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NIOSH Comments to DOL

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Supplemental Comments to OSHA Docket H-052C
submitted by
National Institute for Occupational Safety and Health
Reviewing "Medical Surveillance Data in the Cotton Textile Industry"
by Dr. Harold Imbus

The Occupational Safety and Health Administration (OSHA) has requested a review from the National Institute for Occupational Safety and Health (NIOSH) of the report submitted by the American Textile Manufacturers Institute (ATMI) entitled, "Medical Surveillance Data in the Cotton Textile Industry", by Harold Imbus, M.D., Sc.D. This submission is the second by ATMI, since the announcement of proposed rule changes in February, 1982. The first submission was a very brief account of two surveys, one covering 150,000 workers and the other 50,945 workers. NIOSH's review of the first submission criticized the surveys because of their lack of any discussion of methodology. Although it is not stated directly, this new submission appears to be an expanded report of the second survey mentioned in the first submission, since both start with a base population of 50,945. This second submission is considerable more detailed in its analysis of data than the first, but again its methodology is unclear. For this reason this review will detail the shortcomings of the methodology rather than comment on any of the data presented in the more than 80 tables, figures and exhibits.

Selection

The study population consisted of 50,945 employees from seven ATMI-member companies. Since only workers with detailed pulmonary function data and dust data were analyzed, the final figure for analysis was 41,173. According to a recent (August 8, 1981) New York Times article, ATMI has approximately 200 member companies. It is likely these seven member companies are not representative of all 200 members or of the textile industry as a whole. Although the author does not make any comments regarding the sample selection and its relationship to the industry as a whole, the covering letter by Mr. W. Ray Shockley, Executive Vice-Presendent of ATMI, includes a caution for interpretation that "as a whole, the companies that responded to the Questionnaire have made greater efforts to reduce exposure levels and have achieved lower overall exposures than the companies that did not respond to the Questionnaire". Mr. Shockley suggests, therefore, that the exposure data "presents a more favorable picture . . . than actually obtains in the industry as a whole". If this is true, the corollary to this is that the response data (health effects) also may present a more favorable picture than in the industry as a whole at all gradations of dust exposure. The basic problem is that this survey is compiled from data gathered for compliance purposes, and is not based on a statistically sound strategy which would be essential for making inferences from the study group to the "universe" from which the study group came.

Ascertainment

The collection of the data in a uniform fashion is critical for pooling information. ATMI suggests that the data were collected in the manner prescribed by OSHA in its Cotton Dust Standard. But this Standard was instituted for compliance purposes and its methods allow for quite a bit of variability in technique, which makes pooling of data gathered from different sources for compliance purposes very difficult. For example:

1) The questionnaire was the standard BMRC, most likely the one detailed in the OSHA standard of June 23, 1978. Were all these questionnaires administered by trained interviewers, or were any self-administered?

2) Was the diagnosis of symptomatic byssinosis provided to the author by each plant for each individual, or did they themselves take the raw data and assign the results to a definition? It is one thing to state that the Schilling's Grades for byssinosis were used, but it is quite another to state exactly which questions from the questionnaire were used to produce the diagnosis. Schilling's Grades include symptoms such as periodic cough, "Monday" shortness of breath, as well as, periodic chest tightness and historical periodic chest tightness. It would have been helpful to know if all or only some of these questions were used in developing the definition by byssinosis, because the sensitivity of the definition can be altered considerably.

3) The report states that all post-shift pulmonary function tests were done between "four to six hours into the workshift, as required by th OSHA Standard". NIOSH's reading of the OSHA Standard is that the post-shift spirometry shall be repeated "no sooner than four hours and no more than 10 hours, after the beginning of the work shift" (Federal Register, June 23, 1978, page 27357). Although it is therefore "legally" acceptable to conduct post-shift examinations between four and six hours after the work-shift has begun, as a scientific matter NIOSH conducts its studies so that post-shift examinations are done after six hours of work, to allow sufficient time for shift drops to occur. Therefore, NIOSH is very concerned that the acute-shift-change data may be inadequate to assess objective response to dust exposures due to the short time between the pre- and post-shift examinations.

4) Researchers know that in large epidemiologic endeavors as more types of data are needed to assess an individual exposure and response, the greater the chance for missing or acquiring technically unacceptable data. For example, in this study one respondent company's data was not used because dust exposure information was not forthcoming. Similar problems can occur with pulmonary function data, especially where both pre- and post-shift information is required. If the 41,173 remaining workers had complete and technically acceptable pulmonary function data, it would have been helpful to know from what larger population of study subjects these individuals came. If the 41,173 include some individuals with technically unacceptable data (pre- or post-shift, or even questionnaire data), then

readers shoud know to what extent data had to be thrown out. And if no data were thrown out, either the companies have perfect technicians, equipment and subjects or some technically unacceptable data have been included in the study.

5) For computing mean FEV_1 shift-changes the data on a subset of 20,127 employees were used. This is fine if we knew that the subset was not markedly different from the initial 41,173 (or for that matter 50,945). In fact, ATMI gives us no demographic breakdown at all (sex, race, geography, age, job tenure) of any of the populations mentioned in the report.

6) It would be helpful to know how the dust exposure levels were assigned to each individual. Are these values a result of one measurement or an average of more than one measurement? Were the individuals assigned dust levels according to the closest vertical elutriator by which they worked or were they given a group or job "mean"? Were the dust levels taken on the exact same day as their pulmonary functions, so that they could be matched directly with response, or were they taken on other days? If they were taken on other days, was the percent cotton content of the dust similar on the different days? Without knowing these answers it is extremely difficult to judge how reliable the dose-response data are.

7) ATMI presents two-years longitudinal data (three data points) on 9,271 from one company. Because of this large number of persons it considers the data to be "meaningful", but it takes more than just large numbers to achieve meaningfulness. For one thing three points of longitudinal pulmonary function data are not generally sufficient to detect trends. In addition, we do not know what the size was of the initial population from which these 9,271 longitudinal "survivors" are derived. We do not know how these "survivors" may have differed demographically from the "non-survivors" or whether their initial pulmonary function results were different from the initial result of the "non-survivors". With such large numbers the cohort could have been divided into age, sex, race, smoking, and job tenure groups, to eliminate or reduce the effects of these characteristics on the FEV_1. The report instead produced regression lines, but we are not told what independent variables are in the regressions.

ATMI explains that "due to the volume of data and the necessity to compile, in a short period of time, a thorough statistical analysis of data was not possible". NIOSH concluded that this second submission by ATMI, despite its volume, sheds no more light upon the health effects of exposure to cotton dust in the textile industry than did the first submission, and should be disregarded by OSHA in its rulemaking effort.

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15. Supplementary Notes

16. Abstract (Limit: 200 words) This testimony offered a review of a report submitted by the American Textile Manufacturers Institute (ATMI) dealing with medical surveillance data in the cotton textile industry. This review was restricted to comments on the shortcomings of the methodology used in the study rather than on any of the data presented. The ATMI study used seven member companies for its investigation. NIOSH contended that these seven companies were not likely to be representative of all 200 members of the ATMI or of the textile industry as a whole. ATMI asserted that the companies which responded to the questionnaire from which data was taken for the report were those companies who have made greater efforts to reduce exposure levels and have achieved lower overall exposures than the companies which did not choose to respond. The study was actually based on data gathered for compliance purposes and not on a statistically sound strategy which would be essential for making inferences from the study group to the whole population from which the selected study group came. NIOSH also questioned the accuracy of the pooling of data gathered from different sources for compliance purposes and provided several examples where questions arose about the pooling methods used and the completeness of the results thus obtained. NIOSH concluded that, in spite of the large size of this second report by the ATMI, it provided no more illumination of the problem than did the first report and should be disregarded by OSHA in its rulemaking efforts.

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