

CORRESPONDENCE

An epidemiological study of workers potentially exposed to ethylene oxide

Sir,—We were surprised to see the recent publication by Wong and Trent (1993;50:308-16) of a mortality study of 18 728 workers exposed to ethylene oxide. Wong and Trent have analysed the data from the study originally conducted by ourselves at the National Institute for Occupational Safety and Health (NIOSH) in collaboration with the National Cancer Institute (NCI). Wong and Trent did their study based on the personnel records that we microfilmed and sent to them at the request of the companies studied. They have included 18 728 workers instead of our 18 254 (for reasons we do not understand), and they also have one additional year of follow up.

Nowhere in their article do Wong and Trent cite our work,¹ which was published fully a year before their article was accepted for publication (Wong was a reviewer of our work before its acceptance). Nor do they make clear that we initiated and designed the original study, that we collected the data at the 14 study plants (after visiting 35), that Wong was hired by the industry involved as a consultant, and that he was provided with the data we collected as a way of conducting an independent audit of our selection of the exposed from among all plant employees. Wong and the companies involved then decided to go further and conduct their own analysis of the data. Much of this background to the study has been described.²

For Wong and Trent to state that "we studied by far the largest cohort of workers exposed to ethylene oxide to date" without explaining this background is a misrepresentation of who actually did this study.

Wong and Trent's results are similar to ours, as might be expected (both analyses are straightforward life table analyses), although their interpretation tends to downplay the carcinogenic risk of ethylene oxide. Despite general agreement, there are some problems with their analyses, primarily due to the fact that they did not code detailed work histories. For

example, their analyses by latency (time since first exposure) are invalid, as they did not code dates of first exposure. This may account for some inconsistencies between our findings of positive trends for all cancers and haematopoietic cancer with latency and their failure to find such a trend.

We believe that the reanalyses of data, for the purpose of using new analytical techniques or for meta-analysis, is often worthwhile and NIOSH has often made its data available for these purposes. We strongly object, however, to Wong and Trent having conducted an essentially duplicate analysis without citing the prior analysis or fully explaining the origins of the data. We do not know the policy of your journal regarding this issue, but we suspect that you were unaware of our prior analysis.

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- 1 Steenland K, Stayner L, Greife A, *et al.* Mortality among workers exposed to ethylene oxide. *N Engl J Med* 1991;324:1402-7.
- 2 Steenland K, Stayner L, Greife A. Assessing the feasibility of retrospective cohort studies. *Am J Ind Med* 1987;12:419-30.

Authors' reply

Sir,—To respond to the comments raised by Steenland and Stayner, an understanding of the background of our study¹ and the NIOSH study² is necessary. In the mid-1980s, the National Institute for Occupational Safety and Health (NIOSH) approached the Health Industry Manufacturers Association (HIMA) for access to its member companies' data. Specifically, NIOSH was interested in conducting a cohort mortality study of workers exposed to ethylene oxide. One of us (OW) acted as HIMA's consulting epidemiologist to assist both HIMA and NIOSH in identifying the appropriate data for the study. The initial agreement between HIMA and NIOSH was that NIOSH would provide all the necessary data for HIMA or its consultant to audit and verify NIOSH's data and analysis. In particular, such data would include coded work history information and death certificates obtained by NIOSH. After NIOSH had completed microfilming employment records at the participating companies,

NIOSH recanted its earlier agreement of providing all the necessary data to HIMA for an audit and verification.

In 1988, HIMA awarded us a contract to conduct an independent study of employees of its member companies who were exposed to ethylene oxide. For demographic and work history information, HIMA member companies provided us with more than 44 000 employment records. These records included not only the NIOSH microfilms but also additional records not microfilmed by NIOSH (microfiche, hard copies, and computer tapes). For exposure classification, we relied primarily on the walk through surveys conducted by NIOSH industrial hygienists at facilities of HIMA member companies. Data collected at these surveys included information provided by HIMA member companies, such as process histories, industrial hygiene data, job descriptions, discussions with company industrial hygienists, etc. In anticipation of future comparisons between our study and the NIOSH study, we used the same cohort definition of a minimum of 90 days of exposure. In reviewing the NIOSH microfilms, we discovered illegible records, inconsistent dates, and gaps in employment histories. It was necessary for us to contact individual companies to resolve these discrepancies. We then coded and computerised all the employment records. Our review of these records identified a cohort of 18 728 employees.

We sent the data to the Social Security Administration (SSA) for vital status determination. To supplement the SSA follow up, we also sent the data to the National Death Index (NDI) and member companies for determination of vital status. We also checked our cohort against the SSA Death Master File (DMF). For those identified to have died, we obtained death certificates. We completed our study and presented the results to HIMA in late 1990 and a final report was submitted to HIMA in 1991. Our 1992 paper is a shortened version of this report. We did not consider it necessary nor appropriate to include the above lengthy discussion of the background of the two studies in our publication. In retrospect, however, we regret the oversight of not citing the NIOSH study.