

In a preliminary report released in August 1974 and in a paper presented in March 1975 at a New York Academy of Sciences Conference on Occupational Carcinogenesis, Dr. Infante reported that the rate of birth defects, based on hospital records, in each of the three Ohio towns was significantly higher than the average for the state of Ohio, and also for the balance of the three counties in which the towns were located.

Dr. Infante further reported a major excess in birth defects of the central nervous system (CNS), which he considered to be "the greatest cause for concern," and also in adult deaths from CNS cancer.

These reports attracted wide press attention and speculation, even though Dr. Infante, in his Academy of Sciences paper, had warned:

"These preliminary findings do not link polyvinyl chloride production facilities with the increased occurrence of congenital malformations and CNS tumors in adults, but indicate the need for further study of possible contributing factors."

While the press totally ignored this statement, a careful analysis of the data contained in the report lends credence to the reservations expressed in the paper's conclusion.

For example, for comparison purposes the report examined the birth defects rates in nine communities without PVC facilities, but which were located in the same general geographical area as the three plant towns. Two of them were found to have birth defects rates higher than any of the communities with PVC facilities.

Not only was this discrepancy unexplained, but the report also combined cases of CNS malformations from one of these two communities -- North Ridgeville -- with those from

the three plant towns in developing the basic statistics. This unusual procedure was explained in the report by stating that North Ridgeville was "proximate" to one of the plant towns. In reality, the two are nearly 10 miles apart -- approximately twice the distance that the Environmental Protection Agency has determined, through extensive air monitoring, as the maximum that vinyl chloride gas can travel through the air before decomposing into other, non-toxic, materials.

The inclusion of North Ridgeville data in the report is thus misleading and inappropriate.

In addition, if one examines the data from the four towns separately, rather than in combination, the fact emerges that while one of the plant towns -- Painesville -- did have over half of the observed CNS birth defects, the non-VCM town had 25 percent of the total. Another of the plant towns -- Avon Lake -- which has had a VCM facility in its midst for the longest period of time of all three communities, had no CNS defects at all.

Nearly the same situation applied in the case of CNS cancers among adults. The report, once again, added cases from North Ridgeville to the three plant towns. When examined separately, only Painesville and North Ridgeville, which has no VCM facility, showed an excess of adult CNS cancer deaths. The other two VCM plant towns showed no excess.

When the hard data from the three VCM plant towns and North Ridgeville are examined individually, more unexplained differences than similarities in CNS malformation and adult cancer rates emerge. The procedure of "combining" data from three widely separate communities -- Painesville is located about 30 miles to the west of Ashtabula and Avon Lake lies another 50 miles west of Painesville -- plus a town without a VCM facility, effectively obscured these significant differences.

Equally as important as the manner in which the data was compiled and presented is the fact that no attempt was made to determine whether any of the mothers involved (or their husbands) had ever been exposed to vinyl chloride, either by working in one of the VCM plants or by living in close proximity to them. Nor were any measurements made to determine if there was any vinyl chloride at all in the ambient air in these communities. Furthermore, interviews were not conducted of any of the subjects to determine, for example, if there was a history of birth defects in the family or if the mothers might have been exposed during pregnancy to some other toxic substance. Finally, no attempt was made to compare the current birth defects rates with those existing before the VCM facilities were constructed.

Birth Defects Questions Studied by CDC

Because of the questions raised by Dr. Infante's Ohio study and the publicity that his results were receiving, the Center for Disease Control (CDC) of the U.S. Department of Health, Education and Welfare undertook an investigation of the possible relationship between vinyl chloride exposure and birth defects in humans.

The results of this investigation were published in the July 19, 1975, issue of Morbidity and Mortality, an official CDC weekly publication. In the first section of the two part study, a comparison of birth defects rates in hospitals in two widely separated cities with VCM installations -- one in Pennsylvania, the other being Painesville, Ohio (which was included in Dr. Infante's study) -- showed no rate increase in the Pennsylvania community as compared with the state average. The CDC investigation did find an increase in CNS malformations in Painesville, similar to that reported by Dr. Infante.

The second part of the CDC study involved a through investigation of the 15 cases of CNS malformation recorded at the Painesville Hospital from 1970-1974. For each malformation case, two normal births were investigated as "controls" for comparison purposes. The results of this research, which covered a number of factors not included in Dr. Infante's study, can be summarized as follows:

- None of the interviewed parents of the children with CNS birth defects ever worked at either of the two VCM polymerization plants in Painesville (one set of parents could not be located, but records show they did not work at the plant at the time of their infant's birth).
- In the "control" group, two of the fathers of "normal" children were working at one of the VCM plants at the time of their infant's birth.
- Neither of the parents in either group lived within two miles of either of the two plants.
- A statistical analysis of the actual distances between the two VCM plants and both residences and workplaces of the parents of "cases" and "controls" showed no difference between either group.

The CDC concluded, on the basis of its own investigations and a through analysis of the existing research data, that while the possibility could not be ruled out that VCM might be teratogenic (capable of causing malformations), the evidence to date did "not establish any association between (birth defect) cases and vinyl chloride exposure".

The results and conclusions of the CDC investigation were also published for professional scrutiny in the November 29, 1975, issue of Lancet, a prestigious British medical journal.

Second CDC Investigation Undertaken

Despite the publishing of the CDC research, some individuals continued to refer to Dr. Infante's study as the definitive, and indeed the only, investigation in the area of vinyl chloride exposure and birth defects. Dr. Infante, in defense of his own work, argued that there were several methodological errors in the CDC study that could account for its negative findings.

In order to settle the question once and for all, CDC decided to undertake a second, even more definitive investigation. The methodology for the study was modified to take into account Dr. Infante's objections. Charleston, West Virginia, where a vinyl chloride plant had been located since 1938, was selected as the study site. The investigation began in February 1976 and the results submitted in report form to the Director of CDC by the Cancer and Birth Defects Division of the Center's Bureau of Epidemiology on July 26, 1976.

Study Finds "No Relationship"

As with the earlier study in Painesville, Ohio researchers contacted the parents of all children born with CNS defects in Kanawha County (Charleston and suburbs) from 1970 to 1974. A "control" group, consisting of the parents of "normal" children born in the same hospital immediately before or after a child with a CNS defect, were also interviewed. Air pollution, prevailing wind and other data were also collected.

The results of this investigation can be summarized as follows:

- Except for 1974 (the last year included in the study) rates of CNS birth defects in Kanawha County were higher than total U.S. rates.
- Five "case" parents out of 41 (those with children born with CNS defects) and no "control" parents reported a family history of CNS defects.

- Two "case" fathers and two "control" fathers were employed in the VCM plant at the time their children were conceived. Three additional "control" fathers had worked in the plant on a contract basis for a short time and therefore also had possible exposures.
- No mothers in either group had ever worked at the plant.
- Using sophisticated analytical techniques, no significant differences were found between the two groups as to their places of residence in relation to the plant at the time of their infants' conception.

The study noted, however, that of the nine "case" parents and ten "controls" who lived within three miles of the plant, most of the "case" parents tended to live east of the plant, while most of the "control" group lived south of the plant.

Because of this curious case "cluster," CDC, according to the report, "gave particular attention to the possibility that the cluster may have been caused by increased VCM emissions." While winds in the Charleston area are highly variable, the West Virginia Air Pollution Control Commission reported that suspended particulate matter, a good indicator of wind direction, was heavier in the southwest, thus "suggesting a prevailing wind from the northeast," i.e. away from the "cluster" and the plant.

Furthermore, if the case "cluster" was the result of VCM plant emissions, CDC theorized that "one would also expect an approximate correlation between a decrease in atmospheric VCM levels and a fall in CNS defect rates." According to the report, no such correlation was found.

The report therefore concluded: "The investigation did not reveal an association between the case clustering within 3 miles of the plant and exposure to VCM or other chemicals."

In its summary of the entire study, CDC concluded that "no relationship between infants with malformations and parents' exposure to vinyl chloride could be established."

Vinyl Chloride and Fetal Deaths

In early February 1976, Ralph Nader's Health Research Group released to the press the text of a study scheduled to be printed in the April 3, 1976 issue of Lancet. The study by Dr. Infante et al, was conducted at a single PVC resin plant in Pennsylvania. It showed that the wives of workers exposed to heavy concentrations of VCM had a statistically significant greater number of stillbirths and miscarriages than the wives of workers exposed to little or no VCM.

While the research results certainly merit further investigation, there are a number of factors in the study that have raised some doubts concerning the sweeping conclusions that have been reached from the research.

For example, the number of families participating in the study -- only 62 in the "exposed" group -- is quite small. Secondly, the wives themselves were not interviewed by the researchers, nor were their ages at the time of conception obtained. All data in the study was based solely on the "recall" of the husbands. Similarly, hospital or other medical records were not checked, nor was any attempt made to contact the wives' doctors for their possibly valuable input.

Even more importantly, there is no indication in the report that any attempt was made to correlate fetal death rates with either length or degree of exposure. This is especially vital in light of the fact that the husbands in the "exposed" group who were 30 years of age and older (and who presumably had the greatest accumulated exposure), did not report

an excess of fetal deaths when compared to those 30 and older in the "control" group.

In addition, when women with chronic stillbirth and miscarriage problems were eliminated from the study (standard procedure in research of this type), the difference in fetal death rates between the "exposed" and "control" groups was not reported as statistically significant by the authors.

Finally, even if subsequent research should confirm these tentative conclusions on vinyl chloride and fetal deaths, it should be emphasized that, since the research was conducted, VCM exposure levels throughout the industry have been reduced a hundred-fold or more. Even if a problem did exist, it has already been eliminated.

Conclusion

Since 1974, a number of studies have been undertaken to determine the potential mutagenic or teratogenic hazard of vinyl chloride exposure. Extensive experiments conducted by the U.S. Center for Disease Control have failed to discover any relationship between birth defects in children and their parents' exposure to vinyl chloride. This research refutes an earlier, less definitive study conducted in three towns in Ohio.

One study undertaken at a single plant in Pennsylvania showed that the wives of workers exposed to heavy concentrations of vinyl chloride had a greater number of stillbirths and miscarriages than the wives of workers exposed to little or no VCM. While numerous questions have been raised about the methodology of this study, it is clear that additional research is required in this important area of industry and public concern.

20-10-000 (1-72)

SHELL OIL COMPANY

SHELL CHEMICAL COMPANY

DEER PARK MANUFACTURING COMPLEX

TO R. G. DILLARD

DATE MARCH 8, 1976

FROM MANAGER-SAFETY & INDUSTRIAL HYGIENE
DEER PARK MANUFACTURING COMPLEXSUBJECT INDUSTRIAL HYGIENE-
EXPOSURE MONITORING
PROGRAM
Deer Park

Attached is the Industrial Hygiene Exposure Monitoring Plan developed by Jerry Ransdell for 21 chemicals of greatest concern within the complex.

This plan sets out a two-year, prioritized program for monitoring employee exposure to the selected chemicals. The plan assumes continued full-time involvement of two laboratory technicians and about one-half of the Industrial Hygienist's time. The priorities for chemical monitoring were established on the basis of guidelines from Manufacturing Safety & Health on toxicity, as well as local factors such as potential for exposure, and the number of employees exposed. The required monitoring programs for VCM and Benzene will, of course, be continued, as will the AC monitoring and periodic free silica monitoring.

This plan is currently in effect. It is a part of our overall "Health Standard" program outlined in an earlier document. Managers throughout the complex are encouraged to distribute copies of this plan to their appropriate personnel (extra copies available from Maxine Wallace - 56-247). Additionally, Jerry Ransdell is available to discuss this program at team meetings, or foreman meetings.

It is important that supervisors understand our Industrial Hygiene Programs, and we urge each manager to take positive steps to begin this educational process.

J. L. Rivard
J. L. Rivard

Attachment
JLR:lg

cc: Messrs. R. L. Brunner, Chem. Mfg. & Dist. Mfg. Rep.
H. L. Kusnetz, Manager Safety and Health

B. Promulgation of OSHA Standard

The likelihood of a proposed or finalized standard which details monitoring (initial exposure evaluation and periodic), medical surveillance, compliance methods, etc., is also considered in the establishment of priorities. The Standards Completion Project (SCP) could lead to standards for over 300 materials in the next few years. Materials appearing early on this list (e.g., MEK, MIBK, mesityl oxide, allyl chloride, epichlorohydrin, ethylene dichloride, phenyl glycidyl ether, hydrogen sulfide, butyl glycidyl ether, allyl alcohol, ethyl chloride, trichloropropane, acetone, and hexane) are rated higher in priority as well as materials for which OSHA is considering exposure limit revisions (e.g., free silica, asbestos, benzene).

C. Potential for Exposure

The true hazard of a material depends not only on the toxicity but on the potential for the material to escape into the working environment. This potential is determined by three factors: (1) the physical process (e.g., amount of material present, high temperature and pressure resulting in fugitive leaks, and process operations which are open to the atmosphere); (2) employee work practices (e.g., process sample collection and housekeeping); and (3) the materials' physical properties (e.g., volatility and density of vapor in air).

D. Number of Exposed Workers

As the number of exposed workers increases, more people are potentially affected so the survey priority of a material is adjusted upwards.

Since the prime consideration in this surveillance plan is to evaluate the risk to employee health, factors (A), (B), and (D) are given the strongest consideration.

II. INDUSTRIAL HYGIENE SURVEILLANCE PLAN

On the basis of factors presented in priority setting, twenty-one materials are identified for surveillance. This total includes materials for which monitoring is in progress as well as materials that have not been monitored. This plan, as summarized in table 1, calls for the continuation of vinyl chloride and benzene monitoring with gradual reductions in monitoring as exposure levels decrease or as exposure levels are confidently defined. Such reductions are anticipated at the end of 1976. The AC/ECH monitoring should continue through to completion with only minor monthly sampling to check improvements from AC abatement work. The survey scheduling of the other materials are discussed subsequently.

The total manpower requirements for the surveillance plan consists of: (1) 28.5 man-days per month to continue the present vinyl chloride monitoring, the present benzene monitoring, the planned monthly allyl chloride monitoring, and the planned monthly free silica monitoring; and (2) 350-450 man-days to complete initial exposure evaluations for the other materials.

Completion of the initial exposure evaluations, while maintaining the periodic monitoring, will require two full-time laboratory technicians and approximately 50 percent of the industrial hygienist's time through 1977. Eighty to ninety percent of the monitoring would be in the Chemical Plant. Ten materials are in the Chemical Plant only and another nine materials are in both the Chemical Plant and Refinery with approximately eighty percent of the monitoring for such materials occurring in the Chemical Plant.

A. Priority Setting

The 21 materials are categorized into four groups to facilitate priority setting and survey planning: (1) carcinogens, mutagens, and teratogens (known or highly suspected); (2) chlorinated hydrocarbons; (3) ketones; (4) products of significant toxicity. Category (1) rates the highest priority in terms of the toxicity factor followed by groups (2) and (4). The potential for exposure is present with every material in each group. The exposure potential rating for groups (2) and (3) are about equal and generally higher than for materials in group 1. Group 4 materials vary in this respect with free silica rated highest followed by hydrogen sulfide. The remaining materials fall somewhere between group (3) and group (1). The number of exposed workers for each material is shown in the appendix with the number of job classifications scheduled for surveillance shown in table 1.

Priority based solely on the OSHA standard status is as follows. Vinyl chloride and asbestos rate highest because of existing standards. Because of impending proposed standards, group (3), benzene and free silica follow after vinyl chloride and asbestos. OSHA activities indicate glycidyl ethers, allyl alcohol, hexane and hydrogen sulfide would follow group (3) proposed standards. The next stage of standards development would include group (2) and ethylene dibromide with chlorine appearing near the end of the SCP list. No standards promulgation is foreseen for the aromatic amines in EPON Curing Agents for at least the next few years.

B. Monitoring Schedule

The vinyl chloride sampling results for 1975 indicate that eventually the frequency of monitoring can be reduced. Likewise, the 1975 results for benzene are low and a reduction in monitoring is likely. As the AC abatement program proceeds and exposures drop, so