

Personal Mail

From: James E. Enstrom, PhD
Sent: Friday, March 20, 1998 2:49 AM
To: Dr. C. W. Jameson
Subject: Report on Carcinogens, Ninth Edition



ETSNHEFS.doc

Dear Dr. Jameson:

In accordance with the February 3, 1998 announcement in Federal Register, I am submitting comments regarding the proposed listing of environmental tobacco smoke as a carcinogen in the Report on Carcinogens, Ninth Edition as part of the National Toxicology Program. These comments are in the form of an attached manuscript that presents the results of a new epidemiological study, "Environmental Tobacco Smoke and Mortality Among a Sample of the United States Population."

If you have any difficulty reading this Word 97 document, please let me know. Thank you very much for your consideration.

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ENVIRONMENTAL TOBACCO SMOKE AND MORTALITY AMONG
A SAMPLE OF THE UNITED STATES POPULATION

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ABSTRACT

The relation between environmental tobacco smoke (ETS), as measured by spousal cigarette smoking, and mortality has been examined among nonsmokers in the First National Health and Nutrition Examination Survey (NHANES I) Epidemiologic Follow-up Study cohort. A representative sample of noninstitutionalized U.S. adults aged 25-74 years has been examined in detail during 1971-74 and 1982-84, including an assessment of spousal cigarette smoking. This cohort has been followed up for mortality through 1987. The relation of mortality for selected causes of death to spousal cigarette smoking in 1,047 men and 3,304 women who never smoked cigarettes has been analyzed using proportional hazards models. The relation is not significant for any cause after adjustment for age and sex, or after additional adjustment for ten potentially confounding variables (including diet, education, race, and disease history). Measurement errors in personal and spousal smoking histories are on the order of 10% based on comparing responses in 1971-74 and 1982-84. These results do not support the notion that ETS has a measurable impact on human mortality, but they cannot rule out small effects on individual causes of death.

Keywords: environmental tobacco smoke, passive smoking, NHEFS, mortality, cancer, cardiovascular diseases, epidemiology

INTRODUCTION

There has been much interest in recent years in the role of environmental tobacco smoke (ETS), or passive smoking, in causing deaths from lung cancer and other diseases in persons who have never smoked [1-3]. A major EPA report released in early 1993 summarized existing epidemiologic and other research and concluded that passive smoking causes about 3,000 lung cancer deaths per year among Americans [1]. However, two other summaries raised doubts about this relationship. Two 1986 reviews found an association between passive smoking and lung cancer, although they did not conclude there was a causal relationship [4,5]. Most of the studies done to date have been case-control studies involving lung cancer patients and a few cohort studies dealing with lung cancer, coronary heart disease, and/or all causes of death [1-3]. Many of these studies indicate increased ETS exposure is associated with some increased risk of death from lung cancer and/or coronary heart disease. However, most of the individual studies have not shown statistically significant relationships. The significant relationships have emerged from meta-analysis, such as the one done by EPA, that combined these studies in various ways. However, meta-analysis is intended for summarizing randomized controlled trials and not for evaluating weak epidemiologic associations. Furthermore, several large studies since the EPA report indicate no significant association [6-8]. Given these inconclusive results it is important that additional epidemiologic studies be conducted.

We report here the relation spousal smoking and mortality found in a sample of the general U.S. population that has undergone an extensive lifestyle, nutritional, and medical examination, including measuring spousal cigarette smoking retrospectively, and on which we have previously reported about vitamin C [9,10]. This study collected such substantial data that we have been able to analyze passive smoking along with several other potential confounding variables. This cohort provides simultaneous assessment of the relation of passive smoking to mortality for lung cancer, all cancers combined, all cardiovascular diseases, and all causes of death. The cohort is all the more valuable because the data are publicly available and can easily be reproduced. This is an important point because most of the existing studies cannot be independently checked for potential data collection and analysis problems.

METHODS

The NHANES I Epidemiologic Follow-up Study (NHEFS) is a prospective cohort study based on the National Health and

Nutrition Examination Survey conducted by the National Center for Health Statistics (NCHS) on a representative sample of the civilian noninstitutionalized population of the United States [11]. Persons estimated to be at risk of malnutrition (children, the elderly, women of child-bearing age, and the poor) were oversampled in order to improve estimates of nutritional status for these groups. The size and scope of these data provide a unique opportunity to examine etiologic relationships in a large, heterogeneous national population.

The subject of this report is the cohort of 11,348 persons on whom extensive diet and nutrition data were collected during 1971-74 using food frequency and 24-hour recall questionnaires [11]. We created one master file for the cohort of 11,348 nutritionally examined NHEFS subjects by linking together 1971-74 nutrition and medical history data, specially coded 1971-74 vitamin supplement data, 1982-84 follow-up interview data, and follow-up death data through 1987 described elsewhere [12]. Follow-up through 1987 has been completed on 10,874 persons (97% of the 4,479 men and on 95% of the 6,869 women) and there were 1,595 male deaths and 1,242 female deaths.

The underlying cause for each death was coded by NCHS following the rules of the Ninth Revision of the International Classification of Diseases (ICD9). Because of the oversampling of elderly, 37% of the men and 26% of the women were aged 65-74 years at entry, and 82% of all deaths occurred among persons aged 65-89 years at death. Cigarette smoking data in 1971-74 were obtained on only 3,854 persons in the cohort. Lifetime cigarette smoking histories and spousal cigarette smoking were obtained for 9,602 persons (91% of the 10,550 persons traced) in the 1982-84 follow-up interview, including a proxy interview with a spouse or other informant for most of those who had died. Using both the 1971-74 and 1982-84 data, cigarette smoking histories, were available on 10,128 persons (90% of the cohort). The spousal smoking question asked "Did your spouse ever smoke cigarettes?" The two groups of nonsmokers have been selected for analysis with respect to spousal smoking exposure. Persons who never smoked cigarettes (NSC) are those who never smoked cigarettes in 1982-84 (1,047 males and 3,304 females). Persons who never smoked (NS) are those who never smoked cigarettes, cigars, and/or pipes in either 1971-74 or 1982-84 (614 males and 3,213 females).

NHANES I collected extensive 1971-74 dietary data through personal interview [11]. These included 24-hour dietary recall data (all foods consumed during the midnight to midnight period preceding the interview) and 3-month food frequency data (frequency of food intake for the preceding three months). The content of each food consumed was determined by NCHS using the nutritive values of food items appearing in the U.S. Department of

Agriculture Handbook No. 8. These values were summed to yield total dietary intake. Food frequency data for several major foods were collected in the original 1971-74 examination and in the 1982-84 follow-up interview.

Cox proportional hazards models have been analyzed for subgroups defined by sex, spousal smoking history, and other selected variables for persons who never smoked cigarettes and for persons who never smoked. This has been done for all causes of death, lung cancer (ICD9 162), all cancers (ICD9 140-208), and all cardiovascular diseases (ICD9 390-459). The sample weights associated with the oversampling of certain NHANES I subjects have not been used in our analysis. The Cox proportional hazards linear model makes it possible to investigate the relation of the spousal smoking to mortality while controlling for eleven potentially confounding variables [13,14]. The eleven variables and ordered subgroups within each variable (in parentheses) are as follows: spousal cigarette smoking history (yes, no), age (25 to 74 years), sex (male, female), race (white, nonwhite), history of serious diseases (no, yes), education (0-8, 9-11, 12, 12+ years), recreational exercise (little or no, moderate, much), alcohol consumption (never, <1x/mo, 1-4x/mo, 2+x/wk), body mass index, calories (<1000, 1000-1499, 1500-1999, 2000+), fat (<40, 40-59, 60-79, 80-99, 100+mg), serum cholesterol (<200, 200-239, 240+mg/dl), dietary vitamin A (<1000, 1000-2999, 3000-4999, 5000+IU), and vitamin C index (<50mg, 50+mg & no reg supps, 50+mg & reg supps).

RESULTS

Table 1 shows the basic characteristics of 1,047 men and 3,304 women who never smoked cigarettes as a function of spousal cigarette smoking history. There are some substantial differences for men but only minor differences for women.

To examine the relationship of ETS smoking to mortality, analysis has been done using the Cox proportional hazards linear model to fit the binary dependent variable of mortality at the end of the follow-up period to eleven key independent variables. The independent variables included are those used in our previous analysis of vitamin C intake and mortality [10,11]. Table 2 shows results in pairs for males who never smoked cigarettes and for males who never smoked (never smoked cigarettes, cigars, or pipes). Additional results are shown married persons because both spouses are alive at the time of death of one spouse and possibly the spousal smoking histories are more accurate. Each pair of results shows the relative risk (RR) and 95% confidence interval (CI) comparing yes and no exposure to spousal cigarette smoking. The first of each pair includes only the variables of age, sex,

and spousal smoking. The second of each pair includes age, sex, spousal smoking, and eleven potentially confounding variables described above. Also shown are results for the relative risk of active smoking, comparing ever and never cigarette smokers within the entire cohort.

Table 3 shows results for females who never smoked cigarettes and who never smoked and Table 4 shows results for both sexes combined. The relative risks for all causes for men and women who never smoked are probably those that can be most directly compared with the results of other prospective studies. The confounding variables have almost no effect on the RR in any. The fully adjusted RR for all causes is 1.22 (0.79-1.88) for men who never smoked, 0.94 (0.80-1.11) for women who never smoked, and 0.96 (0.82-1.12) for both sexes combined. None of these or other results in Tables 2-4 come close to showing a statistically significant relationship for any cause of death.

To demonstrate the phenomenon of statistical fluctuation, RR (fully adjusted) = 1.59 (0.93-2.73) for the effect of passive smoking on cardiovascular disease among men who never smoked. This RR is "greater" than the RR (fully adjusted) = 1.25 (1.05-1.48) for the effect of ever versus never active smoking on cardiovascular disease. A second demonstration is RR = 0.48 (0.14-1.62) for the effect of passive smoking on cancer among men who never smoked. The magnitude of RR in both cases makes no etiologic sense at all and points out the dangers of assigning too much importance to RRs that are not significantly different than 1.00. Obviously, it is possible to construct additional models, but we have presented results from several reasonable models and they consistently support no significant relation between spousal cigarette smoking and mortality among persons who never smoked.

Because cigarette smoking histories on most of the subjects were not obtained until the 1982-84 follow-up interview, there is concern about the accuracy of results involving smoking variables in this cohort. However, it has been demonstrated previously that the conventional relationships between active smoking and mortality are reproduced quite well in this cohort using the retrospectively obtained smoking histories, that in many cases come from proxy respondents [15] . Another consideration is consistency of smoking histories as reported in 1971-74 and 1982-84 for those persons who supplied information at both times. A special analysis has been made of 688 spouse pairs where both the husband and wife are included in the NHEFS cohort. Table 5 shows that among 171 females who never smoked cigarettes in 1971-74, 164 (95.9%) reported never smoking cigarettes in 1982-84. Among 67 females who never smoked cigarettes and had a spouse who never smoked as of 1971-74, 60 (89.5%) reportedly had a spouse who never smoked as of 1982-84. Additional comparisons are shown in Table

5. Thus, there are classification errors on the order to 5-10% with regard to active and passive smoking in this cohort. Somewhat similar findings have been reported previously [16] . These classification errors must be kept in mind when assessing the RRs close to 1.0 reported previously for this cohort.

DISCUSSION

NHEFS was a detailed national epidemiologic study with important, although limited, data on spousal cigarette smoking. This study shows no relation between spousal cigarette smoking in males or females who never smoked, either before or after adjustment for 11 potential confounding variables. The statistical power of this study is limited, especially for males, but is strong enough to exclude any increases in total mortality greater than about 12% for females and both sexes combined. It is not possible to rule out a very weak relationship between ETS and mortality, especially for individual causes of death. However, the lack of any significant associations in this study provides no support for a causal relationship.

Obviously, this is only an observational study and not a randomized controlled trial. This study did not make a detailed assessment of exposure to passive smoke but did ask a key question about spousal cigarette exposure, that is similar to questions asked in other ETS studies. This study has the advantage of being a prospective study that has data on all causes of death and that can be independently analyzed. Additional research is required before it can be concluded that there is a causal relationship between ETS and mortality.

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Table 1. Key demographic characteristics and nutrient intake for NHEFS males who never smoked cigarettes and females who never smoked cigarettes as a function of spousal cigarette smoking history.

<u>1971-74</u> <u>characteristic</u>	<u>Spousal cigarette smoking history</u>			
	<u>Males</u>		<u>Females</u>	
	<u>Ever</u>	<u>Never</u>	<u>Ever</u>	<u>Never</u>
Number of subjects	223	824	2,022	1,282
Age (mean in years)	52	56	51	50
(% \geq 65 years)	33	49	34	35
Race (% white)	83	84	82	84
Marital status (% married)	87	81	71	67
Education (% \geq 12 years)	60	48	51	59
Height (mean in inches)	68	68	63	63
Weight (mean in pounds)	179	170	150	147
History of serious diseases (% yes)	7	11	10	8
Cigarette smoking history (% ever)	6	6	2	1
Alcohol consumption (% never)	13	37	47	49
Recreational exercise (% much)	22	23	12	13
Other physical activity (% much)	52	42	43	41
Calories (mean)	2,295	2,015	1,407	1,470
Fat (mean in gm)	98	81	57	58
Serum cholesterol (mean, mg/100 ml)	222	218	225	223
Dietary vitamin A (mean in IU)	5,764	5,617	4,792	5,019
Dietary vitamin C (mean in mg)	89	96	78	91
Vitamin supplement use (% regular)	16	19	23	27

1971-87 deaths

57

294

377

250

Table 2. 1971-87 NHEFS cohort males who never smoked cigarettes (NSC) and who never smoked (NS) analyzed by spousal cigarette smoking history as determined in 1982-84 for selected causes of death. Relative risk of death (RR) and 95% confidence interval (CI) are determined for males by yes versus no spousal cigarette smoking. Cox proportional hazards model was used to adjust for age alone and for age and 11 potential confounding variables (race, disease history, exercise, education, alcohol, body mass index, calories, fat, serum cholesterol, dietary vitamin A, and vitamin C index). * means no results shown because < 5 lung cancer deaths.

Group and adjustment variables	No. of males	No. of deaths	Relative risk (RR and 95% CI) by cause of death			
			All causes	All CVD	All cancer	Lung cancer
<u>All males who never smoked cigarettes</u>						
Age only	1,047	351	0.94 (0.71-1.25)	0.99 (0.68-1.46)	0.97 (0.53-1.78)	*
Age & 11 var	1,035	348	1.02 (0.76-1.38)	1.08 (0.72-1.60)	0.93 (0.50-1.73)	*
<u>All males who never smoked</u>						
Age only	614	197	1.11 (0.74-1.66)	1.40 (0.85-2.30)	0.53 (0.16-1.73)	*
Age & 11 var	609	196	1.22 (0.79-1.88)	1.59 (0.93-2.73)	0.48 (0.14-1.62)	*
<u>Married males who never smoked cigarettes</u>						
Age only	860	267	0.94 (0.68-1.30)	0.95 (0.61-1.47)	1.02 (0.54-1.92)	*
Age & 11 var	851	265	1.02 (0.73-1.43)	1.05 (0.66-1.66)	0.97 (0.50-1.87)	*
<u>Married males who never smoked</u>						
Age only	506	155	1.02 (0.64-1.62)	1.27 (0.71-2.26)	0.62 (0.19-2.06)	*
Age & 11 var	501	154	1.08 (0.66-1.78)	1.40 (0.75-2.63)	0.58 (0.17-1.98)	*
<u>All males who ever/never smoked cigarettes (using 1971-74 & 1982-84 cigarette smoking info)</u>						
Age only	3,969	1,411	1.40 (1.24-1.58)	1.32 (1.12-1.55)	1.47 (1.14-1.91)	10.16 (3.72-27.7)
Age & 11 var	3,923	1,392	1.31 (1.16-1.48)	1.25 (1.05-1.48)	1.35 (1.03-1.76)	8.83 (3.22-24.2)

Table 3. 1971-87 NHEFS cohort females who never smoked cigarettes (NSC) and who never smoked (NS) analyzed by spousal cigarette smoking history as determined in 1982-84 for selected causes of death. Relative risk of death (RR) and 95% confidence interval (CI) are determined for females by Yes versus no spousal cigarette smoking. Cox proportional hazards linear model was used to adjust for age alone and for age and 11 potential confounding variables.

Group and adjustment variables	No. of females	No. of deaths	Relative risk (RR and 95% CI) by cause of death			
			All causes	All CVD	All cancer	Lung cancer
<u>All females who never smoked cigarettes</u>						
Age only	3,304	627	0.94 (0.80-1.10)	1.04 (0.83-1.30)	0.90 (0.64-1.26)	1.25 (0.31-5.01)
Age & 11 var	3,278	622	0.93 (0.79-1.09)	1.02 (0.82-1.28)	0.91 (0.65-1.29)	1.13 (0.27-4.77)
<u>All females who never smoked</u>						
Age only	3,213	610	0.95 (0.81-1.12)	1.06 (0.85-1.33)	0.92 (0.65-1.30)	1.27 (0.32-5.08)
Age & 11 var	3,188	606	0.94 (0.80-1.11)	1.05 (0.83-1.31)	0.92 (0.65-1.30)	1.14 (0.27-4.80)
<u>Married females who never smoked cigarettes</u>						
Age only	2,299	331	0.82 (0.66-1.02)	0.95 (0.71-1.28)	0.73 (0.47-1.13)	0.57 (0.08-4.03)
Age & 11 var	2,285	329	0.84 (0.67-1.05)	0.99 (0.73-1.34)	0.75 (0.48-1.16)	0.57 (0.07-4.74)
<u>Married females who never smoked</u>						
Age only	2,237	323	0.82 (0.66-1.02)	0.96 (0.71-1.30)	0.74 (0.48-1.14)	0.58 (0.08-4.09)
Age & 11 var	2,223	321	0.84 (0.67-1.06)	1.01 (0.74-1.37)	0.75 (0.48-1.17)	0.58 (0.07-4.80)
<u>All females who ever/never smoked cigarettes (using 1971-74 & 1982-84 cigarette smoking info</u>						
Age only	6,025	1,085	1.43 (1.26-1.62)	1.35 (1.13-1.62)	1.43 (1.10-1.85)	5.45 (2.55-11.65)
Age & 11 v	5,977	1,077	1.50 (1.31-1.71)	1.45 (1.21-1.76)	1.37 (1.04-1.81)	5.24 (2.38-11.55)

Table 4. 1971-87 NHEFS cohort subjects who never smoked cigarettes and who never smoked analyzed by spousal cigarette smoking history as determined in 1982-84 for selected causes of death. Relative risk of death (RR) and 95% confidence interval (CI) are determined for females by yes versus no spousal cigarette smoking. Cox proportional hazards linear model was used to adjust for age and sex alone and for age, sex, and 11 potential confounding variables.

Group and adjustment variables	No. of subjects	No. of deaths	Relative risk (RR and 95% CI) by cause of death			
			All causes	All CVD	All cancer	Lung cancer
<u>All subjects who never smoked cigarettes</u>						
Age & sex	4,351	978	0.93 (0.81-1.07)	1.03 (0.85-1.24)	0.92 (0.68-1.23)	2.06 (0.58-7.28)
Age,sex,11 v	4,313	970	0.94 (0.82-1.08)	1.04 (0.85-1.26)	0.92 (0.68-1.24)	1.86 (0.52-6.73)
<u>All subjects who never smoked</u>						
Age & sex	3,827	807	0.97 (0.83-1.13)	1.11 (0.90-1.36)	0.88 (0.64-1.21)	1.19 (0.31-4.51)
Age,sex,11 v	3,797	802	0.96 (0.82-1.12)	1.10 (0.89-1.36)	0.87 (0.63-1.20)	1.00 (0.25-4.06)
<u>Married subjects who never smoked</u>						
Age & sex	2,743	478	0.85 (0.69-1.04)	1.02 (0.77-1.34)	0.72 (0.48-1.08)	0.52 (0.08-3.47)
Age,sex,11 v	2,724	475	0.88 (0.71-1.08)	1.07 (0.81-1.41)	0.74 (0.49-1.11)	0.46 (0.06-3.81)
<u>All subjects who ever/never smoked cigarettes (using 1971-74 & 1982-84 cigarette smoking info)</u>						
Age & sex	9,994	2,496	1.41 (1.29-1.54)	1.32 (1.17-1.50)	1.46 (1.21-1.75)	7.09 (3.96-12.69)
Age,sex,11 v	9,990	2,469	1.38 (0.26-1.51)	1.33 (1.17-1.51)	1.35 (1.11-1.63)	6.49 (3.60-11.73)

Table 5. Percentage distribution of females who never smoked cigarettes in 1971-74 and/or 1982-84 among all NHEFS spouse pairs classified by 1971-74 and 1982-84 personal smoking status and spouses of these females classified by 1971-74 and 1982-84 smoking status.

Females who never smoked cigarettes in 1971-74	1982-84 cigarette smoking status		Total	Not ascertained
	Never	Ever		
95.9 (164)	4.1 (7)	100.0 (171)	(9)	
Females who never smoked cigarettes in 1982-84	1971-74 smoking status		Total	Not ascertained
	Never	Ever		
93.2 (164)	6.8 (12)	100.0 (176)	(515)	
1971-74 smoking status of females who never smoked cigarettes	1982-84 spousal cigarette smoking status			Total
	Never cigarettes	Ever cigarettes	Not ascertained	
Never smoked	89.5 (60)	9.0 (6)	1.5 (1)	(67)
Former cigarettes	7.5 (6)	83.7 (67)	8.8 (8)	(80)
Current cigarettes	2.6 (2)	89.6 (69)	7.8 (6)	(77)
Cigars and/or pipes	90.5 (19)	9.5 (2)	0.0 (0)	(21)
Not ascertained	39.5 (175)	59.8 (265)	0.7 (3)	(443)
Total	38.9 (262)	59.4 (409)	2.5 (17)	(688)