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bone lesions presented with mild to marked thrombocytopenia ($30-119 \times 10^9/\text{litre}$). Bone marrow aspirates in 6 patients permitted exclusion of disturbed platelet formation or osteomyelofibrosis/sclerosis, but in 12 of them splenomegaly was found. Except for slight reticulocytosis in 8 and leucopenia in 5 of the workers, other haematological tests were negative. The reduction of the number of leucocytes and platelets as well as reticulocytosis appeared to be attributable to splenomegaly, but further studies on the nature of thrombocytopenia were thought necessary, and it was suggested by the authors that a decrease in the number of platelets might serve as an early and easily detectable symptom. The high prevalence of thrombocytopenia (as determined by phase-contrast microscopy) found later on detailed analysis of platelet function and other parameters of blood coagulation in the total cohort of PVC production (and also fabrication) workers from this plant strengthened this suggestion (Bachner et al. 1974a, b, 1975a, b, 1976; Selirt-Bachner and Erzel 1977). Wegman (1975) also commented upon abnormal platelet counts in 13 of 37 PVC fabricating workers who had only handled PVC powder which, however, might have contained substantial amounts of residual monomer. In contrast, Lillis et al. (1975) detected thrombocytopenia in only 1 of 354 polymerization workers, but an electronic cell counter was used for platelet counts (personal communication).

According to Selirt-Bachner and Erzel (1977), the mean platelet count in a cohort of 132 PVC polymerization (and processing) workers was significantly lower than that in a nonexposed control group of 150 healthy men. As could be expected, Bachner et al. (1975b) also demonstrated a positive correlation between the degree of thrombocytopenia and the prevalence of an enlargement of the spleen (palpable splenomegaly or spleen size determined by selective scintigraphy with ^{199}Hg -bromo-mercury-hydroxypropane-labelled red cells) in 70 PVC polymerization workers (see Table 19). It ap-

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Table 19. Prevalence of enlargement of the spleen^a among 70 PVC-polymerization workers in relation to increasing degrees of thrombocytopenia (Bachner et al. 1975a)

Group	No. of workers examined	Platelets ($\times 10^9/\text{litre}$)		Enlargement of the spleen
		Range	Mean	
A	14	> 130	168	3 (21%)
B	24	100-130	117	11 (46%)
C	25	70-99	87	19 (76%)
D	7	< 70	44	6 (86%)

^a As determined by palpation or by selective spleen scintigraphy.

pears, however, that the development of thrombocytopenia is not dependent on the presence of splenomegaly since we observed mild thrombocytopenia ($100-120 \times 10^9/\text{litre}$) in a small number of workers in whom spleen size was definitely within normal limits on selective spleen scintigraphy (Milzfleckenindex $< 4.5 \times 10^{-3}$ according to Fischer and Wolf 1963).

Thrombocytopenia was accompanied by abnormalities in platelet function tests. There was an increase in the number of large ($> 10 \mu\text{m}$) 'juvenile' platelets (increased

platelet spreading), enhanced response (platelet aggregation) to addition of ADP and collagen (Born test) and increased availability of phospholipid-containing platelet factor 3 (Bachner et al. 1975a). This pattern was thought to be compatible with the notion of an increased turnover rate due to derangement of microcirculation (CDIC) in liver and spleen and defective reticuloendothelial system (RES) clearance of activated clotting factors (Bachner et al. 1974b). Ward (1976) and Ward et al. (1976) suggested that thrombocytopenia could be construed as confirmatory evidence of an immune complex disorder. Heusemann and Stutte (1977a) noted unusual focal aggregation of platelets in klatsch preparations of spleen tissue and increased platelet pooling (platelets trapped within the subsinusoidal meshwork of pulp cords) in the red pulp of the spleen on electron microscopy as well as phagocytosis of thrombocytes by sinusoidal macrophages. Schaffner et al. (1976) found platelet thrombi in and around hepatic sinusoids in mice after exposure to VCM. A direct toxic action of VCM (or metabolites) on the bone marrow has not been demonstrated so far.

Although the pathogenesis of thrombocytopenia in VCM-induced disease is not fully understood, it seems at present most likely that it is caused by increased turnover and consumption of platelets within the abnormal vascular spaces of the liver and spleen. A similar type of consumption coagulopathy was described as complication of spontaneous haemangiosarcoma of the liver by Truell et al. (1973). A haemostatic defect more complex than mere pooling and destruction of platelets in the enlarged spleen has also been commented upon in the paper by Gerrits et al. (1974) in connection with splenomegaly of various noncirrhotic origin.

4.4.2 Central and Peripheral Nervous System

Miscellaneous nonspecific and somewhat indefinite symptoms have been described in connection with chronic inhalational exposure to VCM in PVC-production workers, such as dizziness, disorientation, blurring of vision and memory, headache, irritability, excessive fatigue and somnolence, sleep reversal or insomnia and other pseudoneurasthenic symptoms (Suchá et al. 1963, 1975; Schorrek 1969; Lilis et al. 1975 and others). This pre-narcotic syndrome was interpreted as a manifestation of a potentially reversible acute toxic encephalopathy. Its danger to the individual was thought to lie mainly in resultant inadequate reactions to critical situations (Schorrek 1969). However, Vale et al. (1976) reported that several individuals in a group of 95 comparatively young ex-workers, the majority of whom had no other symptoms, complained of fatigue, headache, listlessness and depression, with onset of symptoms having been delayed as long as 2 years after cessation of employment.

With reference to such 'pseudoneurasthenic complaints', which may be interpreted as the mildest degree of a toxic encephalopathy, Penin et al. (1975) examined a group of 21 autoclave cleaners at varying intervals after cessation of exposure, all of whom presented with other (cutaneous, angioneurotic, hepatic) manifestations of vinyl chloride disease. Clinical symptoms of a more or less distinct encephalopathy (including cerebellar ataxia in 4) were found in all but one of them. EEG recordings were normal in only five of these patients; in the others, paroxysmal, dysrhythmic or a so-called subvigil electroencephalogram was observed. Evidence of distal polyneuropathy, found in 19 patients, was attributed in the first place to an abnormal peripheral circ-

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lation with resultant hypoxic damage. The pathogenesis of a possibly VCM-induced encephalopathy is not clear. It would be conceivable that clinical and bioelectric alterations found in some patients, in whom portosystemic encephalopathy could be excluded, may have been due to toxic or hypoxic brain damage. However, no other convincing evidence has so far emerged to indicate that chronic irreversible cerebrotoxic damage may have resulted from prolonged exposure to VCM, notwithstanding the possibility of an induction of brain tumours.

4.4.3 Pulmonary Changes

The suspected development of nonmalignant pulmonary changes due to VCM and/or PVC dust exposure is still a matter of controversy. Soon after VCM was recognized as a potent carcinogen, three groups of employees ($n = 290, 250, 445$, respectively) from three large North American PVC-producing plants (A, B, C), characterized by different duration and levels of past environmental exposure to VCM as well as to PVC dust, were studied with respect to chest x-ray film abnormalities and pulmonary function defects as assessed by spirometry and determination of maximum expiratory flow volume (Miller 1975; Miller et al. 1975; Lillis et al. 1975, 1976, 1977). All cases with previous exposure to asbestos, silica or coal dust had been excluded in these studies. Unexpected linear, reticular and, less often, rounded opacities on chest x-ray films were found in about one-fifth of the two groups of employees from plants A (highest exposure) and B (22.7% and 18.8%, respectively), but in only 4.3% of those from plant C, with the lowest exposure level. The prevalence of these radiological abnormalities, for which no pathogenetic explanation was available, was found to be significantly increased with longer duration of VCM-PVC exposure (more than 10 years), but the prevalence of a positive history of smoking, although identical in both groups A and B, was also found to be significantly higher in workers with abnormal chest x-ray plates. The overall prevalence of a positive history of chronic bronchitis (British Medical Research Council criteria) was 20.4% in group A (highest exposure) and 16.0% in group B, although group B was significantly older. The somewhat higher prevalence of chronic bronchitis in workers with abnormal chest x-ray plates did not attain statistical significance.

On the other hand, age did not appear to be an important factor. Pulmonary function tests showed a strikingly high prevalence of obstructive changes, but since both smoking and age were related to changes in pulmonary function, it appeared difficult to isolate potential specific effects of occupational exposure to VCM and PVC dust. A restrictive pattern was found in 9.3% of group A and in only 2.3% of group B, although group A was significantly younger. In conclusion, this extensive study, including a total of 985 workers exposed in the past to VCM as well as PVC dust, may point to a potential multiple factor effect of smoking and VCM-PVC exposure. In this connection, it is of interest to note that according to a cohort study of mortality among VCM polymerization workers the SMRs for respiratory cancer as well as for 'other respiratory disease' were found to have been in excess of expected figures (156 and 176, respectively) (Marsteller et al. 1976).

Bronchopulmonary changes thought to be due to long-continued, intense exposure to PVC dust were observed by several authors (Parmeggiani and Sassi 1955; Brouillard

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1969; Szende et al. 1970; Vertkin and Mamontov 1970; Frongia et al. 1974; Darke 1976; Arnaud et al. 1978). Considerable exposure to PVC dust is the rule in the drying, bagging and storage areas of PVC-producing plants. Photographs contained in Karstad's paper (1976) give a general idea of the potential dust exposure. Measurements of the concentration of PVC dust at various sites of the bagging operations were reported as long ago as 1955 by Parmeggiani and Sassi. In 1969 Broussard mentioned the possibility of development of chronic bronchitis caused by the inhalation of PVC dust. The insoluble and inactive dust particles were thought to accumulate in the lungs blocking alveolar spaces and being taken up by alveolar cells. This could lead to elimination of these cells via lymph vessels to regional lymph nodes, with either enlargement of the hilar region or a micronodular aspect of interstitial pulmonary fibrosis without hilar lymph node enlargement but progressive respiratory insufficiency.

Szende et al. (1970) reported the case of a 31-year-old worker who presented with severe dyspnoea: a chest x-ray examination revealed diffuse micronodular pulmonary lesions. He had been engaged for only 1 year in shovelling PVC powder at a processing factory. Lung biopsy revealed moderate diffuse fibrosis and small focal granulomatous lesions containing ovoid or polygonal birefringent foreign material which could be eluted by treatment with a known solvent of PVC. Microscopic examination of PVC dust particles collected at the patient's place of work showed them to be morphologically identical with the particles found in the patient's lungs.

Another anecdotal case of pneumoconiosis after 23 years of employment in a PVC bagging area, with radiological evidence of diffuse micronodular infiltrates and granulomatous lesions found in a lung biopsy identical with those recorded by Szende et al., was published by Arnaud et al. in 1978. Histology of open lung biopsies in 1 of 14 VCM-exposed British workers, who complained of breathlessness, revealed focal alveolar wall thickening with macrophages in alveolar spaces and increased reticulin and collagen on electron microscopy (Darke 1976). Although chest x-ray appearances were normal and routine respiratory function tests showed only slightly impaired CO_2 diffusion in six individuals, perfusion and ventilation scans revealed strikingly abnormal pictures, including marked perfusion defects of upper lobes. Darke pointed out that some of the men worst affected had been engaged in the polymerization of 'plastisol', a very fine PVC powder with particle size around $0.5 \mu\text{m}$.

Selikoff (1976) called attention to results obtained by Frongia et al. (1974), who observed significant histopathological changes in the lungs of guinea-pigs and rats exposed for 2-7 months to inhalation of the airborne PVC dust in a PVC bagging area. Lesions began to appear at 2 months of exposure (alveolar histiocyte-macrophage reactions); they proved to be fairly marked after 4 months, with appearance of foreign body giant cells, and proceeded to development of large interstitial granulomatous foci. Vertkin and Mamontov (1970) who examined 96 workers engaged in the manufacture of articles made from PVC powder, also found a considerable proportion of them were suffering from functional and morphological alterations of the broncho-pulmonary system, which they ascribed to their exposure to PVC dust. They quoted results of earlier animal experiments conducted in 1963 by Golovaryuk and later by Shlyakhtskii. These last authors had apparently shown that exposure of animals to PVC dust may lead to the development of chronic pneumonia and eventually to a sort of mild fibrosis of the lungs.

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Certain types of PVC dust (one of two samples tested) were found to exhibit a strong haemolytic potential due to the presence of an undetermined but readily soluble surface-associated agent which was not VCM (Richards et al. 1975). These authors also studied the effect of the haemolytic sample of PVC dust on lung fibroblast cultures, but they did not obtain any significant results.

Contrary to earlier indications (Lange et al. 1974a) and despite continued efforts we failed to detect any significant restrictive changes of pulmonary function in the overwhelming majority of patients we had occasion to examine.

It may be of interest to note that Maltoni et al. (1974b) reported a high prevalence of pathological changes of respiratory epithelium (squamous metaplasia, squamous dysplasia, typical and atypical adenomatous proliferation) in sputum samples from employees of Italian VCM-PVC factories.

Nevertheless, contrary to the now well-established role of VCM in the production of nonmalignant lesions of bone, skin, small vessels, liver and spleen, it is still open to debate precisely what importance can be ascribed to pulmonary changes within the spectrum of VCM-induced disease.

4.4.4 Genetic Effects of VCM

The discovery of the carcinogenic properties of VCM also stimulated interest in its mutagenic potential. A number of studies have been carried out that demonstrated a mutagenic response to VCM or its metabolites in microbial test systems. Point mutations due to base-pair substitution have been produced in various strains of *Salmonella typhimurium* by VCM in the presence of animal and human liver microsomes as a system of metabolic activation (Rannug et al. 1974, 1976; Barrich et al. 1975a, 1976; McCann et al. 1975; Malaveille et al. 1975; Garro et al. 1976). Mutagenicity of VCM metabolites was also demonstrated in yeast strains (Loprieno et al. 1976, 1977; Shahin 1976) and in mammalian cells (Huberman et al. 1975). In comparison to nonexposed controls, a significantly higher incidence of chromosomal aberrations (fragmentation, rearrangement) in lymphocytes of workers occupationally exposed to VCM was reported by Ducstman et al. (1975), Funes-Cravioto et al. (1975), Purchase et al. (1975, 1976), and Fomenko et al. (1976). Flieg and Thiess (1974) had failed to demonstrate an increased rate of chromosomal aberrations in six chemical engineers and four PVC fabrication workers. As to the influence on germ cells, Purchase et al. reported that no dominant lethal effects were seen in fetuses of female mice mated with males which had been exposed to 3000, 10 000 and 30 000 ppm VCM for 5 consecutive days. This, however, does not absolutely exclude genetic effects on human gonads. The outcome of pregnancy among wives of VCM-polymerization workers as against wives of rubber and PVC-fabrication workers (Infante et al. 1976a, b) and rates of congenital malformation per 1000 resident live births in three Ohio communities with PVC production plants have also been studied (Infante 1976).

As part of a larger survey of workers' health, interview questionnaires (Infante 1976a, b) showed that after paternal age adjustment a significantly higher incidence of fetal mortality subsequent to paternal exposure was recorded among the wives of VCM-exposed workers. This trend was found to be maintained after elimination of

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UPL 12258

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Epidemiologic Study of Vinyl Chloride Workers: Mortality through December 31, 1972

by W. Clark Cooper*

A population of 10,173 men, employed in 37 plants, was identified as having worked for at least one year in jobs involving probable exposure to vinyl chloride monomer (VCM) prior to January 1, 1973. Of the 9677 men whose vital status was determined, 707 were known to have died. For 699, death certificates were obtained. The standardized mortality ratio (SMR) for all causes was 89, that for all malignancies was 104. The only type of malignancy found in significant excess was in the category of malignant neoplasms of the brain and other parts of the nervous system; 12 deaths occurred where 5.9 were expected, for an adjusted SMR of 203. There were slight but inconclusive upward trends in all malignancies, and for malignancies of the respiratory tract, digestive tract, and central nervous system associated with reported levels of maximum exposure to VCM. When groups in whom less than 20 years had elapsed from the first exposure were compared with those with 20 or more elapsed years, and 25 or more elapsed years, no significantly different SMR's were detected for major primary sites of malignancy. Plans for an updated study of mortality, to include deaths in the period 1973-1979 are briefly discussed.

The epidemiologic studies of vinyl chloride workers summarized in this report were carried out during the period June 15, 1973 through December, 1976 by Tabershaw-Cooper Associates, Inc., and Equitable Environmental Health, Inc., for the Manufacturing Chemists Association (MCA) (now the Chemical Manufacturers Association).

An initial report, dealing with 8,384 workers from 34 plants, was prepared May 3, 1974 (1). A summarized version (2) was published in 1974. The study population was subsequently increased and follow-up was improved. After an interim report in 1976 (3), a final report based on 10,173 workers was prepared in January, 1978 (4). In all of these studies the observation period ended December 31, 1972.

Participating Plants

In mid-1973, the MCA identified 43 plants in the United States, belonging to 19 companies, which either produced vinyl chloride monomer (VCM) or used it in the production of poly(vinyl chloride)

(PVC). Of these, 34 were included in the initial study; four were excluded because they had been in operation less than 5 years, one had stopped production in 1966, and in others information on job histories or exposures was deficient. Three plants were subsequently added to the original 34, so the 1978 report included 37 plants. Of these, 11 produced only VCM, 18 produced only PVC, three produced both, and five plants produced homopolymers and copolymers, with or without VCM and PVC.

The geographical distribution of those in the study, as shown in Table 1, indicates a disproportionate number of workers from the South, particu-

Table 1. Geographical distribution of 10,173 vinyl chloride workers in 1978 report.

Region	U.S. males (1970), %	Workers in study, %
Northeast	23.8	25.9
North Central	27.9	18.4
South	30.9	64.8
West	17.4	0.9

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October 1981

larly from the East South Central and West South Central States. The South, with 30.9% of the total U.S. male population in 1970, supplied 64.8% of the study population.

Of the plants participating, the one which had first begun operations with VCM had done so in 1935, the most recent was in 1968. Four plants had begun in 1942 or earlier, 13 in 1952 or earlier, and 27 in 1962 or earlier.

The Study Population

The objective was to include all male employees whose work had involved exposure to vinyl chloride for at least one year prior to December 31, 1972. The designation of jobs which involved exposure to VCM was made by staff members at individual plants or by a corporate industrial hygienist. In approximately two thirds of the study population, TCA staff copied personnel records on individuals who were identified as having been in exposed jobs. In the remaining portion of the population, detailed information on exposed individuals was provided by plant personnel. The methods used in doing this are described in the complete reports cited earlier.

Study Period

The period of time in which the work-force of a plant was included in the study depended upon the date it began making or using VCM and also upon the earliest date when personnel records were complete for all employees, if that was later than the foregoing. This was done to eliminate periods when there was differential record retention of workers terminated, deceased, or retired. The end of the study period was December 31, 1972.

Estimates of Exposure

In each plant, every job and location with VCM exposure was graded in terms of probable exposure. Originally, a job history form was designed in the expectation that the exposures could be quantified in parts per million. This proved impossible in practice. However, for each plant, jobs and locations involving the highest exposures could be classified as "high", and other jobs classified as "medium" or "low" relative to the "high". It is recognized that this subjective classification is of questionable validity in categorizing the past and present exposure of a given worker. From the number of months spent in jobs with classifications of 3 (high), 2 (medium) and 1 (low), a number of exposure categories were developed for use in later

Table 2. Bases for development of VCM exposure categories.

Criterion	Unit
Duration of exposed employment	Months
Interval from beginning of exposure to end of observation	Months
Estimated maximum level to which an individual was exposed for at least 12 months, classified as high, medium, or low.	High Medium Low
Integrated or cumulative exposure, crediting 1 for each month at low; 2 for each month at medium and 3 for each month at high exposure to VCM	1 2 3
Exposure index (EI) = Cumulative score/average number of months	

analyses. As shown in Table 2, individual exposures in various papers were classified in a number of ways, including the maximum level at which an individual had been exposed for at least 12 months, an integrated or cumulative exposure, and an exposure index based on the cumulative score divided by the number of months.

Follow-Up

As is customary in historical prospective studies, all who had left employment were traced when possible. Methods included form letters sent by mail and use of retail credit follow-up. For the first report, there was insufficient time to utilize Social Security Administration records, but for subsequent reports such follow-up was used.

In the first, or 1974 report, 85% of the study population was located; for the final or 1978 report, the percentage had been increased to 95%.

The mortality calculations were based only on those who were successfully traced, which is equivalent to assuming that mortality among those not found was the same as among those who were found. This usually, but not always, results in some overestimation of mortality.

Calculation of Standardized Mortality Ratios

Each worker in the study, i.e., everyone whose vital status was ultimately known, was considered to have been under observation from the date on which he attained a year of exposed employment or from the date when his plant's records were complete, whichever came later. Observation periods ended December 31, 1972, or on the date of death, whichever occurred first.

Observed deaths were classified by cause according to the 7th (1955) revision of the International

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Classification of Diseases. The expected number of deaths by cause were calculated by using age and cause-specific mortality rates for United States males with the same birth years and age distribution for the years 1950, 1955, 1959, 1965, 1967 and

aths for which death certificates could not be obtained were assumed to have the same cause distribution as the death certificates that were obtained. Appropriate increases were made in calculated SMR's.

The statistical significance of the deviation of each SMR in the study population from an expected value of 100 was tested by a method derived from Chin Leong Chiang (5). The formula for determining the standard error of the SMR was

$$SE = \sqrt{\frac{100 \times SMR}{\text{No. expected deaths}}}$$

If an observed SMR differed from 100 by more than 1.96 standard errors, it was regarded as significant at the 5% level; if it differed by more than 2.57 standard errors, it was regarded as significant at the 1% level. SMR's based on fewer than five observed deaths were usually not tested for significance.

Results

Table 3 summarizes the numbers of individuals, ss of follow-up, person-years and deaths in successive phases of the study. The number of deaths per 1000 man-years of observation, which in general reflects the age distribution of the work force, suggests that the proportion of older individuals increased in the study population as it was expanded and follow-up improved. Even so, the 5.88 deaths per 1000 man-years indicates that a relatively young population was being observed; the U.S. male population 20 and above has about 11

Table 3. Numbers of individuals, success of follow-up, person-years, and deaths analyzed in successive phases of the study.

	Report 1, 1974	Report 2, 1976	Report 3, 1978
No. of men	8,384	9,109	10,173
No. found	7,128	8,714	9,677
% found	85%	96%	96%
No. deaths	352	525	707
No. certificates	328	511	669
Total man-yr	77,846	94,221	120,203
Deaths/1000 man-yr	4.52	5.57	5.88

October 1981

deaths per 1000 man-years. Some published occupational epidemiologic studies will show 20 or more.

Duration of Exposure to VCM

In the first report, only 15.2% of those studied had begun exposure prior to 1950 (22 years before end of the observation period). In the third report, 33.4% had had 20 or more years for observation since exposure began. This resulted from finding more early employees by improved follow-up, and the inclusion of an older group from one plant in the augmented population.

Standardized Mortality Ratios

Standardized mortality ratios (SMR's) for selected causes of death are shown in Table 4, based on the 352 deaths analyzed in Report 1 and the 707 deaths analyzed in Report 3. Results in the first report led Tabershaw and Gaffey (1) to conclude that vinyl chloride may be associated with cancer of a number of sites, notably digestive cancer, respiratory cancer, cancer of other and unspecified sites (primarily those of the central nervous system) and lymphomas. This was based not on statistically significant excesses in each category, but upon apparent trends when different levels and durations of exposure were compared.

With the enlarged study group, the SMR for malignancies in the entire population dropped slightly, as did the SMR's for malignancies of the buccal cavity and pharynx, digestive tract and respiratory tract. However, tumors of the brain and central nervous system, when examined separately, still appeared to be in excess.

A number of analyses were done in the third report in an attempt to sharpen the focus on work exposures.

There appeared to be a slight but definite trend in the SMR's for all malignancies, malignancies of the digestive tract, the respiratory tract, and for other and unspecified sites with increasing levels of estimated maximum exposure (Table 5). However, the numbers of expected deaths were relatively few in some categories and the groups differed widely in age distribution as manifested by deaths per 1000 person-years.

To reduce dilution of the study population by men whose exposures had begun only recently, a separate analysis was carried out on those whose exposures to VCM had begun 20 years or more prior to 1972, and on those whose exposures had begun 25 years or more prior to 1972 (Table 6).

Another analysis was made of a population of men who had worked in plants producing only PVC

(where VCM exposures were presumably high), whose exposures had begun 20 years or more before the end of the study period and who had been reported as having medium or high VCM exposures for a year or more (Table 7). This group experi-

enced 210 deaths where 249.7 had been expected. The pattern of mortality from malignancies was not appreciably different from that of the total study group.

In summary, increasing the study population and

Table 4. Observed and expected deaths (O/E) and standardized mortality ratios for selected causes (SMR's adjusted for missing death certificates).

Cause (ICD Mo, 7th Rev)	1974 Report		1978 Report	
	O/E	SMR	O/E	SMR
All causes	352/467	75 ^a	707/795	89 ^a
All malignancies (140-205)	79/77	110	139/141	104
Buccal and pharynx (140-148)	5/2.84	189	5/5.19	102
Digestive (150-159)	19/21.7	94	29/40.8	75
Respiratory (160-164)	45/44.3	112	25/23.9	107
Other and unspecified (190-199)	17/11.75	155	28/20.2	147
Brain and CNS (193)	—	—	12/5.9	203 ^b
Leukemia and aleukemia (204)	3/3.77	85	9/6.65	143
Lymphomas (200-203, 205)	6/6.06	106	11/10.36	112
Major cardiovasc. renal (330-334, 400-468, 592-594)	155/207	80 ^a	347/385	95
Cirrhosis liver (581)	2/15.6	21	14/26.5	56 ^b
No. of workers	7,128		9,677	
Person-yr	77,846		120,203	

^aSignificant at 1% level.

^bSignificant at 5% level.

Table 5. Observed and expected deaths (O/E) and standardized mortality ratios for selected causes as related to maximum level of reported exposure to vinyl chloride monomer (SMR's adjusted for missing death certificates).

Cause (ICD Mo, 7th Rev)	Reported maximum exposure VCM					
	Low		Medium		High	
	O/E	SMR	O/E	SMR	O/E	SMR
All malignancies (140-205)	66/71	96	56/53.5	109	18/16.5	112
Digestive (150-159)	14/20.9	72	10/15.6	67	5/4.4	117
Respiratory (160-164)	19/22.2	92	19/17.1	116	7/5.1	141
Other and unspecified (190-199)	11/9.9	119	13/7.5	180	4/2.7	150
No. of workers	4,925		3,021		1,731	
Person-yr	58,741		39,927		21,535	
Deaths/1000 person-yr	6.16		6.6		3.9	

Table 6. Analysis of deaths based on time from beginning of exposure to end of study period (SMR's adjusted for missing death certificates).

Cause of death (ICD No. 7th revision)	< 20 yr		> 20 yr		> 25 yr	
	No.	SMR	No.	SMR	No.	SMR
All causes	158	77 ^a	549	93	393	96
All malignancies (140-205)	31	95	108	107	73	104
Digestive (150-159)	8	96	21	70	16	74
Respiratory (160-164)	8	80	37	116	22	100
Other and unspecified (190-199)	6	108	22	162	13	146
Leukemia (204)	3	155	6	137	4	137
Cardiovascular-renal	68	84	279	97	211	105

^aSignificant at 1% level.

improving follow-up did not strengthen the suggested associations between VCM exposure and malignancies other than those caused by hepatic angiosarcoma, as will be pointed out later, and a suggested association with tumors of the brain and central nervous system.

Table 7. Deaths in plants producing only PVC, based on workers whose first exposures began before 1952, and who had medium or high VCM exposures (SMR's corrected for missing death certificates).

Cause of death (ICD No. 7th revision)	O/E	SMR
All causes	210/249.7	84*
All malignancies (140-205)	46/46.04	106
Digestive (150-159)	9/13.63	70
Respiratory (160-164)	17/14.75	122
Other and unspecified (190-199)	10/ 6.33	167
Cirrhosis of liver (581)	6/7.95	80

*Significant at 1% level.

Angiosarcomas

Nine angiosarcomas are known to have occurred in the U.S. during the study period, i.e., prior to 12/31/72. As shown in Table 8, eight of these were found in the study, but only three were coded as angiosarcoma on the death certificate. However, four others were coded as tumors of the digestive tract. Unfortunately, two were coded 230x so as to fall out of the category for malignant tumors of the GI tract, and one was coded as cirrhosis of the liver.

As shown in Table 8, the angiosarcoma which was not found was in a man who had died in 1961. We have not determined how he failed to be in the study population. The years of exposure for the eight cases ranged from 4 to 23 years, while elapsed time from beginning of exposure to death ranged from 16 to 24 years.

Tumors of the Central Nervous System

The 12 tumors of the brain had been diagnosed on death certificates as follows: glioblastoma multiforme, 4 (1 confirmed by autopsy); astrocytoma, 2 (2 au-

Table 8. Angiosarcoma deaths and data on VCM exposures.

ICI No.*	First exposed	Year of death	Time from first exposure to death, yr	Total yr exposure	Est. max. exposure	Age at death
USA-02	1955	1971	16	14	High	38
-04	1949	1968	19	18	High	43
-05	1944	1964	20	20	High	52
-07	1944	1968	24	14	Med	45
-10	1946	1970	24	23	Low	70
-11	1951	1968	17	17	Med	60
-12	1949	1969	20	20	High	50
-16	1950	1969	19	4	High	41
-08	—	1961		Not in study group		

*Number used in registry periodically prepared by J. Stafford, Imperial Chemical Industries Ltd., Plastics Division.

Table 9. Summary of brain tumor deaths (ICD No. 205) and data on VCM exposures.

Case no.	First exposed	Yr of death	Time from 1st exposure to death, yr	Total yr exposure	Max. exposure	Age at death
1	1958	1972	14	5	Low	67
2	1967	1972	5	5	Low	43
3	1957	1968	11	7	Med	54
4	1941	1958	17	6	Med	61
5	1960	1970	20	8	High	43
6	1956	1971	15	3	Med	54
7	1947	1971	24	23	Low	57
8	1945	1963	18	18	High	44
9	1949	1971	22	21	Low	58
10	1947	1971	24	23	High	49
11	1935	1966	21	18	Low	59
12	1935	1967	32	22	Low	57

topsies); ependymoma of the 4th ventricle (autopsy); "malignant brain tumor" or "carcinoma of the brain," 5 (with no autopsies). This group is currently being made the subject of more rigorous review. The information obtainable from our records, summarized in Table 9, is insufficient to prove or disprove a cause-and-effect relationship between occupational exposure and these tumors.

Conclusions

A study of 707 deaths in a population of 9677 men who had worked for one year or more in jobs involving exposure to vinyl chloride and whose vital status had been determined as of December 31, 1972, did not show a significant excess of deaths due to malignancies. There did appear, however, to be a significant excess of tumors of the brain and central nervous system, based on 12 such deaths. There also continued to be slight but inconclusive trends toward higher SMR's for deaths from digestive tract and respiratory tract tumors associated with maximum levels of past exposure. No striking changes in malignancy patterns were apparent when analyses were directed toward individuals in whom 20 to 25 years had elapsed since first exposure. The results suggest that, except for a proven association with hepatic angiosarcoma and a strongly suggestive association with central nervous system tumors, vinyl chloride probably is not associated with significant excess cancers of other sites.

It should be emphasized that the epidemiologic study summarized in this report was planned, the populations defined, and analysis under way before cases of hepatic angiosarcoma had been diagnosed

in workers exposed to vinyl chloride (6). An update is scheduled with inclusion of additional deaths in the cohort during the years 1973 through 1979. The study can be improved by a separate analysis of data from the plants which began operations before 1960, and by separating, insofar as possible, exposures to vinyl chloride monomer, polyvinyl chloride, and various copolymers. It is also hoped that criteria for defining exposure and for rating levels of exposure can be improved to permit better indices of integrated exposure.

This study was begun June 15, 1973 under a contract between the Manufacturing Chemists Association, 1825 Connecticut Avenue, N.W., Washington, D.C. (now the Chemical Manufacturers Association) and Tabershaw/Cooper Associates, Inc. It was continued under later contracts with TCA and with Equitable Environmental Health, Inc.

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UPL 12267