Exhibit 226

Cancer Mortality Among Women in the Russian Printing Industry

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Background *This study evaluates cancer mortality among women employed in two large printing plants in Moscow.*

Methods *A total of 3,473 women who were actively employed as of December 31, 1978, with a minimum of 2 years employment were followed from 1 January 1979 to 31 December 1993. There were 47,791 person-years observed, with only 51 women lost to follow-up (1.5%). Standardized mortality ratios (SMRs) were calculated using the population of Moscow to generate expected numbers. Analyses by job (compositors, press operators, and bookbinders), age hired, latency, and duration of employment were conducted.*

Results *Among women employed in the two printing plants, there was a significant excess of esophageal cancer, based on seven deaths (expected = 2.7, SMR = 2.7, 95% CI = 1.1–5.4). Four of the seven esophageal cancer deaths occurred among bookbinders (expected = 1.0, SMR = 4.1, 95% CI = 1.1–10.4), all among workers hired before 1957 (expected = 0.6, SMR = 7.1, 95% CI = 1.9–18.3), the last year benzene was used in bookbinding. Ovarian cancer was also significantly elevated among bookbinders (12 observed, 4.2 expected, SMR = 2.9, 95% CI = 1.5–5.0), which, along with one death from mesothelioma of the abdomen, might be related to the use of asbestos-contaminated talc fillers in paper. Press operators had significantly elevated mortality from stomach cancer (observed = 9, expected = 4.1, SMR = 2.2, 95% CI = 1.0–4.2) and, based on two deaths each, melanoma and bladder cancer.*

Conclusions *Women in this printing industry cohort experienced excess mortality of cancer of the esophagus and stomach, with suggested increases of melanoma and bladder cancer. Further follow-up of this cohort, which would allow more in-depth analysis of rare cancer sites, latency, and duration of employment, is warranted. Gender comparisons within the cohort should also be conducted to clarify the role of occupational and lifestyle factors in the etiology of cancer among workers in the printing industry.* Am. J. Ind. Med. 36:166–171, 1999. *Published 1999 Wiley-Liss, Inc.*[†]

KEY WORDS: printing; women; cancer; occupation; bladder; melanoma; ovary; esophagus

INTRODUCTION

The printing industry involves many occupational exposures, including lead, organic and inorganic pigments, paper dust, adhesives, polycyclic aromatic hydrocarbons, acrylates, and solvents such as benzene, toluene, xylene, ethylene glycol, and carbon tetrachloride [IARC, 1996]. In 1996, IARC classified occupational exposures in printing processes as possibly carcinogenic to humans based mainly on

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reported excesses of bladder and lung cancer [IARC, 1996]. The evidence was weaker for the associations between printing processes and leukemia and cancers of the oropharynx and kidney. Associations may be difficult to detect and interpret because of the heterogeneous processes and exposures in the printing industry.

The available epidemiologic data on cancer and printing processes are based primarily on studies of men. There were few or no women in the industry-based cohorts or case-control studies reviewed by the IARC. There was some information on women, however, from occupational mortality surveys or record linkage studies. Among women employed in the printing industry, significant associations have been observed for melanoma [Malker and Gemne, 1987] and cancers of the lung [Malker and Gemne, 1987; Olsen and Jensen, 1987], bladder [Malker and Gemne, 1987], kidney [Malker and Gemne, 1987], skin [Pukkala, 1995], brain [Cocco et al., 1998], breast [Aronson and Howe, 1994; Pukkala, 1995], ovary [Pukkala, 1995], and cervix [Malker and Gemne, 1987], although many of these associations were based on small numbers.

We conducted a study to evaluate mortality among workers at the two largest printing plants in Moscow, which specialize in book and magazine production. This report describes the results for women, who comprise approximately 70% of the employees of these two facilities.

METHODS

Cohort Definition

All current employees of the two largest printing plants in Moscow as of December 31, 1978, were identified from personnel records. Women with a minimum of 2 years of employment were included in the study. For each subject information was abstracted on year of birth, date hired, employment status (i.e., active or terminated as of December 31, 1993), employment termination date, and process for all jobs held. The jobs were classified into four groups: compositors, press operators, bookbinders, and other, which included jobs thought generally to be without hazardous exposures, such as proofreaders. All employees were assumed to be white.

Cancer Mortality Follow-up

Cohort members were followed from January 1, 1979, to December 31, 1993. The workers' current vital status and addresses were obtained from the Moscow Central Address Bureau. Death certificates for all deceased subjects were obtained from the Moscow Vital Statistics Department. Underlying cause of death was coded according to the Ninth Revision of the International Classification of Disease (ICD-9) [WHO, 1992].

Analysis

The numbers of expected deaths were calculated based on gender, age (5-year age groups), and calendar time (5-year groups) specific mortality rates for the Moscow general population applied to the cohort's person-years of follow-up. Annual mortality rates for all causes, all cancers combined, selected individual cancers, cardiovascular disease, and external causes of death (accidents and violence) 1979–1993 were supplied by the Moscow State Statistical Bureau. Rates for some cancers (liver: ICD 155; pancreas: ICD 157; melanoma: ICD 172; ovary: ICD 183; bladder: ICD 188; kidney: ICD 189; brain: ICD 191–192; leukemia: ICD 204–208) were available for 1992 only and were applied to the other years in the 1979–1993 period.

Using software developed at the National Cancer Institute (O/E) based on methods developed by Monson [1974], standardized mortality ratios (SMRs) were calculated by comparing the observed number of deaths to the expected number. The 95% confidence intervals (95% CI), based on the Poisson distribution, were calculated according to the method described by Breslow and Day [1987]. Analyses by primary job (compositors, press operators, and bookbinders), age hired, latency, and duration of employment were conducted.

Exposure Information

The two printing plants in this study produced books and magazines and involved platemaking (compositors), letterpress and lithography printing, and binding, including blockmaking, casemaking, and casing-in processes. Platemaking techniques have changed over time from composing by manual typesetters to monotypists, linotypists, and stereotypists. Compositors were exposed to lead dust and fumes. The limited area air sampling data that are available show that levels were much higher historically than the current threshold limit values, with levels dropping over time (Table I). Press operators worked on rotary and flat-bed letterpress machines and on offset printing machines. The operators were exposed to ink mists, paper dusts, and solvents. The ink mists contained benzo(a)pyrene, other polycyclic aromatic hydrocarbons, benzidine-based dyes, and carbon black. Russian paper contains kaolin and talc as filler pigments, so printing workers probably had exposure to asbestos, which contaminated commercial talc. The amounts of fillers in paper used in book production, either in letterpress operations (320–370 kg/ton) or for offset printing (120–190 kg/ton), was much greater than that used in newsprint (2.5–13.4 kg/ton). Benzene was used in the bookbinding processes in these plants until 1958.

TABLE I. Area Air Concentrations (mg/m^3) by Process and Calendar Year in Moscow Printing Plants

Process	Agent	Calendar year			Current TLV*
Composing rooms	**Lead**	**1925–1927**	**1974**	**1989**	**0.01**
Type metal	Fumes	0.37–0.76	0.010–0.030	0.004–0.009	
Foundry	Fumes	0.05–0.60		0.008–0.010	
Manual typesetting	Dust	0.09–0.15	0.006–0.012	0.001–0.011	
Monotyping	Fumes		0.006–0.048	0.002–0.004	
Linotyping	Fumes		0.008–0.012	0.008–0.015	
Press rooms			**1979**		
	Ink mist		22.1		5
	Paper dust				
	At press		28.0		6
	1.5m from press		17.6		
Bookbinding			**1979**		
	Paper dust		0.05–18.1		6

*TLV: threshold limit value.

TABLE II. Number of Women, Person-Years, and Deaths Among Moscow Printing Plant Employees, by Primary Process of Employment

	Number of women employees	Person-years	Number of deaths
Total	3,473	47,791	573
Composing rooms	423	6,041	61
Press operators	524	7,303	96
Reel-fed rotary letterpress	290	4,903	43
Flat-bed letterpress	171	2,396	35
Offset lithography	63	814	18
Bookbinders	1,271	17,174	242
Other (e.g., proofreaders)	1,255	17,273	174

RESULTS

The cohort consisted of 3,473 women who accumulated 47,791 person-years of follow-up as of December 31, 1993. A total of 2,849 (82%) women were alive, 573 (16%) were deceased, and 51 (1.5%) had unknown vital status. Cause of death was available for 568 of the deaths. Over 94% (n = 3,260) of the cohort held only one job, with almost all of the subjects with more than one job having additional employment in bookbinding. Because of this high level of employment stability, subjects were classified and results were presented according to the primary process of employment only. The characteristics of the cohort by primary process are presented in Table II.

Among the total cohort, 703.3 deaths were expected, yielding an SMR of 0.8 (95% CI = 0.8–0.9) (Table III). Overall, there was a significant excess of esophageal cancer, based on seven deaths (expected = 2.7, SMR = 2.7, 95% CI = 1.1–5.4). There were no other significant excesses or deficits among the total cohort nor among compositors. Press operators had significantly elevated mortality from stomach cancer (observed = 9, expected = 4.1, SMR = 2.2, 95% CI = 1.0–4.2) and, based on two deaths each, melanoma and bladder cancer. Analyses by type of press were limited by small numbers.

Four of the cohort's seven esophageal cancer deaths occurred among bookbinders (expected = 1.0, SMR = 4.1, 95% CI = 1.1–10.4), all among workers hired before 1958 (expected = 0.6, SMR = 7.1, 95% CI = 1.9–18.3), when use of benzene in bookbinding was discontinued. The three deaths each from kidney cancer and leukemia also occurred exclusively among women bookbinders hired before 1958, yielding nonsignificantly increased SMRs of 2.5 and 2.6, respectively. Ovarian cancer was also significantly elevated among bookbinders (observed = 12, expected = 4.2, SMR = 2.9, 95% CI = 1.5–5.0), with greater risk observed among women hired after 1957 (observed = 5, expected = 1.2, SMR = 4.8, 95% CI = 1.5–11.1) than among women hired before 1958 (observed = 7, expected = 3.7, SMR = 1.9, 95% CI = 0.8–3.9). Women employed 15 or more years (observed = 7, expected = 2.0, SMR = 3.5, 95% CI = 1.4–7.1) had greater risk than women employed 2–14 years (observed = 5, expected = 2.7, SMR = 1.9, 95% CI = 0.6–4.3).

One death from mesothelioma of the abdomen occurred among the cohort. The case worked at the printing plant from age 18 to the date of her death.

Significant deficits in total mortality (observed = 174, expected = 287.4, SMR = 0.6, 95% CI = 0.5–0.7) and in

TABLE III. Number of Observed and Expected Deaths, SMR,[a] and 95% CI for Women Employed in Moscow Printing Plants by Primary Process of Employment

Cause of death (ICD-9)	All printing plant employees				Compositors				Press operators				Bookbinders			
	Obs	Exp	SMR	95% CI	Obs	Exp	SMR	95% CI	Obs	Exp	SMR	95% CI	Obs	Exp	SMR	95% CI
All causes (001–999)	573	703.3	0.8	0.8–0.9	61	70.3	0.9	0.7–1.1	96	86.8	1.1	0.9–1.4	242	258.8	0.9	0.8–1.1
Malignant neoplasms (140–208)	158	169.8	0.9	0.8–1.1	16	18.3	0.9	0.5–1.4	32	24.0	1.3	0.9–1.9	74	62.8	1.2	0.9–1.5
Buccal cavity, pharynx (140–149)	1	1.4			1	0.2			0	0.2			0	0.5		
Esophagus (150)	7	2.7	2.6	1.1–5.4	1	0.3			1	0.3			4	1.0	4.1	1.0–10.4
Stomach (151)	29	31.3	0.9	0.6–1.3	3	3.2	0.9	0.2–2.7	9	4.1	2.2	1.0–4.2	12	11.7	1.0	0.5–1.8
Colon (153)	17	16.6	1.0	0.6–1.7	2	1.7	1.2	0.1–4.2	2	2.2	0.9	0.1–3.1	8	6.1	1.3	0.6–2.6
Rectum (154)	12	10.2	1.2	0.6–2.1	1	1.1			0	1.4			5	3.8	1.3	0.4–3.1
Liver (155)[b]	3	3.3	0.9	0.2–2.7	1	0.3			0	0.4			1	1.2		
Pancreas (157)[b]	6	7.2	0.8	0.3–1.8	0	0.8			2	1.0	2.0	0.3–7.4	3	2.7	1.1	0.2–3.3
Larynx (161)	1	0.4			0	—			0	—			0	—		
Lung (162)	9	11.7	0.8	0.4–1.5	0	1.2			3	1.6	1.9	0.4–5.3	3	4.4	0.7	0.1–2.0
Melanoma (172)[b]	2	1.5	1.3	0.2–4.8	0	0.2			2	0.2	8.7	1.1–31.3	0	0.6		
Breast (174)	19	27.1	0.7	0.4–1.1	1	3.1			3	4.2	0.7	0.2–2.1	10	9.9	1.0	0.5–1.9
Cervix uteri (180)	6	6.1	1.0	0.4–2.2	1	0.7			1	0.9			2	2.2	0.9	0.1–3.3
Corpus uteri (182)	5	6.7	0.8	0.2–1.8	1	0.8			2	1.0	2.0	0.2–7.2	0	2.3		
Ovary (183)[b]	13	11.3	1.2	0.6–2.0	0	1.3			1	1.7			12	4.2	2.9	1.5–5.0
Bladder (188)[b]	3	1.4	2.2	0.5–6.3	0	0.1			2	0.2	12.5	1.5–45.1	1	0.5		
Kidney (189)[b]	6	4.2	1.4	0.5–3.1	2	0.5	4.4	0.5–15.7	1	0.6			3	1.6	1.9	0.4–5.6
Brain, nervous system (191–192)[b]	4	3.1	1.4	0.5–3.1	0	0.4			1	0.5			3	1.2	2.6	0.5–4.6
Leukemia (204–208)	4	5.1	0.8	0.2–2.0	0	0.6			0	0.7			3	1.9	1.6	0.3–4.6
Cardiovascular diseases (390–459)	384	424.1	0.9	0.8–1.0	42	40.0	1.1	0.8–1.4	53	47.8	1.1	0.8–1.5	134	156.0	0.9	0.7–1.0
External causes (900–999)	19	30.4	0.6	0.4–1.0	2	3.5	0.6	0.1–2.1	2	4.2	0.5	0.1–1.7	5	11.0	0.5	0.2–1.1

[a]Standardized mortality ratios (SMRs) are not presented if the observed number of deaths is less than two.
[b]Comparison Moscow rates for these cancers were available for 1992 only and were applied to the other years in the 1979–1993 period.

cancer mortality (observed = 36, expected = 64.7, SMR = 0.6, 95% CI = 0.4–0.8) were reported for the 1,255 women in clerical and other jobs generally thought to have little potential for hazardous exposures.

DISCUSSION

In the 1996 IARC review of cancer associated with printing processes, there were no results reported for women in industry-based cohort studies [IARC, 1996]. The present investigation of almost 3,500 women employed in two printing plants in Moscow provides unique information on the possible cancer risks among women in this industry.

We observed an excess of esophageal cancer among the women in this cohort, which was consistent with a similar excess among male magazine printing workers reported by Luce et al. [1997]. The esophageal cancer excess appeared greater among press operators in the study by Luce et al. [1997], whereas the excess was greater among bookbinders in the Moscow workers, although both observations were based on small numbers. Bookbinders' exposures included solvents, adhesives, and paper dust. The esophageal cancer excess was greatest among Moscow women hired before 1957, the last year benzene was used in the bookbinding operation. A nonsignificant twofold risk of esophageal cancer was reported in a study of a large cohort of

benzene-exposed workers in China [Yin et al., 1996], but risk did not increase with cumulative exposure to benzene [Hayes et al., 1996]. The Moscow bookbinders probably also had some exposure to asbestos, a likely contaminant of the talc fillers used in paper. There are a few reports linking asbestos to esophageal cancer [Ward et al., 1994; Kanarek et al., 1980], but the evidence is limited, with most asbestos-exposed cohorts not showing an esophageal cancer excess [Monson, 1996]. Esophageal cancer has also been linked to exposure to polycyclic aromatic hydrocarbons [Nadon et al., 1995; Norell et al., 1983; Gustavsson et al., 1993], textile dyeing and finishing [Dubrow and Gute, 1988], and metal dust exposure, especially beryllium [Yu et al., 1988]. The strongest risk factors for esophageal cancer, however, are alcohol consumption and use of tobacco [Munoz and Day, 1996]. It is not known if the cohort had different patterns of alcohol and tobacco consumption than the Moscow general population, but cancers of the buccal cavity, liver, and lung, sites associated with these exposures were not elevated among women employees in the printing plants.

Ovarian cancer was significantly elevated among the Moscow bookbinders. The relative risk increased with duration of employment. Pukkala [1995] also reported an excess of ovarian cancer among Finnish women employed as printers. The magnitude of the ovarian cancer excess was similar in the two studies (Moscow: SMR = 2.9; Finland: SMR = 2.2). The excess may have been due to the possible exposure of printing plant employees to asbestos, which has been linked to ovarian cancer in studies of gas mask assemblers and other occupations [Wignall and Fox, 1982; Acheson et al., 1982; Newhouse et al., 1985; Edelman, 1992]. The presence of asbestos in the printing plant is further suggested by the occurrence of a death from mesothelioma of the abdomen in a woman who worked at the plant from age 18 to the date of her death, effectively ruling out the possibility that her asbestos exposure came from some other occupational source.

Press operators had significantly elevated mortality from stomach cancer, which has been reported previously among newspaper printing workers in London [Greenberg, 1972] and rotogravure workers in Sweden [Svensson et al., 1990]. Based on only two deaths each, the press operators also had excesses of melanoma and bladder cancer. Excess mortality from melanoma was also reported among lithographers in Denmark, based on five cases [Nielsen et al., 1996], and in a meta-analysis of nine studies, based on 23 cases [Dubrow, 1986]. The bladder cancer excess is consistent with numerous studies that were the primary basis for the IARC classification of possible carcinogenicity to humans of occupational exposures in printing processes [IARC, 1996].

The women in the Moscow printing plants did not have significant excesses of leukemia or cancers of the lung, oropharynx, or kidney, cancers cited as associated with printing processes in the IARC evaluation [1996]. Twenty years elapsed from the cessation of benzene exposure in 1958 and the start of follow-up in 1979, a longer time period than the expected latency for most leukemias. Some nonsignificant excesses of the a priori suspect cancer sites were observed. For example, a nonsignificant excess of kidney cancer (observed = 2, expected = 0.5, SMR = 4.4, 95% CI = 0.5–15.7) occurred among compositors, who had exposure to lead and solvents. Lead accumulates in the kidney and has been linked to both human and animal kidney cancer [IARC, 1987; Steenland et al., 1992]. Solvents, especially dry cleaning chemicals, have been linked to kidney cancer [McLaughlin et al., 1996]. Dosemeci et al. [1999] report gender differences in the risk of kidney cancer among solvent-exposed workers, with greater risk observed among the women.

The present study has several limitations, including the reliance on mortality data instead of incidence, the lack of Moscow mortality rates for several cancer sites during many of the calendar years under study, and the lack of detailed exposure information. Also, chance cannot be ruled out as a possible explanation for study findings, particularly those based on small numbers.

Further follow-up of this cohort, which would allow more in-depth analysis of rare cancer sites, latency, and duration of employment, is warranted. Sites of special interest include melanoma, leukemia, and cancers of the esophagus, ovary, and stomach. The large number of women in this cohort provides a unique opportunity to evaluate the role of printing process exposures in the etiology of ovarian cancer and other tumors among women. Gender comparisons within the cohort should also be conducted to clarify the role of occupational and lifestyle factors in the etiology of cancer among workers in the printing industry.

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