

A PROPOSAL FOR A HEALTH STUDY OF VINYL CHLORIDE WORKERS

PRESENTED BY

TABERSHAW-COOPER ASSOCIATES, INC.

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Introduction

Tabershaw-Cooper Associates, Inc. is happy to respond to the request from the Manufacturing Chemists Association for a proposal to study the health of vinyl chloride workers. Our organization is well qualified to carry out such a project because our staff has had extensive experience in the areas of occupational medicine, industrial hygiene and epidemiology.

Our personnel includes three full-time occupational health physicians, two experienced industrial hygienists whose services are available as required, and a health studies staff concerned with the acquisition and analysis of health data in an occupational setting. The health studies staff is composed of a full-time professional epidemiologist, a statistician-programmer and appropriate clerical personnel. It is organized to conduct health studies, is cognizant of the need for timeliness in such studies, and can be responsive to new demands without administrative delay. The health studies staff is experienced in successful techniques of tracing and follow-up, and has operating computer programs for the complex calculations involved in health status studies.

At the present time, TCA, Inc. is responsible for organizing and maintaining a physical examination and industrial hygiene program for occupational work groups, and is carrying out several long-term follow-up health studies in selected industries. Among the latter, the study which is closest to completion has successfully followed and accounted for slightly over 96 percent of the study population.

Possible methods of study

There are essentially three ways to study the effects of occupational exposure, each of which can be useful in appropriate situations. One is to measure the functioning of selected physiologic systems which one suspects may be affected, in either a cross-sectional or serial study, hoping to detect subclinical changes not accompanied by diagnosable disease. While presumably of high sensitivity, this technique inevitably leads to serious questions as to the significance of minor physiologic deviations, which must be resolved by studies of morbidity or mortality.

A second approach is to measure the prevalence or incidence of diagnosable illness or morbidity, either in a cross-sectional survey or by analysis of reported illnesses or absenteeisms over a period of time. Cross-sectional surveys are useful for chronic illnesses of relatively long duration such as silicosis, but are of little or no value in many other conditions such as lung cancer. Morbidity is virtually impossible to measure from records of a population on a retrospective basis, since it is affected by many extraneous factors, such as health plan coverage, policies of plant medical care, and the quality of medical records.

A third approach is to observe the pattern of mortality in an exposed population and to compare it with the general population and with other occupational groups. While it cannot be expected to answer all questions regarding effects of exposures, a normal mortality pattern is reassuring. If there is excess mortality from causes associated with a specific body system, this can provide valuable clues as to cause-and-effect relationships and for appropriate biological monitoring to detect early disease.

A mortality study is a logical precursor to any further investigations for at least three reasons. First, the study provides a data base in the population to be studied, so that subgroups identified by age, length of service, job title, etc., can be found and investigated at a later date. Second, the process of studying mortality provides an opportunity to review and describe the quality of records, so that the feasibility of other health investigations can be assessed. Third, if any deviant pattern of mortality is actually found, it will usually indicate what areas of morbidity should be studied or what subgroups of the population should receive further attention.

TCA, Inc., believes that an essential step in appraising the health implications of working in vinyl chloride production is to know the cause-specific mortality pattern. We therefore propose to conduct an epidemiological study of mortality in vinyl chloride workers. The study would start with existing records and would follow workers to determine their current status. The objectives would be:

- (1) to compare the mortality of individuals who have worked in vinyl chloride plants with that of the general population, corrected for area, age and sex;
- (2) to compare mortality patterns within the population of vinyl chloride workers, based upon estimated occupational exposure; and
- (3) to compare mortality among vinyl chloride workers with the mortality of other occupational groups which TCA, Inc. has studied.

Study design

Although a more detailed study plan will be developed as actual plant populations and processes are defined, the following outline covers the essential elements.

Among the 19 companies participating in this study there are 13 plants in the continental United States and 1 in Puerto Rico devoted exclusively to the production of vinyl chloride (VC), and 28 polyvinyl chloride (PVC) plants in which some workers may be exposed to the vinyl chloride monomer in the early stages of the production process.

On the basis of the Manufacturing Chemists Association survey of these participating companies, a study population of plants will be chosen. It will include all 14 of the VC plants, except those which have been in operation a year or less, and any PVC plants which report non-trivial numbers of workers exposed to the monomer. (See the Budget section for details).

In each plant, the study population will consist of all workers who were employed for a least one year, beginning at the earliest date for which records are available, and ending on December 31, 1972. It has been estimated that this group will consist of approximately 5,000 current employees. Our experience indicates that retirements, terminations and deaths before December 1972 will increase the total study population to about 7,500.

For each person, age, date of employment, nature and duration of employment, and ethnic origin (if possible) will be determined. For those who have died, copies of the death certificates will be obtained, either from plant records or from the public health authorities. These will be classified by cause of death, using the same rules as are used in national death statistics.

Those who left employment will be traced to establish their present status, using post office notification, drivers license records, and other methods which in the past have enabled us to trace over 96 percent of our study population.

In addition, as much information as possible on occupational exposure will be obtained from plant management. At a minimum, we expect to be able to classify job positions as involving either high, medium or low exposure to vinyl chloride. Both personal and plant data will be kept in the strictest confidence, and no individual worker or plant will be identified by name in any analysis or communication about the data.

Data collection

A TCA, Inc. team will photograph all relevant personnel records at each plant. Involvement of plant personnel during the course of the study will be minimal, unless desired by local management. The data collection team will require a contact person at each plant through whom arrangements can be made and information channeled to local management. The only physical equipment required at the plant is a worktable with a nearby electrical outlet. Our practice is to record data for active employees first and return the records to the files immediately, and then to examine the records for retirees, terminations and deceased employees.

Data analysis

Depending on the actual population size and the duration of follow-up activities, it appears probable that about 800 to 1,000 deaths will occur in the study group.

The basic mortality analysis will begin with a calculation of the number of person years of observation contributed by the study group at each year of age and at each point in time during the study period, using a computer program prepared specifically for this purpose. These data will be used together with the observed deaths at each age and each point in time to calculate mortality rates, which will be compared with the mortality to be expected in the comparable U. S. population, as obtained from national statistics. Techniques of this kind are well developed and have been used for some time in chronic disease studies. (See California Tumor Registry, Cancer Registration and Survival in California, California State Department of Public Health, 1963.)

The above analysis will be repeated for specific causes of death, paying particular attention to competing risks, or interaction among different causes of death.

In addition, analysis of general and cause-specific mortality will be repeated for subgroups of the study population identified as having high, medium and low exposure. The resulting mortality figures will be interpreted not only in light of their statistical significance, but for their relevance to known and suspected mechanisms of action of vinyl chloride, and for their implications with respect to future studies of special areas and groups.

The validity of the conclusions reached from a study of this kind depend crucially on the competence with which data are collected and processed, and the appropriateness of the comparative mortality analysis. TCA, Inc. is uniquely qualified in both areas. The

procedures and analysis proposed here have been tested successfully in other industries and as a result, TCA, Inc., has a data bank of mortality profiles, which provide a realistic standard against which to compare vinyl chloride workers, and which furnish a second benchmark in addition to the general population statistics. TCA, Inc.'s resources in occupational medicine and industrial hygiene further guarantee that the results of the mortality analysis will be evaluated in relation to the current state of knowledge in these fields.

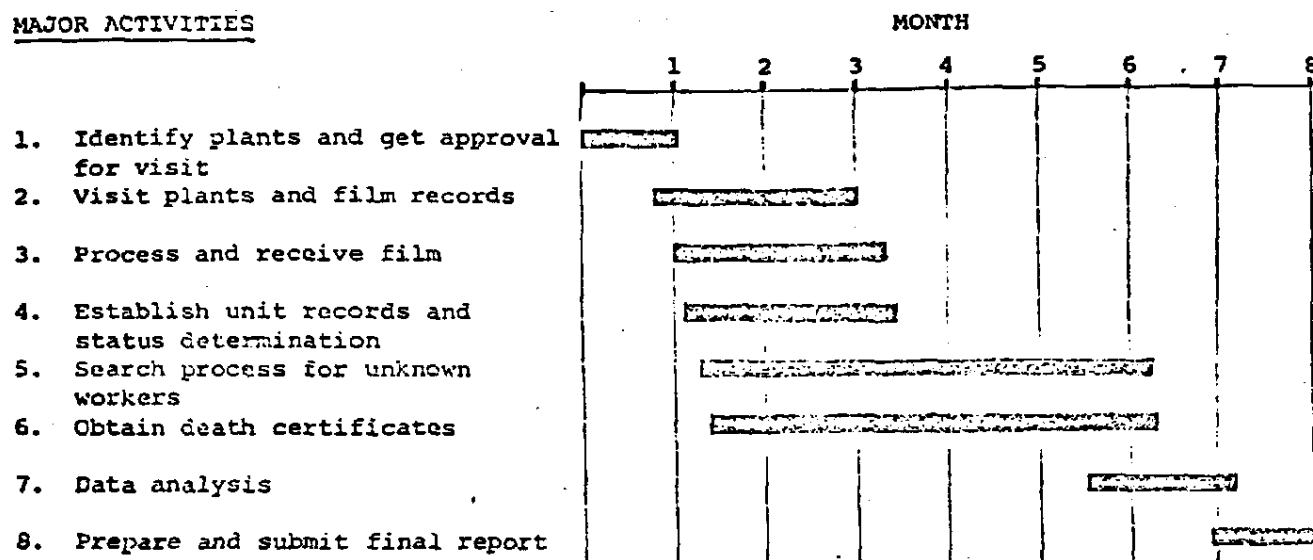
Timetable

Exhibit I outlines the basic timetable of the major activities involved in the mortality study. The proposed study will require eight (8) months for completion. Once the plants are identified and approval is received, the records collection from the plants will require approximately two months. Processing of the film and classification of the records will require an additional month. At the same time, follow-up procedures will be initiated. The search process for the status of unknown workers and the collection of death certificates for those who have died are the key follow-up activities and are the most time consuming in the mortality study. These activities are also the ones most beyond our immediate control and it is for this reason that the study can not be successfully completed in a shorter time span. Every effort will be made to achieve a follow-up level of 95% or more and if this is accomplished earlier than anticipated, TCA, Inc. will strive to supply the Manufacturing Chemists Association with a written report in less than eight months. Progress reports will be made on a mutually agreeable schedule through the course of the contract.

EXHIBIT I

MORTALITY STUDY FLOW CHART

MAJOR ACTIVITIES



- (a) to compare the mortality of individuals who have worked in vinyl chloride plants with that of the general population, corrected for area, age, and sex;
- (b) to compare mortality patterns within the population of vinyl chloride workers, based upon estimated occupational exposure; and
- (c) to compare mortality among vinyl chloride workers with the mortality of other occupational groups which TCA, Inc., has studied.

This study is expected to require at least 8 months for completion and reporting. A copy of the protocol is attached.

IV. Recommendations for Action

1. VCM producers and consumers will undertake plant atmospheric monitoring programs.
2. The industry members have agreed to exchange analytical test methods to expedite the above program.
3. The industry members of the MCA group have agreed to implement the 1972 ACGIH adopted TLV value of 200 ppm for VCM in producing and consuming plants and to work towards lower levels such as 50 ppm.
4. The results of the animal and epidemiological test programs now in progress will be followed closely by the MCA Technical Task Group on Vinyl Chloride Research and the results referred to a qualified group such as the National Academy of Sciences for review.
5. The MCA group welcomes the participation of NIOSH in the evaluation of the test data and the formulation of additional programs which may be indicated.