufacturing plant. Estimations of the VCM level at the school, based upon direct monitoring and calculations, exceed current occupational limits under particular conditions.

The plant has been in operation for twenty years and during the major portion of this period the occupational threshold limit value (TLV) was 500 parts per million (ppm) for the time weighted average (TWA) over a 40 hour week. By 1974 the TLV was reduced to 1 ppm because of a greater appreciation of the hazards posed by VCM exposure. VCM is a recognized human carcinogen and additionally has been associated with a number of non-carcinogenic pathological conditions often referred to as vinyl chloride disease.

The purpose of this research program is to determine if children who attended this school have manifest any unusual occurrences of disease conditions. The study will also delineate the factors characteristic of each condition such as latent period, exposure concentration-effect relationship, sex or other cofactor dependency. The results of this study are directly important to assist in evaluating the risk to children due to exposure from carcinogens. Certainly information derived from this research will be of direct benefit to the cohort and their families.

In view of the importance of this subject, the Health Effects Research Laboratory of the USEPA issued a request for proposals to conduct such a study (RFP DU-78-B180, July 1978). The merit and approach of the responses to this request were evaluated and the present study was selected (Science Applications, Inc., Los Angeles, Principal Investigator, Richard Ziskind, Ph.D).

No information on ambient air levels of vinyl chloride was presented, nor is it known whether the plants use vinyl chloride or PVC. Also no consideration was given to other environmental factors that might contribute to the incidence of cancer, such as infectious agents, other industrial exposures, background radiation, genetic factors, or exposure to other chemicals. Personal habits such as smoking were not considered.

The occupational exposure studies dealt with, of course, an adult and principally male population. It has been postulated (Hefner, 1975 and also Watanabe, 1976) that risk to young children may be greater because of the reduced activity of several enzyme systems which are thought to be important in the metabolic processes that facilitate body elimination of VCM.

There are no data already available with which to survey the health status of children who had been exposed to elevated levels of VCM. It is only by virtue of the proximity of the plant to the school that this highly unique cohort exists. Unlike a community situation every child has been exposed at the same location over a known time period. Since the myriad of potential outcomes of vinyl chloride exposure in childhood are unknown (making the case/control approach impossible), and since records are available to identify this unique exposure group, the cohort study design is the only feasible method to accomplish the research objectives.

The questionnaires will be administered by the contractor, SAI, and tabulated in form suitable for processing by the BMDP Biomedical Computer program software. The general purpose is to develop the necessary detailed health status data for the cohort in order to compare the exposed cohort with that of zero exposure population statistics. Pathological conditions to be examined include carcinogenic and noncarcinogenic disease occurrence by site, degree of exposure, latent period, sex, etc. Other factors which will be considered include socio-economic grouping, occupational history, and various cofactors such as smoking, drinking and drug use. Data use could include, as appropriate, risk elucidation to the cohort with recommendations of procedures for early detection of particular disease conditions. The results of the study will be used by the EPA to contribute to its ongoing assessment of the risk posed to the general population due to airborne carcinogenic release.

1.3 Existing Data

As recently summarized in the joint NIOSH/OSHA Current Intelligence Bulletin 88 (September 21, 1978), vinyl chloride is known to cause angiosarcoma of the liver and cancers at other sites in laboratory animals and in humans. Tumor sites reported in animal studies among four species (rat, mouse, rabbit, hamster) include mammary gland, skin, liver, lung, kidney and lymphatic. A number of epidemiological (cohort and community) studies and case reports have been conducted with the principal definite finding linking occupational exposures with angiosarcoma of the liver and cancer of the central nervous system. There have been reports in the literature (Christine, 1974 and also Schanche, 1974) of angiosarcoma occurring in individuals living in proximity to a vinyl chloride facility. These case reports did not survey the health status of the community. Only one such community study has been reported (Infante, 1976). This research concluded there was a statistically significantly greater number of deaths due to tumors of the central nervous system in the Ohio communities studied where vinyl chloride production facilities are either located or are nearby. Milby (1977) noted the limitations of the study as follows:

Ideally, these non-responders will be small in number, and representative of the remainder of the group that is interviewed. Otherwise, a bias may be introduced into the findings. In order to examine the comparability of responders and non-responders, information on demographic variables recorded at the time of school attendance will be compared between the two groups.

Subjects who are successfully traced, but who do not consent to be interviewed, can still be characterized as living, and used in the calculation of overall mortality rates. For those subjects who, for some reason, begin the interview, but refuse to complete it, the demographic variables at the beginning of the questionnaire can be compared to those of the subjects who finish.

The questionnaire is self coding as an aid to data management. It is being pretested on members of the program staff, and close associates in the age range of interest. The survey has been designed to examine the overall health status and history of the respondent as well as immediate family members. The procedure used is as follows:

- A contact letter will be sent to each subject explaining the reasons for the study; requesting their participation; discussing confidentiality of their responses; explaining the voluntary nature of their participation; and stating the procedures which will be followed.
- Telephone contact will be made, questions answered and an appointment set up. The subject's marital status will also be assessed, and provision set up to interview the spouse, if any.
- Interviews will be conducted in person rather than through mail unless absolutely impractical.
- The questionnaire includes the areas of: medical history; review of systems (to assess for possible diseases in various organ systems); reproductive experience (where appropriate); confounding variables including socioeconomic status, smoking, drinking, drugs, medication, hobbies, employment history.

2.0 DESCRIPTION OF SURVEY PLAN

2.1 Respondent Universe

The Saugus Elementary School pupil record cards reveal that from the years overlapping plant operation (1959-present) 5000-6000 students attended the school. The student's record card contains attendance, vital statistics, residence and parental information. The first phase of this research will encompass 1000 students initially exposed during the period between plant opening and June of 1964. This approach has been adopted since it initially focuses on the sub-group most likely to evidence VCM effects (due to a possible latent period) and allows the agency to refine the research protocol as may be necessary based on findings.

2.2 Survey Design

2.2.1 Overview

All students who attended the Saugus Elementary School for at least ~~one~~ month, from September 1958 to June 1964, supplied the basis for pilot group formation. These students (numbering approximately 1700) will be ordered according to months of exposure, and the top 1200 students with the greatest number of exposure months will become the pilot study cohort, targeted for follow-up and interview. This cohort formation scheme allows for the inclusion of students with the greatest exposure, and a latent period since first exposure of 15 to 20 years.

The remaining 500 students (those on the lower end of the exposure months scale), and the students attending from June 1964 to the present with at least one month's exposure, will form the basis for the secondary phase cohort.

Figure 2-1 illustrates the respondent selection and location procedures. As can be seen a number of independent locating strategies will be used. One major problem encountered in follow-up designs of this type is nonresponse of the cohort members. Members of the original exposed cohort can become non-responders in two ways: either because they are not traceable (lost to follow-up) or because they refuse to participate in the interview.

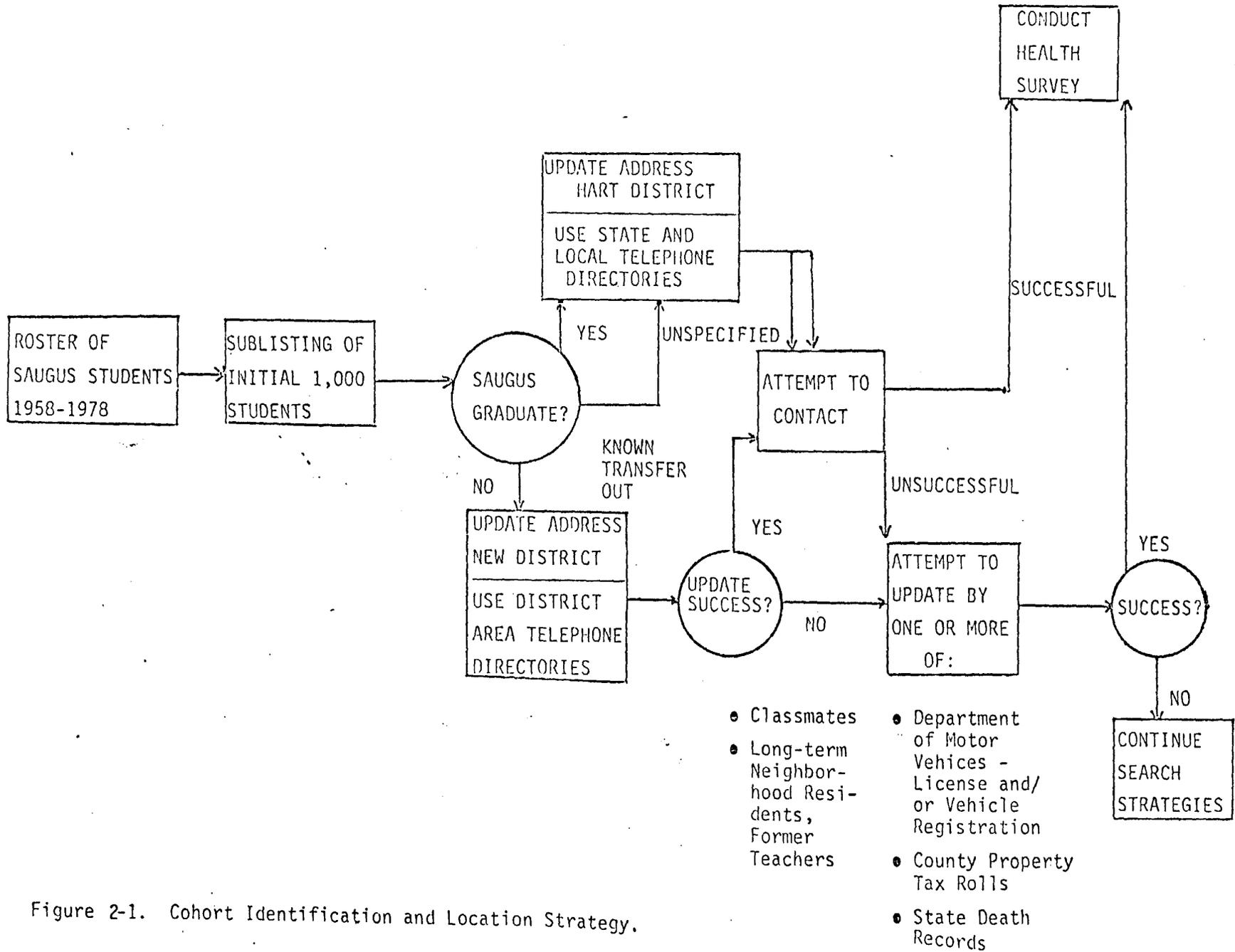


Figure 2-1. Cohort Identification and Location Strategy.

- Interviewers will record all answers to questions, even if response is "Don't know" or inappropriate. Responses of this type will be handled in the coding. Only diseases in Q 10 through 15 that the respondent or family has had will be coded, in order to save space in the data file. These diseases will be coded after the interview on page 46 .
- A random 10 percent sample of the completed questionnaires will be checked by telephoning the respondents to determine first, if the interview has in fact taken place, and second, if the questionnaire agrees with the answers to a few short questions repeated to the respondent over the phone.
- Medical information releases will be requested in order to facilitate developing more specific details concerning disease conditions and also to verify responses on a random spot basis.
- The questionnaire has been formulated for use in both the pilot and the subsequent study of the remaining 4000 students. Therefore some information taken will be used for quantitative comparison with the control group developed in the second phase. This includes information on non-specific symptoms such as headaches and dummy variables (such as gall stones and lower back pains) which are not known to be connected with vinyl chloride exposure. We will also use these questions to assist in spotting individuals who may be simply over-reporting all diseases. See table.

TABLE

HEALTH HISTORY DISEASES AND SYMPTOMS

By Questionnaire ID Number (see Q 10 to 15 and Q 27 to 28)

	Associated with VC exposure	Not associated with VC exposure (Distractor or Dummy Variables)
Diagnosed Diseases	01, 02, 04, 07, 15, 16, 17, 19, 20, 21, 22, 27, 29, 35, 36, 37, 38, 41, 42, 46, 47, 50	03, 05, 06, 08, 09, 10, 11, 12, 13, 14, 18, 23, 24, 25, 26, 28, 39, 40, 43, 44, 45, 48, 49, 51, 52
C-10 Undiagnosed Symptoms	53, 54, 55, 59, 60, 61, 64, 65, 66, 68, 69, 70, 71, 72, 75, 76, 77, 80	56, 57, 58, 62, 63, 67, 73, 74, 78, 79, 81

2.2.2 Question Rationale

2.2.2.1 Internal Validity and Reliability Checks

Q1,42,43(birthdate, age, city and state of birth) are included as validity and reliability checks. For each respondent, we know birthdate and city and state of birth from school records. Correct birthdate and birthplace responses will be used as validity checks, and consistent birthdate and age as a reliability check.

In assessing outcome, many (about half) of the diseases and conditions in the health history section are distractors, or dummy variables. That is, they have no known association with vinyl chloride exposure. These also will be used as quality checks. Subjects who report an increased number of VC related illnesses or symptoms would not be expected to report an increased number of non-related illnesses. If they do, this may indicate that these subjects are simply over-reporters of disease, and are not truly experiencing effects of VC exposure. (See Table)

Another validity check will be the use of subject's medical records, available after the subject signs the release form. We expect to abstract the medical records of all subjects who report VC-associated diseases, and a sample of the records of subjects who do not.

2.2.2.2 Socioeconomic Status

Since we are ultimately interested in events that have occurred in the respondent's life from grade school to the present, ideally we should be able to characterize the respondent's socioeconomic status (SES) both in childhood (as reflected by parents SES) and in the present.

Respondents' SES in the present will be characterized by:

1. Occupational history, including present, or most recent job (Q 8, 9).
2. Educational level attained (Q 2, 3).

Since many persons in our study group's age range will still be in school, we need to ask about current enrollment, as well as highest level completed.

in order to look at possible disease risk in the study subjects through genetic predisposition or environmental effects. The combined influence of genetics and environment can be assessed in subjects who lived with their biological parents. In subjects who were raised with step-parents or guardians, the questionnaire will, of necessity, focus on the family of orientation, since the subjects knowledge of his natural parents is likely to be limited. Genetic predisposition will not be assessed in these subjects, although familial effects of a common environment, lifestyle, socioeconomic status, and health practice will still be accounted for.

2. Other Chronic Health Problems, not included in the list of specific diseases.

3. Measures of General Health Status

- a. Serious medical problems requiring three or more visits to a doctor.
- b. Hospitalizations
- c. Medications, taken for a period of three months or more. Medication use is also a possible confounder.
- d. Limitations in activity because of disability or poor health.
- e. Days spent in bed during the past 12 months.
- f. Number of doctor visits during the past 12 months.

4. Symptoms or conditions not diagnosed by a doctor (including non-VC-related symptoms)

For each disease specifically diagnosed, each hospitalization, each doctor visit, the interviewer will be instructed to ask for the name and location of the doctor and hospital, and will record this information on page 26.

Q 22-26 (Limitations, bed days, and doctor visits) are reproduced from Q 24, 27, 28, 34, and 18 of the National Health Interview Survey, 1978, Bureau of the Census. The Health Interview Survey represents a large reservoir of general population health statistics, which will be used for comparisons, it is crucial that these questions be phrased and coded identically.

For example, a person who has completed the 12th grade, and is enrolled in college, may be of different SES than someone who had completed 12th grade, but never advanced beyond. Also, recording the name and location of the current school will help in future tracing, if necessary for a prospective study.

Parents SES will be characterized by recording brief occupational and educational histories of the parents or guardians (Q 6,7). Both past and present occupations will be recorded because wide discrepancies could signal rapidly shifting SES during the respondent's life. Further, current status of the parents (especially if deceased) may help in future tracing.

Q 5 (natural parents or guardians) will be necessary, first, for the interviewer to tailor the parent questions to the respondent's situation, and second, for interpreting family disease history.

2.2.2.3 Occupation

Occupational histories (Q 8,9) from the respondent will be gathered for 2 purposes:

1. To characterize the respondent's SES
2. To determine if there are environmental exposures besides elementary-school VC exposure that may influence health status.

We feel it is necessary to place these sections outlined above in the opening portion of the questionnaire, preceeding the Health History.

First, they will serve as warm-up questions, to loosen-up the respondent before administering the crucial, but challenging, Health History. Second, it is standard practice to place deomographic variables at the beginning of questionnaires. For those respondents, who for some reason, do not complete the questionnaire, we will at least be able to compare them demographically with the rest of the subjects.

2.2.2.4 The Health History (Q10 through 28) includes

1. Specific Conditions or Diseases Diagnosed by a Doctor. This list includes conditions not thought to be related to VC exposure, to act as a response check. Familial occurrence of disease will also be ascertained

The simplest way to gather this information is for the interviewer to ask about drug use history, similar to the alcohol and smoking items. However, we anticipate that our study subjects might be reluctant to answer questions about drug use truthfully. Each one knows that he or she is not a randomly selected, anonymous respondent, but a person who has been actively traced and contacted. It is not unreasonable that they may doubt our assurances of confidentiality in revealing illegal acts.

We have attempted to minimize the respondent's fear by several means.

1. The interviewer will give the respondent an short, self-administered drug questionnaire, on which the respondent will both read the question and enter the response. Every question will have an equivalent response, so that there will be no way of the interviewer knowing if the respondent has admitted to drug use or not.

2. All questions are phrased in the past tense to avoid forcing the respondent to confess to current use.

3. Each item will have a "Don't wish to answer" option.

4. The interviewer will repeat the assurance of complete confidentiality, that names will never be linked to results.

5. The respondent will seal the completed form in an envelope, before handing it back to the interviewer.

However, these measures may not fully convince the respondent of confidentiality, because the responses are not truly anonymous. The answer form is still identified by the subject's I.D. number, and is returned directly to the interviewer.

Therefore, in order to evaluate the impact this method versus complete anonymity has on subjects' responses, we will undertake a methodological comparison. By random allocation, one half of the subjects will take the drug questionnaire in the I.D. numbered, sealed envelope form described above. The remainder of the subjects will be given an identical questionnaire form, but without any identifying number on it. The respondent will complete the questionnaire in the interviewer's presence, but take the sealed envelope after the interview, and return it to us by mail. In this form, it will be apparent to all concerned that the drug-use questionnaire will have total anonymity.

The Health History will be used for several purposes:

1. To assess the occurrence of specific VC related events in the study group.
2. To assess the general overall health status of the group.
3. To act as a validity check, by the use of unrelated distractor or dummy variables (see Section 2.2.2.1).

2.2.2.5 Smoking and Alcohol Consumption

Cigarette, cigar, and pipe smoking (Q 35 through 38) are associated with a variety of human diseases, including respiratory and malignant diseases, and therefore must be accounted for. Alcohol consumption is likewise important, because it is directly associated with liver pathologies and some cancers. Q 39 and 40 are comparable to Q 13 and 16 in the Current Trends questionnaire, Non-Medical Use of Psychoactive Substances, National Institute on Drug Abuse, 1976. The findings of this national probability sample, divided into age groups 12-17, 18-25, greater than 25, will be used for comparison with the exposed cohort, before the incorporation of a control group.

2.2.2.6 Drug Use Questionnaire

The non-medical use of drugs, while far more sensitive a topic than cigarette or alcohol use, also requires assessment. Marijuana smoking has been linked to respiratory disease, alteration of lung function, and increased susceptibility to infection. Drugs such as barbiturates and opiates potentially affect the liver in several ways. The act of taking drugs by injection carries the risk of contracting viral hepatitis. As these drugs are detoxified by the liver, they may interfere with liver function, interact with alcohol in damaging the liver, and conceivably alter the liver's ability to detoxify other substances, such as carcinogens. Lastly, there exists the possibility that the drugs themselves may be carcinogenic.

While the prevalence of hard drug use in the general population is not high, the age range of our cohort (middle to late 20's) constitutes a high risk group. This, coupled with the potentially great effect of drugs on the major target organ of vinyl chloride, necessitates some form of drug use assessment.

By restricting our questioning to children of married couples, we will still encompass by far the majority of births experienced by our cohort. At the same time, we will avoid such embarrassing scenes as taking information from an unmarried woman, still living with her parents, about her pregnancies, or asking a married man about children sired out of wedlock, and how we can get in touch with his mistress. At the very least, this information will be of dubious validity, and more probably will result in the interview being terminated.

Detailed information concerning gestation and birth outcomes are much more likely to be recalled accurately by the women who underwent the experience than by men. For a female study subject who is married, we will simply add the reproductive history questions to the main questionnaire. However, since environmental exposures of both parents can affect the births in this cohort, we will require detailed occupational and environmental hazard information from her husband. This will be obtained by administering to the husband a short spouse questionnaire, containing occupational history questions identical to the ones in the main questionnaire.

For a study subject who is a married man, the pregnancy and birth histories that are required will only be accurately obtained from his wife. For married male subjects, the reproductive history section of the main questionnaire will be omitted by the interviewer. Wives of subjects will be administered a version of the spouse questionnaire with these items included, in addition to the occupational history questions.

The educational and occupational portions of the spouse questionnaire will be used to characterize the SES of the couple. This is especially useful when the exposed subject is a married female, as her occupation and education may not reflect the SES of the couple.

It is essential to the reliability of the questionnaire that study subject and spouse versions of the same question be asked in exactly the same wording.

The marital status of the subject will be established at the time of the telephone contact, and provisions for interviewing the spouse will be made at that time.

The anonymous mail-back method, while quite possibly eliciting more candid responses, will only allow characterization of respondents allocated to this method as a group only, not as individuals. This group can be compared to published data on drug use among similar age groups, such as the Non-Medical Use of Psychoactive Substances, National Institute on Drug Abuse. While we would be able to contrast the prevalence of drug use in the anonymous group to the general population, we would not be able to compare, for example, the drug use among subjects with a history of liver disease vs. those subjects without. Comparisons such as these can be made among subjects in the ID-numbered group.

We will be able to compare the success of these two methodological approaches in terms of response rates, proportion of "Don't wish to answer" responses, and drug use histories. Random allocation of the two questionnaire types will mean that the drug use histories should tend to have equal distributions between the groups. A significant departure could indicate that the two questionnaire types differ in the validity of the information elicited.

We will still be able to cross-tabulate drug-use responses with other variables of interest for half our subjects, and the entire group can be compared to published statistics.

2.2.2.7 Spouse Questionnaire

Since there have been reports of chromosomal abnormalities among VC workers, and possibly increased occurrence of neural tube defects in communities near VC plants (Infante 1976) one of the major outcomes of interest to this study is congenital malformations in the offspring of our subjects. This requires the taking of a detailed history of past pregnancies and births and the current status of all children.

For several reasons, we have decided to restrict the reproductive histories to subjects who are married. Pregnancy outside of marriage is such a strikingly sensitive issue that information elicited on this will probably not be valid. These pregnancies are likely to be either terminated in abortion, or denied by both parents, or of unknown paternity, or of outcome unknown to the father. In order to properly evaluate the reproductive history, extensive information on confounding variables (e.g. age, race, socioeconomic status, occupational exposures) are required from both parents. The chance of interviewing both parents is far greater if they are married than if they are not.

2.4 Contractor Information

The performing contractor is Science Applications, Inc., 1801 Avenue of the Stars, Suite 1205, Los Angeles, California 90067. The research program will be conducted out of their Los Angeles, California office. It is their responsibility, under the contractual arrangement, to conduct the project according to the protocol proposed in response to the EPA RFP DU-78-B180. The Agency has reviewed their technical proposal and the subsequent contract deliverable - Health Effects in Children Exposed to Vinyl Chloride - Study Protocol, SAI-068-79-532, 16 November 1978. Technical and financial monitoring is being maintained by the Agency through means of formal contract documentation requirements including - Work Plan, Study Protocol, Monthly - Quarterly - Annual and Final Reports. In addition a copy of the Quality Controlled Data Base in the form of computer tape will be supplied to the Agency. Regular informal telephone contact is maintained between the Principal Investigator and the Agency Technical Program Manager.

A number of procedures have been adopted to assure the confidentiality of collected data. A coded identification number has been assigned for each respondent. The correspondence between identification number and identity will only be known by the few key principals in the program. All data handling such as computer coding and statistical analyses will be performed utilizing only the numbers as identifiers. After the questionnaire is completed the respondent's name and critical identifying information such as address and phone number will be separated from the remainder and the code number substituted prior to data handling. Each interviewer will be trained to administer the questionnaire in a uniform manner. They may not depart from the narrative. Each will be informed that divulging information to a third party is strictly forbidden and immediate grounds for dismissal. Interviewers will be required to provide three character references (family members excluded). Training is scheduled to be about 5-6 sessions of 4-6 hours each and consist of the following elements: brief explanation of the study, confidentiality requirements, appearance, interviewing techniques, coding and detailed supervised practice with the questionnaire. In addition

IF STUDY SUBJECT IS:

	<u>Married Male</u>	<u>Married Female</u>
The subject will get:	Main Questionnaire (without reproductive history)	Main Questionnaire (with reproductive history)
and		
The Spouse will get:	Spouse Questionnaire (including education and occupation) and reproductive history.	Spouse Questionnaire (without reproductive history)

2.2.2.8 Religion

Certain religious groups follow practices that tend to influence disease risk. The Mormons and the Seventh Day Adventists, for example, by generally abstaining from tobacco and alcohol have lower rates than the general population for several cancer sites. A large representation of these religions in our study group will influence (1) the applicability of general statistics for comparison and (2) the choice of a control group.

2.2.2.9 Items Completed By The Interviewer

The questions on page 44-45 are standard items that will be completed afterwards by the interviewer. These include the environment of the interview, the language used, the race of the respondent, the respondent's level of interest, and the participation of others present.

Assessing race by having the interviewer record this (rather than asking the respondent) is standard procedure for OMB-approved questionnaires (see for example the Upstate New York Diet Study). Race is a sensitive issue. Asking an obviously White, Black, or Oriental person his race will appear ridiculous to the respondent (and may be offensive), and will be embarrassing to the interviewer. From our prior knowledge of the ethnic makeup of this group, we anticipate relatively few non-white subjects.

2.3 Agency Statistical Review

The agency statistician who has reviewed this work plan and who has been involved in selection of the contractor is:

Dr. William Nelson, Director
Office of Statistics and Data Management
Health Effects Research Laboratory
Research Triangle Park, NC 27711

3.0 TABULATION AND PUBLICATION PLANS

3.1 Publication

The Contractor will submit periodic reports as discussed above. The final report on the pilot program is expected to be published as an EPA document and made available to the public under NTIS or alternative distribution. This material will be reviewed to assure no breach in confidentiality is made. Interim reports will only receive internal Agency distribution. It is anticipated that oral presentations and peer reviewed journal articles may be developed which describe program methodology or results. Any submittals made by SAI during the contracting period will be reviewed by the Agency.

3.2 Tabulation

The questionnaire has been formatted to facilitate its direct coding onto the computer. The BMPD Biomedical Computer Programs (P-series 1977) will provide the principal statistical analyses software package. The exposed cohort will be considered as an entire group; differentiated as a function of calculated exposure; as a function of period from initial exposure; by sex; marital and reproductive status, etc. Analyses will include calculation and tabulation of the following categories:

- Data Description
- Data in Groups - description, t test and one-way analyses of variance
- Frequency Tables - measures of association, departures from independence
- Regression - linear and non-linear
- Analyses of Variance and Covariance
- Plots and Histograms

The development of comparison (zero exposure population) data to serve as a baseline will consist of published literature sources during the pilot program and the use of a control group for the subsequent study. During the pilot phase alternative control groups will be considered.

to these safeguards, questions related to drug use history will be separately administered by a more confidential procedure. The respondent will be asked to complete a series of such questions by filling out the drug questionnaire on a separate form. The interviewer will not know how the respondent is answering. The respondent will seal the drug questionnaire form in an envelope, and either return it to the interviewer at the time of the interview, or return it to the program staff by mail, as part of a methodological trial. This trial will assess the impact of assured confidentiality (ID number on drug questionnaire) versus complete anonymity (no ID number) on the respondent's willingness to disclose sensitive and illegal acts (see Section 2.2.2.6).

The Agency views this study as having a potential prospective component for which provision has been made to periodically renew contact with members of the cohort and update their health status. It is expected, at this time, that both the contractor and the agency will retain the survey material for the purposes of follow-up. The Agency has slated periodic site visits during which storage compartments will be inspected. All sensitive materials will be maintained under locked and limited access conditions. Since SAI's Los Angeles facility has both Department of Energy and Department of Defense Top Secret Clearance approval, it is anticipated that adequate resources are available to meet this program's needs.

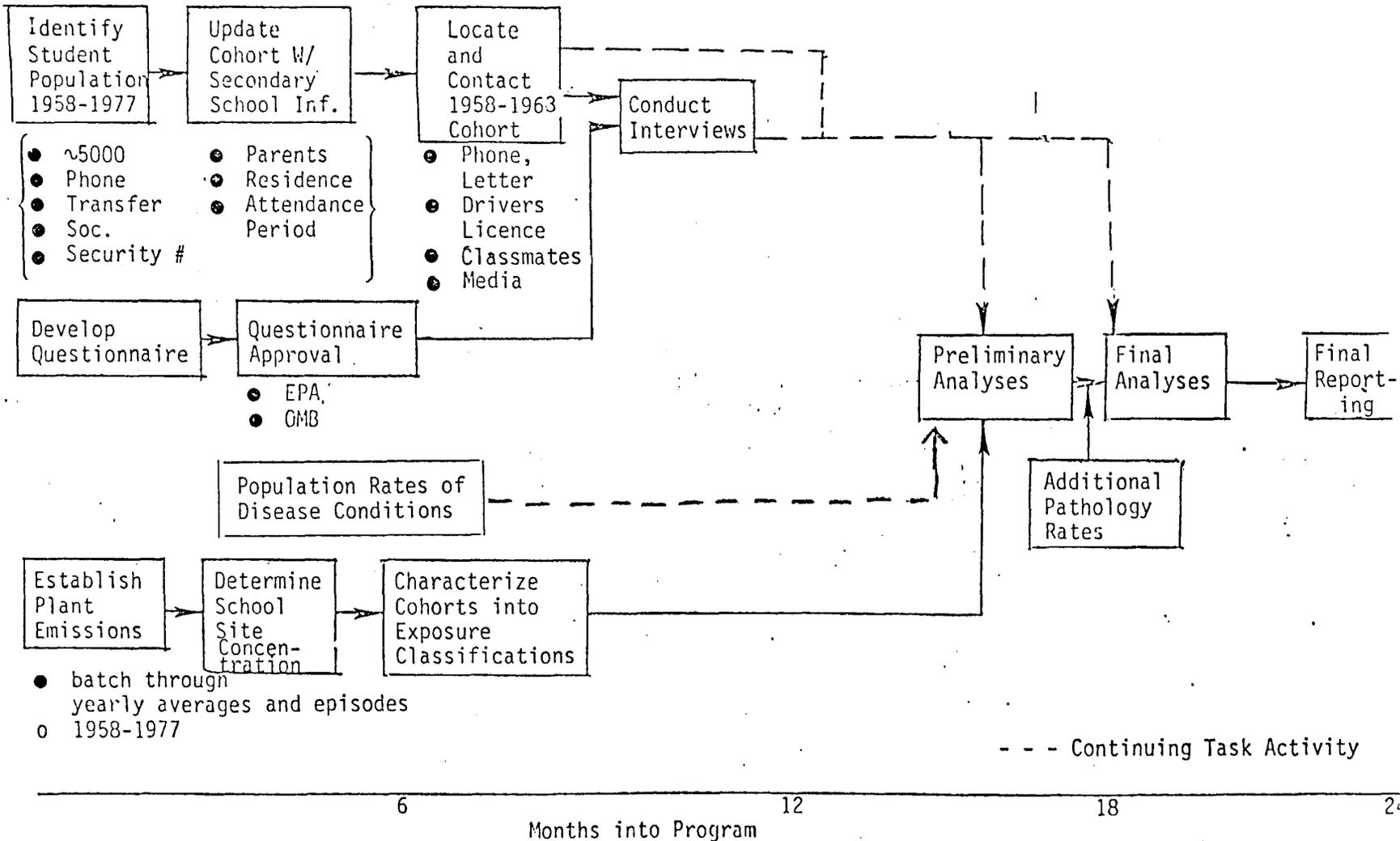
4.0 SCHEDULING

Figure 4.1 illustrates the planned schedule for the entire project. The pilot program starting date was October 1, 1978. Figure 4-2 presents a more detailed breakdown of the program subtasks. Data collection dates for the pilot phase are scheduled between 8 and 18 months after program start (1 June 1979 - 1 April 1980). Final report completion is 1 October 1980. The second phase would include data collection throughout most of its one year period of performance.

Therefore no comments can be made as to that potential respondent universe at this time. Specific data base sources for the pilot phase have been identified and include: Third National Cancer Survey; USC Cancer Surveillance Program; National Health Survey - various Vital and Health Statistics Reports; Alameda County Health Survey; Center for Disease Control Hepatitis Surveillance rates; UCLA Chronic Obstructive Respiratory Disease Study.

Submit Study Protocol

- Within 45 days
- Comprehensive Document



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Figure 4.2. Schedule and Program Elements for Pilot Program

6.0 ESTIMATION OF RESPONDENT REPORTING BURDEN

Based upon several trials with program staff, it is estimated that the interview will require about one-half hour. Each respondent will be interviewed only once. In the pilot study, this will require about 1000×0.5 hours = 500 hours. The spouse questionnaire is expected to last 5 to 10 minutes, depending upon whether the reproductive history is included. We cannot estimate precisely the total burden of the spouse interview, because we do not know how many of the study group cohort have married. If we assume one-half are married, the burden would be about $(1000/2) \times 0.17$ hours = 85 hours.

The second phase will interview approximately 4,000 additional respondents, requiring about 4000×0.5 hours = 2000 hours. Spouse questionnaires will also be added here, as needed. Since the subjects in the second phase will be younger than those in the first phase (many will still be teenagers), we might estimate the proportion married as one-third. The spouse burden in this group might therefore be $(4000/3) \times 0.17$ hours = 227 hours.

5.0 CONSULTATIONS OUTSIDE EPA

The contracting organization is Science Applications, Inc. The Principal Investigator is Richard A. Ziskind, Ph.D., and key program staff include Gary H. Spivey, M.D., M.P.H. epidemiology consultant; Daniel F. Smith, epidemiology; Ruth Sheridan, air quality modeling; Michael Rogozen, source evaluation.

In addition to agency personnel a number of individuals have reviewed and provided input to the development of the study protocol. These include:

John R. Holmes, Ph.D., Chief Research Division, California
Air Resources Board

Duane Reed, M.D., Medical Epidemiologist, Department of
Health Services, State of California

James Foster, Ph.D., Superintendent, Saugus Union School
District, California

Hamilton C. Smyth, Ed.D., Superintendent, Hart Union High
School District, California

Howard Hill, President, Keysor-Century Corporation, Saugus,
California.

8.0 COST TO FEDERAL GOVERNMENT

The total cost of the pilot study over its full two year time period will be \$110,922, with funding provided by the U.S. Environmental Protection Agency, Research Triangle Park, N.C. Cost for the subsequent one year phase is estimated at \$232,000.

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