Proposal for a Longitudinal Study of the Respiratory Health of Talc Workers

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I. Proposed Study

A longitudinal study of pulmonary function and respiratory symptomatology in employees of Windsor Minerals is proposed. The primary objective of this study is to further delineate the relationship between occupational exposure to non-asbestiform talc and its ore and respiratory health. The specific aims are:

1. To determine if changes in pulmonary function and/or reported respiratory symptoms greater than those observed in Vermont comparison groups without dust exposures can be detected in workers with occupational exposures to non-asbestiform talc.

2. To determine if rate of change of pulmonary function and/or respiratory symptoms are related to environmental levels of respirable dust in the talc mines and mill.

A secondary objective is to assess the feasibility of one or more followup techniques to determine whether selective removal from the work force occurs due to respiratory illness.

II. Rationale

Talc workers in Vermont are in an unusual setting--the talc in Vermont is claimed to be essentially free of either silica or asbestos, both of which are often found in conjunction with talc deposits. Hence, an opportunity exists to study the effects of talc in the absence of hazardous contaminants. Previous studies (Rubino, et.al., 1976; Kleinfeld, et.al., 1964, 1967, 1974) have been made on workers

exposed to talc containing such contaminants. In 1972, Sylwester and Green (1976) surveyed the talc workers in one talc mine and mill in Vermont as part of the Pulmonary SCOR (Specialized Center of Research) at the University of Vermont. Excess reported symptoms were found, but no significant pulmonary function decrement due to dust exposures was observed. Two other studies have recently been carried out on talc workers in Vermont--Harvard University has completed a one-year prospective study of pulmonary function in Vermont talc workers, but results are not yet available. A principle goal of that project was to obtain evidence for a proposed talc occupational standard initially proposed in the report of a study of rubber workers exposed to talc (Fine, et.al., 1975). The second project concerning Vermont talc workers has been conducted by NIOSH in cooperation with VOSHA on the mortality experience of talc workers in the state. Again, no results have been published, but a non-technical summary appeared in the Wall Street Journal of November 2, 1976, in which an excess of mortality is reported from non-cancerous respiratory disease and a lesser excess from lung cancer. The study and the methods used have not yet been published and are not available for review and evaluation as of February, 1977.

The effects, if any, of occupational exposure to non-asbestiform talc are therefore not yet clearly defined. Also, the possible interactions between talc exposure and variables such as age, smoking history and respiratory status prior to occupational exposure to talc have not been fully evaluated. This study is proposed as a logical

extension of the SCOR and Harvard surveys. The longitudinal design will provide an opportunity to relate changes in respiratory health over time, if any, to selected employee characteristics and environmental conditions. If deleterious effects on respiratory health are detected appropriate preventive measures can be developed.

III. Pulmonary Function Model

The basic pulmonary function decrement model that is hypothesized herein is illustrated in Figure 1. The average population pulmonary function trend is assumed linear (at least over the relatively short period of this study) with components due to age, smoking history, sex, etc. This, however, is merely the trend observed and it is hypothesized that the actual functions are cyclic, with average population pulmonary function in winter due to increased respiratory infection and symptoms, and with highest average function in summer due to lower prevalence of infection. McKerrow and Rossiter (1968) reported an annual cycle in $FEV_{0.75}$ in 28 pneumoconiotic working ex-miners of 44 ml amplitide, and a cycle of 10 ml in laboratory workers. The ex-miners average cycle was at a minimum in early February, and a maximum in early August when fit by a sine curve but there also was wide variation in peak times in individuals. The cycle could not be explained by weather variable cycles, and they suggest that it may be an intrinsic biologic rhythm.

A second hypothesis is that the variance of lung function estimates will be greatest in winter and least in summer, due to larger between and within individuals variation from both increased preva-

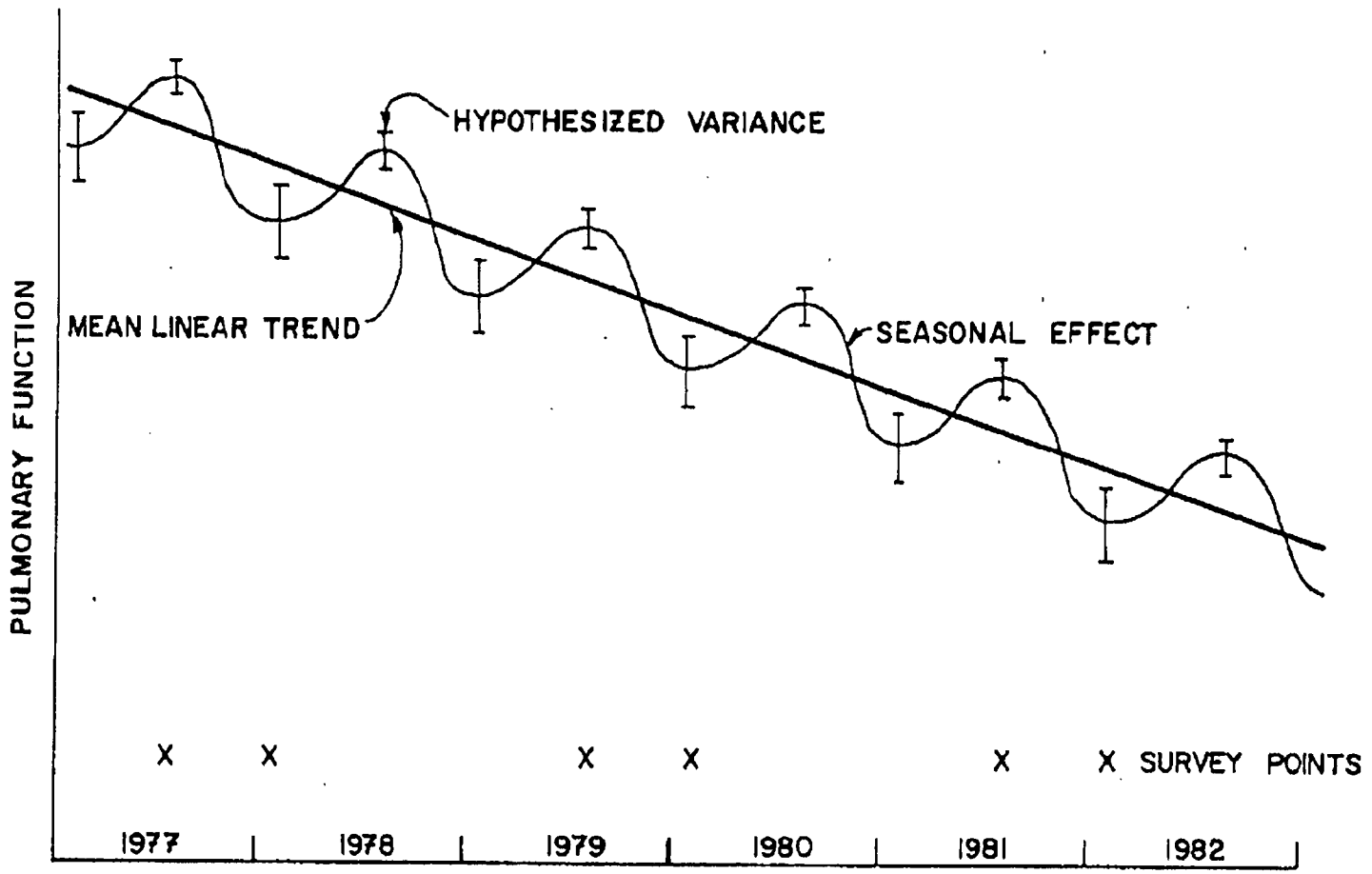

FIGURE I. Hypothesized lung function model, with seasonal variation around a linear average pulmonary function trend.

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lence and varying degrees of severity of acute upper respiratory infections and exacerbation of chronic respiratory problems. Sargeant and Tromp (1964) report increased bronchitis, colds, and influenza (with possibly increased variation in pulmonary function) in the period December to February, though they report a slightly offset cycle for asthma peaking in late autumn and relatively low in mid-winter. McKerrow and Rossiter (1968) did not present variation by time of year. While Figure 1 illustrates equal excursions around the trend from year to year, this may not be assumed--events such as influenza epidemics could severely bias pulmonary function surveys at a point in time, but do not occur in all winters.

Several guidelines are suggested by this model: 1) long-term pulmonary function <u>trend</u> surveys will encounter less "noise" (variance) due to superimposed temporary conditions if made in summer, 2) surveys to be compared with other surveys should be taken in the same seasons, 3) surveys to detect <u>absolute</u> values of pulmonary function (rather than trends such as annual decrement) should either a) average winter and summer surveys, or b) occur in fall or spring to approximate better the average value of the function of interest.

The statements discussed above will now be re-stated as hypotheses:

1. Average summer lung function in the population will be higher than in winter.
2. Winter surveys will exhibit higher variance than summer surveys.

To investigate these hypotheses as well as detect basic pulmonary function decrement rates in Windsor Mineral talc workers the following study design is proposed (refer also to Figure 1): not less than three sets of surveys of the entire cooperating Windsor Minerals employee population will be made in both winter and summer at 2-year intervals, with a minimum length of study of 4½ years resulting. Comparisons will be made between mean winter pulmonary function and reported symptoms, and mean summer values to test hypothesis 1; further, the differences in variances encountered in winter and summer will be compared and tested for difference.

IV. Possible Annual Cycle Survey

After the initial pair of surveys (scheduled for summer of 1977 and winter of 1977-78), a special annual cycle study will be explored for feasibility. Accompanying budgets do not provide for conduct of the special study. Such a budget would be negotiated separately should the special study be undertaken. If it is found to be feasible to detect monthly trends, as estimated from the initial winter and summer survey results, with a sample size that can be reasonably obtained, a subsample (stratified by dust exposure) of the Windsor Minerals employee population will be surveyed monthly for one year to estimate the magnitude of the annual cycle. This special monthly survey series is not critical to the basic questions of detecting pulmonary function decrement in talc workers and comparison groups, but it would contribute to pulmonary function studies in general.

Not less than 14 monthly samples would be conducted--13 to completely bracket one 12-month period, with one survey prior to this to minimize the training or familiarity effect in the main monthly surveys themselves.

V. Pulmonary Function Comparison Values

Published predictive equations for expected or normal lung function will be used to establish comparison values for observed lung function of Windsor workers. Equations will be used both from studies elsewhere and for Vermont workers without dust exposures (SCOR data).

A complicating factor in the proposed longitudinal survey is the proposed institution of a spirometric hiring standard at Windsor Minerals. This will result in a continually increasing proportion of workers at Windsor Minerals who were selected for good lung function. It will be necessary to stratify Windsor workers into those selected by this standard and those not so selected.

Predictive equations for expected lung function for the workers with initially high values (those hired under the spirometric standard) will be developed from the SCOR data set. Several hundred workers were surveyed in 1972 and 1976 for pulmonary function. These can be stratified into groups meeting and failing to meet the Windsor hiring criteria on the 1972 survey. Then, for those meeting the Windsor criteria, predictive models will be developed using the 1976 followup data. This will provide predictive models for a population selected for initially high lung function, reasonably comparable to the Windsor workers hired after meeting a similar spirometric standard.

The SCOR data offer a second form of comparison. This study proposes surveys at 2-year intervals, and specifically will allow a 4-year followup survey on all workers still at Windsor. The SCOR surveys also document a 4-year followup on many Vermont workers. These workers will be matched to Windsor workers' smoking status and other relevant variables (if possible), and 4-year decrements will be compared.

VI. Specific Approach

A. Employees of Windsor Minerals will be surveyed twice per year (summer and winter) every other year for five years (a total of 3 pairs of seasonal surveys). Each survey will include administration of a questionnaire and spirometry. In addition, optional studies of a subsample may be carried out, as discussed above.

B. Environmental sampling for respirable dust will be conducted in the mine and mill during the same five-year period, characterizing exposure in all types of work areas during each year of the study. This will serve principally as a validation for the samples regularly collected by Windsor Minerals.

C. Terminating employees of Windsor Minerals will be invited to continue participation in the study for a minimum of one year after termination. (Any who terminate during the final year of the project will be asked to participate to conclusion of the study period.)

VII. Methods

A. Spirometry

Spirometric tests will include FVC, FEV_1, and PEFR. Measurements will be made with a Hewlett-Packard 47401 Lung Function Analyzer with graphic and numerical output, or similar equipment.

B. Questionnaire

A modification of the SCOR (Sylwester and Green, 1976) questionnaire will be used. Modifications will include the addition of questions on employment history, brand of cigarette smoked, weight, and physical activity.

C. Job Positions

All changes in employees' job positions and reasons for changes will be recorded by Windsor Minerals personnel at the time they occur, on a form to be developed.

D. Medical Records

Information pertinent to the duration and cause of absenteeism for medical reasons will be abstracted from Windsor Minerals medical records after obtaining employee permission. In addition, results of pre-employment physical exams and spirometric tests will be abstracted.

E. Environmental Sampling

Respirable mass samples of dust will be obtained by full-shift personal samplers for all work area types, specifically

including mill crusher and bagging areas, processing areas and mining operations. These data will be used to characterize the current dust exposures in the industry. Such comprehensive sampling will be carried out simultaneously with each full-industry survey (or six times during the project), in order to characterize both winter and summer exposures which may be different due to differing ventilation, etc. Further, Windsor Minerals will continue its own monitoring program of continual spotchecks of respirable mass dust exposures. Compatibility between methods and results of this project and Windsor Minerals methods and results will be investigated. MESA data and other previously collected data will be obtained and these will allow an adequate characterization of dust exposures for the past three years. Exposures prior to that date will be estimated based on known process characteristics and modifications, if any workers are present with such long exposures. Samples collected will be analyzed gravimetrically, and selected samples will be analyzed for free silica and asbestiform fibers. In addition, Windsor Minerals will provide analysis data on ore samples and product samples that are routinely analyzed by their consultants.

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