

PUBLIC-HEALTH ROUNDS AT THE HARVARD SCHOOL OF PUBLIC HEALTH

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Vinyl Chloride: Can the Worker Be Protected?

INTRODUCTION

*David H. Wegman, M.D.**

OVER 80 million American men and women spend one quarter of their lives in a workplace outside the home. The deterioration in health quality that results from exposure to hazards in their workplace is not widely known. The annual toll of job-related injuries is estimated at 2.2 million, and these injuries result in 14,000 deaths.¹ The National Health Survey has estimated that the average worker experiences six days of absence and more than 16 days of restricted activity because of some type of job-related disability per year and that one out of eight workers will receive a job-related injury each year. The incidence of occupational disease was recently estimated at 390,000 new cases and as many as 100,000 deaths per year. Job-related disabilities account for 10 times as many lost man days as from strikes.¹

This human cost can, in large part, be assigned to well known hazards of the workplace or to sporadic human error. The first, at least, is subject to control if we are prepared to accept an increment in price or inconvenience.

In a technologically innovative society, the worker is subject to an additional risk. Morbidity or death may also result from exposure to new processes or agents with unanticipated potential for injury.

The quality of a society should be judged in part on its awareness of the potential for injury in innovative technology. There must be procedures for evaluating the level of danger to which workers are exposed, and for responding to demonstrated dangers. The following account illustrates how we have dealt with one specific problem.

PERSPECTIVES

John M. Peters, M.D.[†]

Most of the known occupational diseases are chronic, untreatable and fatal. Despite the fact that the prevention of occupational diseases is highly desirable, they are not subject to systematic surveillance in the United States today by industry, unions, the government or universities. In addition, physicians frequently fail to recognize occupational disease. In this context the discovery of a new occupational

disease most commonly results from an unusual group of clinical manifestations or disease occurring in an industrial cluster, as was true of vinyl chloride.

Vinyl chloride is a gas used to make polyvinyl chloride, the basis of widely used plastic products such as phonograph records, meat wrappers, upholstery covering, plastic containers, toys and pipe for water supplies. The production of vinyl chloride and polyvinyl chloride is a post World War II industry that has been growing for the last 20 to 25 years.

In January, 1974, in Louisville, Kentucky, three cases of a rare neoplasm, angiosarcoma of the liver, were reported in workers exposed to vinyl chloride.² If these had not been such unusual tumors, they would have gone unnoticed. If cancer of the lung, bladder or bowel had developed in these workers, we would probably not know about the connection between vinyl chloride and cancer. These tumors occurred in workers who had been exposed for roughly 20 years. It is probable that we are just beginning to see a larger epidemic.

It is instructive to examine the accumulation, over time, of information about the biologic effects of vinyl chloride. In 1938 there was a report describing acute toxicity from vinyl chloride to guinea pigs, mice and dogs.³ In 1949 a report of cases of liver damage from vinyl chloride in human beings was published.⁴ In 1961, studies of chronic toxicity on rats, rabbits, guinea pigs and dogs revealed that liver damage occurred at levels above 50 parts per million.⁵ In 1966 another very unusual disease associated with vinyl chloride, acro-osteolysis, was described.⁶ This condition, characterized by the dissolution of the bones of the fingers and toes, was clearly related to vinyl chloride exposure. In 1970 a study showing the development of cancer in animals appeared.⁷ Since announcement in January, 1974, of the first three patients with angiosarcoma of the liver an additional 26 such cases have been identified.⁸ Several epidemiologic studies⁹⁻¹¹ have consistently found an association of vinyl chloride exposure with tumors in sites other than the liver. One study indicates a time trend with increasing rates of all cancers in the exposed population.⁹

It is hard to escape the conclusion that, well before 1974, there was enough evidence to support the presumption of a serious occupational hazard. What was, and is, lacking is a national policy of screening new materials for potential hazard before their dissemination in the workplace, a policy that might have prevented widespread exposure to vinyl chloride. Should we have a policy for screening chemicals? Could we implement such a policy if we had one?

Dr. Rudolph J. Jaeger will tell us what we might have learned from animal studies.

TOXICOLOGY

Rudolph J. Jaeger, Ph.D.[‡]

The central problem in toxicology is extrapolation to man of the toxic responses observed in the laboratory animal. Individual species vary widely in their susceptibility to injury from a given compound, and none meet the requirements of equivalency to man in biologic response, short latency, low cost and convenience across the spectrum of agents to be

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tested. Despite these shortcomings inherent in toxicologic studies as now conducted, experiments in traditional laboratory animals could have supported a stronger and earlier presumption of the dangers of vinyl chloride.

Under normal environmental conditions vinyl chloride is a colorless, nearly odorless gas that is highly explosive at modest concentrations in the air — i.e., 4 per cent and above. At 8 per cent and above, it is an anesthetic — a use that was suggested in the 1930's¹² but abandoned owing, in part, to flammability and myocardial sensitization.¹³

What tests of toxicity might be performed on an agent like vinyl chloride? As a first step, experiments might be conducted in which the gas is inhaled by a test species at a given concentration — e.g., 100; 1000; 10,000; 100,000 parts per million (ppm) — for a single acute period comparable to a normal work day of eight hours or less. Except for death due to central-nervous-system depression, vinyl chloride is without immediate lethal action.¹⁴ After a single subacute exposure, the animals will recover without residual damage and live without apparent ill effects for a normal life-span. This lack of acute toxic effect in rats is reflected in the experience of workers who have been rendered unconscious by high concentrations of vinyl chloride and then moved to other jobs with little or no subsequent exposure. They have had no apparent sequelae.

A second test of toxicity in animals involves repeated inhalation exposure for days, weeks, or months. Such experiments are comparable to short-term work situations. In experiments such as these, vinyl chloride produced no dramatic effect on repeated exposure at concentrations up to 20,000 ppm for 92 days.¹⁵ In a study done in 1961 by the Toxicology Laboratory of the Dow Chemical Company, rats, rabbits, guinea pigs, and dogs were exposed to vinyl chloride for seven hours a day, five days a week for periods up to six months at concentrations of 500, 200, 100 and 50 ppm of vinyl chloride. In this study the animals were killed at the end of the exposure period and autopsied.⁵ Growth rates and hematologic indexes were within normal limits. Slight liver enlargement was noted after exposures at concentrations of 100 ppm or more. Minor pathologic changes were also detected in other species at doses higher than 100 ppm. Fifty ppm, a concentration without effect on liver weight, was suggested by Dow as a maximum time-weighted concentration for eight-hour exposure of workers, on the grounds that these conditions of exposure represented levels that did not affect rats exposed for six months.

A somewhat different approach to the study of toxicity is represented by the studies of Maltoni¹⁶ and Viola,⁷ which showed that exposure of rats to 30,000 ppm of vinyl chloride four hours a day, five days a week, for a year, caused malignant neoplasms in a variety of sites, including the liver, brain, kidneys and vascular tissue. In these studies the pathologic findings were sought after the animals' lifetime rather than at an earlier experimental sacrifice point. This was a crucial change of experimental design for the identification of potent carcinogenicity of vinyl chloride.

Maltoni found cancers at exposure concentrations as low as 250 ppm in rats.¹⁶ Furthermore, his data on tumor rate with decreasing dose suggest that there is risk of cancer at concentrations of vinyl chloride below 50 ppm. Thus, a

compound with little acute lethal action and negligible short-term toxicity is a potent carcinogen in rodents under worklike exposure conditions of 50 ppm and less.

What can be learned from this series of events? It required two decades for the development of malignant tumors in human beings, when 12 months of experimentation in lower vertebrates could have established the carcinogenicity of vinyl chloride at exposures comparable to those in the working environment. Although a negative experimental result in animals cannot exclude potential carcinogenicity in man, a positive result under these circumstances is an unambiguous warning. The events described here suggest that useful toxicologic screening can be carried out in locations other than the workplace, and in species other than man.

ENGINEERING

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The manner in which workers are exposed to vinyl chloride varies greatly, depending on their specific roles in the process of production. The industry can be divided into three manufacturing stages — the production of vinyl chloride monomer (VCM), the reaction of this material to form the solid polyvinyl chloride (PVC), and the fabrication of plastic products from polyvinyl chloride.

Over 350,000 workers are exposed to potential hazard at various stages of this industrial sequence. Vinyl chloride monomer is manufactured by a number of different processes in the United States in 15 plants with a total work force of about 1000. In a common process ethylene is combined with chlorine to form ethylene dichloride, which is pyrolyzed to form vinyl chloride. Although this continuous operation is enclosed, leaks from various valves, pumps, and fittings result in exposure of the worker to airborne vinyl chloride gas. Maintenance of process equipment is a major problem in this industry.

Limited data on air concentration are available from the monomer production plants. In normal operations the concentration may be at the level of 1 ppm. Occasional spills, however, will result in peak exposures of hundreds of parts per million.

Fortunately, effective methods of control are available in some parts of the industry. Maintenance obviously must be improved to reduce leaks into the workplace. New procedures must be developed to permit transfer of the monomer and sampling of the product so that the worker need not be exposed during these operations.

In the second industrial stage, vinyl chloride monomer is reacted to form the solid polymer, polyvinyl chloride (PVC). Polymer production is carried out in this country in 36 plants with about 5000 employees. The major exposures to vinyl chloride monomer occur in this part of the industry, and most of the cases of angiosarcoma of the liver have come out of these plants.

Polyvinyl chloride is produced in a batch operation in a glass-lined reactor or pressure vessel. Vinyl chloride monomer is introduced into the reactor with an initiator, a catalyst, and water. The temperature is raised to 60°C, the pres-

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sure is increased, and the material polymerizes over a period of 10 to 16 hours. At the end of this interval, the solid granular polyvinyl chloride is formed, drops to the bottom of the reactor, and is then dried. Some unreacted vinyl chloride monomer remains in the polymer and presents an exposure problem to fabricators of end products. Still, fabrication offers fewer hazards than polymer production. The most common exposure occurs when workers periodically crawl into the reactor to clean the inside surface, a situation in which exposures may exceed 1000 ppm. How can this exposure be reduced? The industry would like to automate the cleaning, but this step has not yet been implemented widely.

Is control of vinyl chloride feasible in this part of the industry? This question sets the stage for the major debate. In testimony before the Occupational Safety and Health Administration, the spokesman for the Society of the Plastics Industry had stated that it is not economically feasible to reduce the levels below 25 ppm. A consulting firm retained by the Department of Labor had stated that it is feasible to bring the concentration down to 2 to 5 ppm in this part of the industry. Other authorities said that air concentrations of vinyl chloride monomer of 1 ppm can be achieved.*

In the third stage, the fabrication sector of the industry, the granular polyvinyl chloride is made into useful commercial and consumer products. The bulk polymer is compounded with various plasticizers, stabilizers, and other additives depending on the ultimate application. The products made from the polyvinyl chloride include intermediate industrial materials such as tubing, rod, bar and sheet, and a host of consumer products.

There are 7500 fabrication plants with nearly 350,000 workers. The exposure to vinyl chloride monomer in these plants is due to the release of the residual monomer from the solid material. The residual monomer in many polymers is in the range of 1000 to 5000 ppm by weight. The hazard in the fabrication industry could be eliminated if the polymer manufacturers reduced the residual amount to 1 ppm.

In summary, although there should be no disagreement that controls must be implemented promptly, there has been much dispute over the levels of control for vinyl chloride that can be achieved, and over their costs.

ECONOMICS

Leslie I. Boden, B.S.[†]

On the list of the 50 most common industrial chemicals, vinyl chloride ranks 23d. Annual United States production of this gas is over 2.3 billion kg. By far the most important use of vinyl chloride is in the production of polyvinyl chloride, of which we also produce about 2.3 billion kg a year at a cost of over \$1 billion. United States production of this important plastic has been growing steadily since 1939 at an average annual rate of 12 per cent. If the polyvinyl chloride

products industry were to be shut down before substitutes could be found and their manufacture begun, perhaps two million jobs and 75 billion dollars worth of production would be lost.¹⁷

The basic institutions of the economy, firms competing for profits, have been well suited to increase rapidly the availability of goods and services. Through the struggle for profits, business has played a central part in producing the innovations that have raised the standard of living in this country to levels that most people formerly believed impossible.

On the other hand, there are several things for which these industrial organizations are poorly suited. They have few incentives to educate the population, lower unemployment, promote income equality, protect the environment, or help improve the health of the public. Often, these goals come into direct conflict with the profit motive. Concern for workers' health, for example, might require the individual company to conduct expensive research, and cause it to delay the introduction of new products and processes. Both responses would place it at a competitive disadvantage.

This situation has led to government intervention in the private market to diminish the impact of occupational disease. There are at present two types of laws designed to make business more concerned about the health and safety of workers. Worker's compensation laws have created state-regulated programs ensuring that a company pays for medical expenses and for part of lost income if an occupational disease develops in a worker. Unfortunately, these laws do not provide the companies with adequate incentives to protect the health of their workers. For example, the worker's compensation costs for medical expenses and support payments to the families of the men who died in Louisville, Kentucky, average about \$64,000. If 1000 workers a year died, the cost of paying this level of compensation would amount to approximately \$0.01 per pound of polyvinyl chloride production, or less than 3 per cent of the cost of its manufacture. This proportion is substantially below the costs of rigid manufacturing controls.

In 1970, Congress passed the Federal Occupational Safety and Health Act.¹⁸ This law attempts to prevent disease by compelling companies to conform to standards that are designed to prevent illness due to toxic exposure in the workplace. The enforcement of this act has, however, been weak, and its effectiveness questionable.

How, then, might the government stimulate adequate testing of the potential toxicity of chemicals that enter the industrial environment? One way to achieve this goal would be the implementation of an occupational health act similar to the Pure Food and Drug Act — that is, new industrial chemicals with definite potential for human exposure would have to be demonstrated to be nontoxic before being approved for use. This step would compel industry to test these substances before they were widely used.

Laws like those just mentioned can help to protect the health of workers, but at a cost. This cost might be expressed in a slower rate of technologic innovation, and thus lower production of some goods and services. It might also be felt in increased prices for goods. These increases result from the added costs of experimentation and changes in the

*Official Report of Proceedings before the Occupational Safety and Health Administration of the U.S. Department of Labor in the matter of proposed permanent standards for occupational exposure to vinyl chloride. Washington, D.C., June - July, 1974 (Available from H R Company, Official Reporters, 320 Massachusetts Avenue, N.E., Washington, DC 20002).

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production process that help to protect workers' health. For example, a spokesman for Firestone Plastics has stated that the costs of lowering vinyl chloride exposure from the 1973 standard to 1 ppm would increase the cost of polyvinyl chloride by 50 per cent.*

The problem is further complicated by the fact that the United States produces less than 30 per cent of the world supply of polyvinyl chloride. If other countries do not implement strict standards, what is to prevent the multinational corporations that produce polyvinyl chloride from building new factories overseas, "exporting" both jobs and disease?

REGULATION

David H. Wegman, M.D.[†]

In my position with the Massachusetts Division of Occupational Hygiene, my first contact with vinyl chloride came in early 1973 with an attempt to evaluate the problem of acro-osteolysis induced by vinyl chloride in Massachusetts workers. The attempt was short lived because other occupational health problems had higher priority. The issue of vinyl chloride, however, was brought back to me with the reports of the cases of angiosarcoma of the liver in January, 1974. As happened elsewhere, we immediately gave the vinyl chloride problem a high priority and began to investigate the four local firms manufacturing polyvinyl chloride from vinyl chloride. Although we were easily able to evaluate current exposure levels in these plants, our efforts to evaluate possible chronic disease foundered because of the small numbers of employees and our inability to locate those who had left employment.

At the same time that we were attempting to determine the magnitude of the problem in Massachusetts, the Federal Occupational Safety and Health Administration (OSHA) was faced with the more difficult problem of establishing national standards.

In July, 1971, OSHA established its first standard on asbestos as a result of heavy pressure from labor.¹⁹ The carcinogenic effect of asbestos was ignored, and the standard was set solely with asbestosis in mind. The next standard promulgated referred to 14 carcinogens but set no "safe" exposure level.²⁰ Then the vinyl chloride story broke publicly, and the resulting widespread interest forced OSHA to deal directly with a single cancer-causing agent. The agency knew that vinyl chloride was carcinogenic at exposure levels yet to be determined, and its use was widespread, and that control of exposure was difficult. The first step was to set an emergency standard at 50 ppm, the level that the Dow Chemical Company had recommended as an upper limit in 1961.⁵ The agency then had six months, by law, to promulgate the final standard. This period included development of both economic and environmental impact statements and the announcement of three days of public hearings. The response to the announcement was so great that hearings continued for three weeks.

As a medical consultant to OSHA, I was asked to address

the problem of the human health effects, and how well substantiated they were. The federal government, through the Food and Drug Administration (FDA), had indicated before the hearings had begun that exposure to vinyl chloride was a serious human health problem that needed immediate attention. On February 21, 1974, the FDA received a petition to withdraw vinyl chloride as a propellant in aerosol products (including hair sprays, aerosolized household products and pesticides), and in only six weeks such an order was issued. Information on how widespread the use of these products had been was unavailable.

It was clear that more than the identification of cases of a rare tumor would be required if a recommendation of any exposure level below 50 ppm were to be made. Generally, standards are set on the basis of acute effects of a toxic material. Vinyl chloride was not known to cause acute problems below the lower explosive limit, and since provisions had been made to prevent explosions, concentrations that could cause acute disease were unlikely.

The chronic effects, however, were difficult to evaluate. "Slap-in-the-face epidemiology" had succeeded in bringing the problem to our attention. It was "quick-and-dirty" epidemiology that gave an initial idea of the size of the problem. Although several attempts to conduct mortality surveys had been made, only a few were sufficiently well designed and carried out to provide useful data. Even they fell short of allowing specific estimates of risk. They did tell the unfortunate story of cancer of the liver as well as lung, brain, skin, and lymphatic system in vinyl chloride workers. Three other studies of current workers showed that vinyl chloride and polyvinyl chloride were also associated with chronic disease of liver and spleen, bleeding conditions, skin and bone disease, and chronic lung disease.²¹⁻²³

On the basis of these findings, my first recommendation was for a standard of 1 ppm as the maximum exposure acceptable on medical grounds. The response of the director of OSHA to this recommendation was most interesting. Although initially he had asked for a medical evaluation of the potential health effects, his final request was for a legal defense of the levels. He believed that regardless of what level he set, he would be taken to court for setting too lenient (by labor) or too stringent (by industry) a standard.

This raised the core question: How well-supported do health effects need to be to be acted upon? For vinyl chloride it seemed reasonable to assume that human beings are at least as sensitive as laboratory animals and that the standard would have to be below 50 ppm. But how far below 50 ppm can a number be selected and defended? The most convincing argument for the figure of 1 ppm was the unusual behavior of vinyl chloride. It would be difficult to imagine a material with more potential for human damage, for it is associated not only with cancer at multiple sites but also with non-neoplastic disease of at least six different organs or organ systems.

EPILOGUE

On October 4, 1974, the Federal Occupational standard for vinyl chloride was issued.²⁴ Although it accepted in principle 1 ppm as the maximum possible exposure, work practices temporarily permitted exposures of up to 25 ppm with-

*Proceedings before the Occupational Safety and Health Administration.

[†]Mass. Division of Occupational Hygiene and Occupational Health Program.

out respiratory protection. This standard was immediately challenged by the Society of the Plastics Industry and various companies when they petitioned the federal courts for a stay in the implementation of the standards.²⁵ The petition was denied, and the United States Supreme Court refused to review the decision.²⁶ Since the promulgation of the standard, apparently only one small plant has closed, and four new plants are nearing completion.²⁷

Polyvinyl chloride was briefly used to make containers for alcoholic beverages. The discovery that migration of detectable amounts of vinyl chloride from the containers to the beverage led to its removal from this use. Definite evidence on the migration of vinyl chloride from food wraps or pipes for drinking water does not exist. Inadequate study has been performed to date to determine whether there is a hazard of vinyl chloride exposure to consumers using nonfood-related polyvinyl chloride products.

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