CORRESPONDENCE

Evidence for adverse reproductive outcomes among women microelectronic assembly workers

Sir,—We read with interest the paper by Huel *et al* (1990;47:400-4). This paper poses both scientific concerns and interesting questions regarding research in a litigious environment. The authors state that over 100 workers had received compensation on the basis of multiple health problems. Clearly, workers who might be involved in litigation as plaintiffs have a strong interest in the recognition and documentation of work related health problems. Could the exposed workers have perceived that their potential for compensation might have been influenced in some way by a positive study? The authors fail to discuss this as a potential source of bias for a self reported outcome. Although spontaneous abortion was defined as "diagnosed miscarriages," and the name of the consulting physician was indicated, the data were collected through a self administered questionnaire. No attempts to validate the outcomes were cited even for a sample of exposed workers and referents. Furthermore, the selection of referents is curious—they were selected by the exposed workers—and as the authors' note, this could create further bias.

Not only is selection bias a concern with regard to the referents, but it may also be so with regard to the exposed workers. Only 144 women were selected from 3371 workers during their period of employment (representing 4% of the worker population). This population contributed to the study a total of only 25 pregnancies during employment. Although the sample size is small, the authors provide no explanation regarding how workers were selected for participation. Were they selected through a well designed randomisation process or were they selected because they volunteered for the study? Could those with problem pregnancies or other health complaints during employment have been more likely to volunteer? Could they have been selected from a list of potential plaintiffs? Any procedure for

selection that does not draw a random sample could create sufficient bias to explain the authors' findings. This is especially true when the sample is meagre with respect to the worker population.

The authors indicate that their matching design would control for potential bias. Matching was performed, however, only on age, race, and number of pregnancies. There was no attempt to match on number of prior fetal losses (the most important known risk factor for spontaneous abortion). Nor was the prior fetal loss risk factor included in the statistical analysis. The classification of spontaneous abortion depended on at least one such event within the study period but the authors do not indicate whether there was any predominance of multiple events in either the exposed or referent group.

A further concern is that the odds ratio for the analysis restricted to the 25 pregnancies during employment was described as having weak precision, but no confidence interval was provided. How weak was the precision? Given the concerns about bias, weak precision would amplify doubts about the conclusions of the study.

Finally, the authors list several references that purport to provide evidence of previously recognised spontaneous abortion among workers engaged in similar occupational activity. One such reference is to the study by Pastides *et al*¹ of semiconductor workers in Massachusetts. This examined a very different population from that described by Huel *et al*. Pastides *et al* found an excess of spontaneous abortions in a small sample of integrated circuit (semiconductor) manufacturing workers, not microelectronics assembly workers or printed circuit board workers. The exposures were different from those described for the New Mexico cohort and the authors believe that their outcomes were most likely due to solvent exposure. Although one cohort in the Massachusetts study with a raised relative risk had worked with solvents, the statistically significant effect found was among workers that were *not* exposed to solvents.

In summary, the shortcomings of this study are of sufficient magnitude to preclude the inference of logical conclusions about reproductive health in the microelectronics industry. The anticipated contributions of other current studies of pregnancy outcomes

in this industry will be important to expand our understanding of this issue which affects large populations of female workers worldwide.

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1 Pastides J, Calabrese EJ, Hosmer DW Jr, Harris DR Jr. Spontaneous abortion and general illness symptoms among semiconductor manufacturers. *J Occup Med* 1988;30:543-51.

The authors' reply:

Sir,—We are grateful to Upfal and Pinney for providing us with an opportunity to elucidate certain aspects of our study of reproductive outcomes among a group of former microelectronic assembly workers. Most of their comments seem to stem from a fundamental misunderstanding or misreading of our article. They consistently refer to the number of pregnancies rather than the number of pairs of former worker referent women. This is reflected by their questions and comments concerning both the study design and the outcomes.

The design that we used has the advantage of providing a double control, one cross sectional and one prospective: each exposed woman, selected through the matching process (53 exposed mothers could not be paired "owing to matching constraints"), had one control and was herself her own control because firstly, matching was performed on strata of parameters including the number of children before the beginning of employment and secondly, the prevalence of reproductive outcomes could be compared after and before the beginning of employment (in this case the odds ratio (OR) was equal to 4.5, significant at the 5% level, which is close to the OR of 4 obtained when taking into account the spontaneous abortions before employment). This information was not included in the article, as it is obviously subject to aging (the mother's mean age (years (SD)) at pregnancy before employment was 21.1 (3.7) and postemployment, it was 27.5 (4.9)).

Throughout their letter, Upfal and