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DIOXIN EXPOSURE

Article 24-B, Public Health Law New York State Department of Health

Albany N.Y. 12237

April 1982

Epidemiological Study of Soft-Tissue Sarcoma

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Project Period: February 1, 1981 - March 31, 1983

Performance Site: New York State, Exclusive of New York City

January 1981

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Abstract

Military experience of men in upstate New York reported with soft-tissue sarcomas will be studied epidemiologically for Vietnam service with potential herbicide exposure. Case ascertainment will be via the New York State Cancer Registry of men 18 through 29 years of age at any time from 1962 through 1971 and followed through December 31, 1980. Age and areamatched control groups will be selected from death certificates and drivers license files. Military service experience will be obtained from notations on death certificates, hospital records, telephone interviews, and Veterans Administration or Department of Defense records. Other factors previously suspected as being associated with soft-tissue sarcoma also will be studied.

In addition, occupation and industry of all men age 20 and over dying with soft-tissue sarcomas as residents or upstate New York from January 1, 1970 through December 31, 1980 will be examined. Matched controls will be selected from death certificates. The purpose of this study is to determine whether any occupation or industry is over-represented among the case group, thus raising a question of whether occupational or industrial expsoure in New York State may contribute to soft-tissue sarcoma.

Specific Aims

- 1) To determine if men in New York State exclusive of New York City of draftable ages during the Vietnam War and reported to the New York State Cancer Registry as having soft-tissue sarcoma through December 31, 1980 were more likely to serve in Vietnam than an age-matched control group.
- 2) To compare areas of service within Vietnam by case and control veterans who served in Vietnam, in order to attempt to assess potential for herbicide exposure.
- 3) To compare the histopathology and anatomic site of softtissue sarcomas amongst Vietnam veterans to the site and pathology of sarcomas in non-Vietnam veterans and non-veterans.

4) To determine whether deaths from soft-tissue sarcoma are associated with occupations or industries in New York State, as identified through death certificate reports.

Legislative Mandate

The New York State Legislature determined that there is a public need to know the health effects of exposure to herbicides containing dioxin for residents of the State of New York, including those Vietnam era veterans who may have been exposed to these substances during their period of military service. The New York State Public Health Law was amended effective September 1, 1980 to require the Commissioner of Health to "initiate an Epidemiological Study of the health effects of exposure to herbicides containing Dioxin." This project is developed as part of the response to this new legislation.

Preliminary Studies

In a report from Sweden, Hardell and Sandstrom (1979) reported a six-fold increase in the risk for soft-tissue sarcomas in workers exposed in phenoxyacetic acids or Phenoxy herbicides have been used to control chlorophenols. unwanted hardwoods in Swedish forests and commercial preparations nearly always are contaminated with dioxin. The Hardell and Sandstrom study explored potential for exposure among 52 men with soft-tissue sarcoma and reported that 19 of the 52 men may have had exposure compared to 19 of 208 control men. Soft-tissue sarcomas are a broad category of tumors derived from different types of cells and the authors did not provide information about which specific histologic types were studied. Nevertheless, a striking conclusion necessitates independent study of this reported association.

The New York State Cancer Registry was searched for soft-tissue sarcomas among men born between January 1, 1933 and December 31, 1953 who had attained the age of 18 years or more. This cohort includes men 18-29 during the years 1962-71.

The sites of cancer selected and International Classification of Disease codes (9th revision) are as follows:

Connective and Other Soft Tissues (171)
Head, Face and Neck (171.0)
Upper Limb, including Shoulder (171.2)
Lower Limb, including Hip (171.3)
Thorax (171.4)
Abdomen (171.5)
Pelvis (171.6)
Trunk, Unspecified (171.7)
Other (171.8)
Site Unspecified (171.9)

In addition, malignant neoplasms of the retroperitoneum and peritoneum (158) as well as those of the thymus, heart and mediastinum (164) will be reviewed in order to locate all possible soft tissue tumors.

The number of men in the Vietnam era cohort reported to the Registry, classified according to the American Cancer Society's 1968 Manual of Tumor Nomenclature and Coding (MONTAC), are as follows:

ICD 1	71 Connective and Other Soft Tissues	Total = 250					
800	Neoplasm, Malignant	18					
807	Squamous Cell Carcinoma, NOS	1					
869		1					
880	Sarcoma, NOS	1.2					
881		2					
882		42					
883	Fibroxanthoma, Malignant	13					
884	Myxosarcoma	1					
885		41					
889		17					
890		11					
891		. 4					
	Alveolar Rhabdomyosarcoma	1 6					
899		6					
904		28					
	Mesothelioma, Malignant	I.					
	Hemangiosarcoma	4					
	Hemangioendothelioma, Malignant	2					
914	Kaposi's Sarcoma	4					
	Hemangiopericytoma, Malignant	6					
	Chrondrosarcoma	Ţ					
937	Granular Cell Myoblastoma, Malignant	Ö					
	Ependymoma, Malignant	Ţ					
949	Ganglioneuroblastoma	Ţ					
950	Neuroblastoma, NOS	1 4 2 4 6 1 1 2 9 15					
954	Neurofibrosarcoma	7 5					
950	Neurilemoma, Malignant	10					

The following tables show the distribution of these tumors by anatomic site and by geographic area within New York State:

Table 1

Connective and Other Soft-Tissue Tumors Among Men in Vietnam Era Cohort

New York State Cancer Registry Anatomic Site

171	Connective and Other Soft Tissues	Total =	250
171.0	Head, Face and Neck	19	
171.2	Upper Limb, Including Shoulder	. 26	
171.3	Lower Limb, Including Hip	101	
171.4	Thorax	. 2	
171.5	Abdomen	2	
171.6	Pelvis	.6	
171.7	Trunk, Unspecified	33	
171.8	Other		
171.9	Site Unspecified	61	

Connective and Other Soft-Tissue Tumors

Among Men in Vietnam Era Cohort New York State Cancer Registry Histologic Type by Anatomic Site

Table 2

	Anatomic Site & Histologic Type	Head, Face and Neck (171.0)	Upper Limb, Including Shoulder (171.2)	Lower Limb, Including Hip (171.3)	Thorax (171.4)	Abdomen (171.5)	Pelvis (171.6)	Trunk, Unspecified (171.7)	Other (171.8)	Site Unspecified (171.9)	
800 807 869 880 881	Neoplasm, Malignant Squamous Cell Carcinoma, NOS Nonchromaffin Paraganglioma, Malignant Sarcoma, NOS Fascial Fibrosarcoma	}		8				2 .		15 2	
883 884	Fibrosarcoma, NOS Fibroxanthoma, Malignant Myxosarcoma	2 4 4	7 2	7 # 1#	} }	1	2	8		6 2	
385 889 890	Liposarcoma Leiomyosarcoma Rhabdomyosarcoma, NOS Embryonal Rhabdomyosarcoma	3	1 4 1	28 6 8	1	ı	2	2 3 1		3 4 2	
891 892 899 904 905	Alevolar Rhabdomyosarcoma Mesenchymoma, Malignant Synovial Sarcoma Mesothelioma, Malignant	1	5	1) 16			-	4 5 1		2	
912 913 914 915	Hemangiosarcoma Hemangioendothelioma, Malignant Kaposi's Sarcoma Hemangiopericytoma, Malignant		1 2 2	1 1 2 1			 	- - - 1		1	
922 937 939 949	Chrondrosarcoma Granular Cell Myoblastoma, Malignant Ependymoma, Malignant Ganglioneuroblastoma	1	•	4				<u> </u>		2 1 1	-
954 956	Neuroblastoma, NOS Neurofibrosarcoma Neurilomma, Malignant	1		3	1		1	1		2 6 10	
	All Histologic Types	19	26	101	2	2	6	3	_	61	

40

Table 3

Connective and Other Soft-Tissue Tumors Among Men in Vietnam Era Cohort

New York State Cancer Registry Geographic Distribution

New	York	State, Exc	lusive	of	New	York	City		Total	=	250
		Buffalo Re	gion				3	7	•		
	•	Rochester	Region				2	7			
-		Syracuse R	legion				3	37			
		Binghamton	Region	า				8			
		Albany Reg	ion				4	5			
		Westcheste	r Regio	on			4	9			
		Long Islan	d _				4	5			
		Unknown Re		•				2			-

Epidemiological reports on soft-tissue sarcomas are scant. Several factors have been hypothesized to be important to etiology but little evidence has been provided in support of these ideas. The main factors are as follows:

1) Trauma. Fibrosarcomas occasionally develop in scar tissue (Stout, 1961). It is doubtful that sarcomas develop from contusing blows although this has not been ruled out. Local sarcoma of the rat may be induced by the subcutaneous injection of many substances. In particular implants of a variety of plastic or metal discs or films can induce sarcomas in rats and mice. The relevance of this to man is uncertain (Lancet editorial, 1969). Greenberg (1976) reported four cases of sarcoma of the buttocks following intramuscular iron injection.

Morman, et al (1979) reported a locally aggressive dermatofibrosarcoma in a soldier who had received multiple immunizations for plague, yellow fever and tetanus. The sarcoma developed at the injection site. Five months after the injection a small nodule was noted, and eight years later gradual enlargement was first observed.

- 2) Infection. Morton (1974,1969) outlined the observations which suggest the close association of a viral agent with human sarcomas. Morton writes:
- "1. Type C viral particles, morphologically similar to the avian, murine, and feline sarcoma viruses, have been seen in human sarcomas.
- "2. All different types of human skeletal and soft-tissue sarcomas contain a common sarcoma-specific antigen to which patients with these neoplasms form antibody. Since all animal neoplasms induced by the same virus contain a common virus-specific tumor antigen, the finding of a common antigen in human sarcomas suggests viral etiology of these neoplasms by analogy.
- "3. Relatives and close associates of sarcoma patients also possess a high incidence of antibody to the sarcoma-specific antigens."

Kaposi's sarcoma has been reported in association with lymphoreticular malignancies (Safai, et al 1930). These investigators note clustering of Kaposi's sarcoma in endemic areas and cytomegalovirus isolation from a Kaposi's sarcoma culture cell line. A nechanism is hypothesized by which cytomegalovirus can lead to the development of multiple primary malignancies in Kaposi's sarcoma patients.

Soft-tissue sarcomas are said to be common in Afghanistan, ranking third among cancers (Sobin, 1968). Sobin believes that sarcomas could be related to arthropod vectors. He contends that subepidermal connective tissue is particularly exposed to mosquitos and other arthropods which pierce the epidermis.

The hamster reticulum cell sarcoma has been transmitted by a mosquito by transfer of tumor cells and the Shope fibroma virus can be transmitted by bites of fleas and mosquitos. Sobin further speculates that the distribution of bites from crawling arthropods, for example, fleas, ticks and bedbugs, may relate to the common location of soft-tissue sarcoma on lower extremities, and finally, he believes that the age incidence is compatible with an arthropod vector. Unfortunately, little data are provided to support these contentions.

No difference in family exposure to domestic cats, dogs and parakeets was found by Hanes, et al (1970) in a survey of households which included 127 persons with sarcoma.

- 3) Radiation. Eleven patients with postirradiation sarcoma have been described by Hatfield and Schulz (1970). These followed radiation treatment of primary carcinoma of the breast, three after megavoltage therapy. Other reports also indicate that radiation may induce sarcomas.
- 4) Familial Occurrence. Li and Fraumeni (1969, 1969, 1975) reported several families with more than one member having rhabdomyosarcoma and other soft-tissue sarcomas or other cancers. Mierau and Favara (1980) felt that all childhood forms of rhabdomyosarcoma are essentially embryonal tumors based on ultrastructural study. In one series four of twenty children with soft-tissue sarcomas had associated congenital anomalies (Sloane and Hubbell, 1969). The simultaneous occurrence of sarcomas in a husband and wife was reported by Goldenberg, et al (1974).
- 5) Chemicals. The possible association with dioxins raises questions about the induction of sarcomas by other chemicals. As noted above, intramuscular iron and multiple immunizations have been suspect. In this study, the main effort to obtain a lead on other potential chemicals will focus on occupation and industry.

Methods

Cancer Study

(a) <u>Case Ascertainment</u> - The case group will be all male residents of New York State exclusive of New York City who were 18 to 29 years old anytime from 1962 - 1971, and who were reported to the New York State Cancer Registry as having soft-tissue sarcoma first diagnosed at any time through December 31, 1980.

The New York State Department of Health maintains one of the world's largest cancer registries. By law all physicians, hospitals, and laboratories must report newly diagnosed patients with cancer to the New York State Cancer Registry. We believe this Registry to be about 90% complete. A copy of the cancer registry report form is shown on the next page.

NEW YORK STATE CANCER REGISTRY REPORT

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(b) Control Group Selection - Two overlapping control groups will be used, each having a control to case ratio of 1:1. The first group of controls will be selected from drivers license files matched on 5-year age group and zip code (see appendix). The method is based on that developed by P.C. Nasca and J.O. Moore. Alternate controls also will be selected and stratification during analysis shall include race. The sarcoma case group will be matched against drivers license files to see the extent to which the case group have drivers license. This will provide an indication of how representative the control sampling fram is of the case group. As most of the case group would have been expected to live had they not developed sarcoma, this live control group is considered most representative of the general population and thus the appropriate control group for this study.

In order to take into account the possibility that informants for dead cases may not be able to provide equivalent information to that for live controls, a dead control group will also be selected for dead cases. Controls found to be ineligible for military service because of a condition which lead to their subsequent selection as a control will be excluded. Together with the matched controls for the live cases, these will provide a second control group for analysis. For each dead case two death certificates will be selected for men of the same 5-year age group, years of education, race and health systems area. Persons dying from all causes except cancer will be eligible to serve as a control.

Positive Control - In addition to the "negative controls" noted above, we will attempt to obtain an age-matched group of "positive controls" that is, men known to have served in Vietnam. These controls will be selected only for sarcoma cases with a Vietnam service history. Information on dates of service, battalion company, etc. for these two groups will be collected and compared.

(c) Tumor Comparisons - Pathology slides will be borrowed from hospital pathologists for review by Dr. Doris Collins of the Division of Labs and Research. Dr. Collins will use a standardized classification form, and be blinded as to the military service experience of the case study. The distribution of histologic patterns of Vietnam veterans then will be compared to non-Vietnam veterans and non-veterans.

Hospital records will be abstracted for anatomic site of the tumor, diagnostic procedures, and historical information. Again, Vietnam veterans will be compard to non-Vietnam veterans and non-veterans. (It should be noted that this section relates only to comparisons with the case group rather than case-control comparisons.)

(d) Interview - Cases and controls, or a close relative or friend if the study subject has died, will be interviewed using a standardized questionnaire. The interview will be done by trained interviewers who have pilot tested the questionnaires. A 10 percent callback will be done by a different interviewer to check on reliability. The survey will be conducted by telephone, or if the study subject prefers, in person. Data will be collected about conditions known or suspected of being associated with sof-tissue sarcoma or which might relate to the possibility of exposure. Thus, in addition to military service history, we will gather data on smoking, alcoholism, occupation, other activities that might be associated with exposure to toxic chemicals, and on questions which relate to the various hypotheses discussed in the background section.

Validation of interview responses relating to military service and further information will be collected by checking against Veterans Administration records. This procedure will be kept blinded as to case or control status insofar as possible.

(e) Analysis - Results will be analyzed using traditional epidemiological and biostatistical methods, including current multivariate statistical techniques. This will include the linear logistic model for matched analysis as described by Holford et al (1978) and the direct consideration of continuous risk variables and for multivariate analysis. Further when a single univariate binary risk factor is considered, this model reduces to the method of miettinen (1974). Statistical power will be shown through the use of confidence limits or other methods.

Associations between selected diseases and putative exposures may arise through a number of biases which affect the collection and interpretation of data from epidemiological studies. The following attention will be given to these potential biases:

(1) Associations may be based on systematic bias due to non-response. We will attempt to reduce non-response to minimum. Past experience of the Division of Epidemiology shows that we can anticipate a response rate of better than 80% in both the case and control groups in interview studies. We also plan to compare respondents and non-respondenta among both cases and controls according to the variables which are present in the record systems used for case and control ascertainment.

- (2) Bias might be the result of preferential recall on the part of case or control subjects. To minimize this potential bias wehrever possible we will use established records to identify or validate military service experience. We also will compare the absolute frequency of military service experience in our study to the data reported form other similar investigations.
- (3) Bias may occur as a reuslt of a systematic difference between cases and controls in terms of access to medical care. We do not expect this to be a major problem for patients with the conditions under study. However, we will collect information about diagnostic procedures and analyze for this possibility.
- (4) An artifactual association or absence of association could occur if eligibility for military service varied between cases and controls. To avoid this, controls found to be ineligible for military service because of a condition which lead to their death and subsequent selection as a control will be excluded. We do not know if other causes of death; for example, motor vehicle accidents, are more or less likely to occur among veterans. We feel the best way of handling this type of possibility is to select the controls broadly from a-1 disease categories except those under study.
- (5) Confounding by other variables is one of the most frequent sources of bias. We will attempt to minimize this possibility through matching, subject restriction, and multivariate analysis. Attention will be paid to the distinction between variables which are true confounders and those which are part of a causal network. NOTE THAT A MAJOR LIMITATION OF THIS STUDY MAY BE AN INABILITY TO MAKE A DEFINITE STATEMENT ABOUT DIOXIN EXPOSURE EVEN IF CASES TURN OUT TO HAVE MORE MILITARY EXPERIENCE THAN CONTROLS.
- II. Part II Study Part II Study will be an analysis of occupation and industry as reported on death certificates. Study subjects will be all male residents of New York State exclusive of New York City listed on death certificates as dying of soft-tissue sarcomas during the period January 1, 1970 through December 31, 1979. Controls will be selected from death certificate files matched on date of birth, years of education, race and health systems area. Occupation and industry from the certificates will be analyzed in order to see if any particular occupations or industries are overrepresented in the case group. This is considered a hypothese generating study that may yield a lead for further investigation.
- III. Human Subjects Risks, if any, from epidemiologic studies of this type are minimal. The use of telephone interviews to collect epidemiologic data seems reasonable in light of the number of interviews to be completed. This method does, of course, preclude the procurement of personally signed participant informed consent forms. A substitute method has been developed to serve this purpose. Prior to the interview we will read a standardized text which explains the purposes of the research and the rights of participants. This method has been reviewed and approved by the Human Subjects Committee of the New York State Department of Health under the

Federal rules and regulations governing the protection of human subjects (Subtitle A of Title 45, Section 46.10(c)). Signed informed consent will be obtained in the event of a personal interview or medical procedure. Individual records will be kept confidential. Division of Epidemiology employees are trained in confidentiality procedures and the offices protected by security measures which help to assure this confidentiality.

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APPENDIX

Male Soft Tissue Sarcoma Study Live Control Selection Procedures.

Request a selected 5-year age group distribution of male licensed drivers by selected zip code areas of New York State, excluding New York City from the New York State Department of Motor Vehicles. Using these data, determine what percentage of those files must be sampled and put on tape in order to generate the appropriate number of controls. Ask the New York State Department of Motor Vehicles to sample licensed drivers using the following procedures:

- 1. Select all male licensed drivers between the ages of twenty-five and forty-nine inclusive who reside in selected zip code areas.
- 2. Stratify each 5-year age group by zip code and using a random starting number between 1 and ____ (to be based on predetermined percentage), choose every ____ th driver in each zip code area until the appropriate number of controls has been selected.
- 3. Create a tape file consisting of the individuals selected in the systematic sample.

Our programmer will then prepare a program which will allow us to print out the information on the tape in a form enabling us to select the controls by random number order. One primary control and five alternate controls will be chosen for each case. They will be matched with the case group, and zip code at the time of diagnosis. This will be done for each case in the following manner:

- 1. From a case list including year of birth and zip code at time of diagnosis find year of birth and zip code for the case.
- 2. Locate the same zip code on the Motor Vihicle printout and the year of birth that matches that of the case.
- 3. Using the random number generator on the calculator, choose the first six controls that can be used.
- 4. Fill in a control selection form in duplicate.

4/12/82

APPENDIX D

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