

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

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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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