

EXCERPTS FROM

A PROPOSAL FOR A HEALTH STUDY OF VINYL CHLORIDE WORKERS

PRESENTED BY

TABERSHAW-COOPER ASSOCIATES, INC.

March 6, 1973

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.

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.

URL 02384

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.

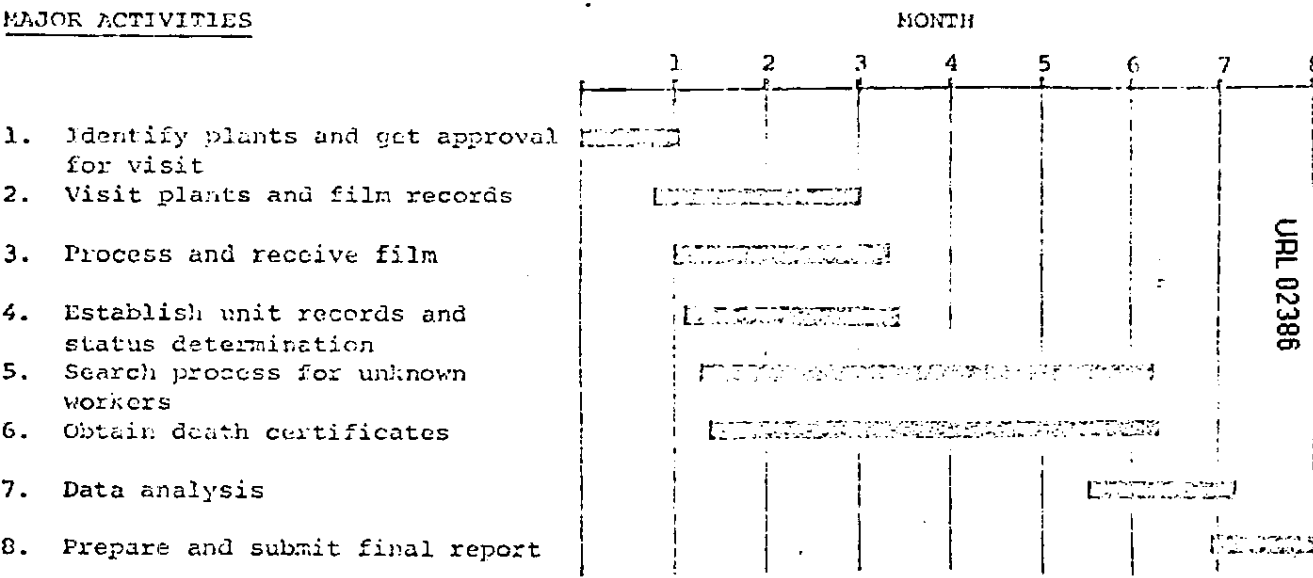
Timetable

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.

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MORTALITY STUDY FLOW CHART

MAJOR ACTIVITIES



PROPOSED BUDGET

Staff Personnel - Health Studies Unit

Project Director, Statistician, Programmer,

Occupational Physician - Toxicologist, Industrial

Hygienist, Clerical Assistants

Total Staff Personnel Costs \$20,580

Direct Costs

Records Collection Film Processing \$ 3,300

Death Certificate Fees 2,000

Data Processing 3,000

Printing, Forms and Supplies 500

Total Direct Costs \$ 8,800

Total Personnel and Direct Costs \$29,380

Overhead, G and A, Profit \$34,615

Total Contract Costs \$63,995

Estimated Travel Costs* \$ 7,350

Total Contract Price \$71,345

- * Travel costs are based on visits to 14 vinyl chloride and 10 polyvinyl chloride plants. This cost estimate will be adjusted once the actual plant populations are identified.

URL 02387

4/4/73

Studies to be under way end of April

Sheffield trying to get permission for Melloni to visit U.S.

Extension of study - Add 100 animals with bedding.

Will send letter asking to authorize present commitment on basis of increased volume
(1,600,000,000⁺ increased capacity (16%) - Increased cost $\frac{15}{105}$

Total commitment slightly less than previously. Original 2 payments same, smaller rebate at end. Original $\frac{40}{40}$ new $\frac{40}{40}$ payment plan.
5 18

Epidemiology study. Dr. ~~Jeff~~ W.R. Haffey - Jethersham. Cooper.

Identify each individual in each plant who had worked at least 1 yr.

Cp. mortality vs U.S. Males.

Active emp. as of close of study

" " & retired

alive

Dead

Terminated previously - present status unknown.

Use grille microfilm machine. Copy data card. Can copy 4,000-5,000 sheets/day.

Can actually handle ca 500 records/day.

Some plant records computerized.

Estimate of degree of exposure high, low & med. by job title.

Only 3-4 people see original records - rest. at punch cards.

No plant ~~and~~ identified & compared with any other in any publication.

Only mortality data - Study confined to personnel records - not medical.

4 of 20 sponsors not represented. Diamond Shamrock, Ohio, Firestone.

B.P. Chemicals.

Can start within 2 months after get