Correspondence

Cancer mortality in an Italian rubber factory

SIR—A recent article (Bernardinelli et al, 1987;44:187-91) and subsequent correspondence (p 647) drew attention to excesses of cancer in rubber workers based on data from an Italian rubber factory. Studies such as this at factory level are important and should be encouraged. They are particularly welcome because of the need to have a broad spectrum of the industry's mortality experience world wide, since reliance solely on data from those countries traditionally well placed to conduct sound factory based studies is restrictive.

In this study from the University of Pavia it is stated at the end of the abstract that: “A high risk for some tumour sites emerged.” We wish, however, to add a word of caution on this interpretation of the data, and in particular about the basis on which this statement is made.

There were in total 35 deaths from cancer—a relatively small number—occurring among 4917 male production workers followed up for various periods between 1962 and 1983. Table 7 lists standard mortality ratios (SMRs) for specific cancers and gives values for statistical significance, using a one sided Poisson test. The tumours listed as significant are: liver (SMR 517 based on two deaths), peritoneum (SMR 535 based on two deaths), maxillary sinus (SMR 3735 based on one death), and prostate (SMR 518 based on two deaths). These data also presume a well written and codable death certificate and an assurance that the liver and peritoneal cancers are indeed primary tumours rather than metastases.

In our view it is unreasonable and ill founded to justify the pronouncement of a “high risk” from these data, placing too much reliance only on high SMR values derived from such small numbers. Furthermore, it is generally accepted as good practice to ignore a Poisson comparison with only one occurrence unless the expected frequency is quite exceptionally low—and some would still hesitate to ascribe a high degree of statistical significance in such a case.

Our principal caveat in appraising the results of this study is mentioned several times in the text by the authors themselves: the time lapse from the opening of the factory is insufficient to allow for the long latent period inherent in most cancers. Those remaining in employment from their start date—a number impossible to ascertain from the data given—would have been exposed for a period of 21 years at the end point of the study, whereas all others will have had less exposure.

It is also impossible to discover the distribution by age at hiring. Table 1 quotes the age group either “at 31 January 1983 or at death.” For their person-years at risk, taken at face value from this table, each individual in the first age group has contributed more than 800 years at risk. Table 2 gives age at hiring but the distribution is by cumulative years of employment. The “Age” column in table 3 is not further specified but its similarity to table 1 for the number of observed deaths suggests it is in that same format. The numbers are not, however, in precise agreement, nor do they add to the total given. There are other minor errors within the analysis. The cancer SMR of 65 for the office group has no worthwhile meaning based on one death, but the fact, mentioned in the previous paragraph, that all deaths in the youngest age group (eight in number, presumably) were due to accidents and suicides certainly merits some further investigation.

An important omission from the study is that no evaluation of the type of work is made. This would allow detection of specific risks associated with particular stages of production, and it is the all important accompaniment for elucidating a true cause and effect relation from occupation.

If the study can be extended in these ways and repeated in about ten years' time it is likely to provide a far more useful and realistic evaluation of the occupational risks in this factory. The danger is that the reader may be misled by the abstract, without having probed further into the text. Exaggeration and overemphasis can only provide disservice to the “common sense” interpretation of epidemiological data.

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Dr Bernardino and colleagues reply:
The study of the pattern of deaths from cancer among rubber industry employees after 1960 has practical and scientific importance because it should show whether changes made in the production process have succeeded in reducing or eliminating the generally accepted occupational hazard.

The aim of our study was to describe the mortality experience of a cohort of male workers during the period 1962-83 hired between 1962 and 1972 by a northern Italian rubber plant which began operations in 1962.

The outcome and the shortcomings expected in a study such as this depend on the length of follow up and were fully discussed. It is the shortness of the follow up period that makes the number of deaths so small, and this makes further analysis of the data, or
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evaluating whether the risk varies depending on the working area, impossible.

The power of the study is small, and even if a risk exists the chance of isolating it from the data is slight. Our conclusions cannot be definitive but they permit us to make hypotheses as to what preventive measures can be taken if the need is seen.

These points our critics seem to ignore. They take a sentence from the abstract: “high risk for some tumour sites emerged” referring to estimates of the SMR for liver, peritoneum, prostate, and maxillary sinus cancer showing a risk at least 400% higher than expected. Given the premise that risk is an epidemiological term used appropriately in the context, and thus cannot be modified, our critics consider the use of the adjective “high” “illfounded.” In our opinion it would be wrong to affirm on the basis of the absolute value of the SMR and its statistical significance the existence of a causal relation between exposure and death from cancer. Nevertheless, a description of the most relevant empirical relations emerging from the data, despite the small number of deaths, is a different thing.

We think that despite our critics we should publish any results that could be important. We think the question should be asked why, despite the inevitable underestimations due to the shortness of the follow up period and the diluting effect due to taking the whole workforce as the exposed group, the excess of risk for some cancer sites was noted.

Further, having analysed the pattern of deaths from cancer and shown a trend between risk of death from cancer and duration of exposure, we examined SMRs for specific deaths.

By publishing the results we hope to reopen the debate on the risks relating to rubber manufacture, something which has also been emphasised by other authors. In our opinion this is a “common sense” interpretation of epidemiological data, and no “exaggeration and overemphasis” has been made in interpreting our results. Our conclusion is as follows: “An association between working in this rubber factory and cancer mortality seems to emerge from our study. The shortness of the latent period, 10 years on average, and the consequent low number of deaths, however, makes it difficult to judge whether this association is causal or not.”

Our critics doubt the validity of the process of certification and codification of the causes of death. We can only reply that:

1 Certification and codification of causes of death within a short period is homogenous. Further, there is no reason to suppose that Italian official statistics are less reliable than those of other European countries.

2 The level of precision with which cause of death is recorded is the same in the sample as in the reference population and thus the comparability of information is guaranteed.

3 Doubt as to the reliability of official statistics of diagnoses of cancers of the liver or peritoneum for instance, is common to all epidemiological studies regardless of in which country they are conducted. Further, in our case the official diagnoses of primary cancer of the liver and peritoneum tally with the clinical records.

The fact that there is no tradition of follow up studies in Italy is not due to difficulty in finding reliable data but rather to the large amount of organisation and time required to keep track of the subjects. The law does not require the provision of an archive of deaths recorded by name in the Italian Central Statistics Office, a facility that is available in other European countries.

Our critics also refer to what they call an absurdity in table 1—there are only eight subjects within the 15–24 age group at the end of the follow up and these subjects contribute 6560 person-years. Thus every subject contributes for 6560/8 = 820 person-years. The explanation for this “absurdity” may be found in any epidemiological manual. In fact, in calculating person-years subjects shift from one class to another. Thus an individual who is 34 at the end of the follow up and was hired at 20 contributes for five years to the 15–24 age group and for the rest of the time to the 25–34 age group. Eight people do not solely contribute to the 6560 person-years; the contribution is determined by all the subjects of the cohort who were hired before they were 24 and who spent some time in this age group but are in an older age group at the end of the follow up.

Our critics go on to say that distribution by age of hiring was not presented; the reason is that we did not want to make the article difficult to read by including too many tables. As may be seen from table 1, however, the cohort at the end of follow up is young and considering that every individual is followed up for at least 10 years, it is relatively easy to estimate the distribution by age of hiring.

Since our aim is exclusively scientific, we would be happy to make our data available to any interested researcher.

Exposure to asbestos and the risk of gastrointestinal cancer

SIR—The review of the relation between gastrointestinal cancer and exposure to asbestos by Edelman (1988;45:75–82) ignores an important factor, the statistical power of the various studies to detect a risk. Studies that do not show increased risks associated with specific exposures may in fact lack the power to
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