REPLY 'INCUBATION TIME OF RELAPSES AFTER TREATMENT OF PAUCIBACILLARY LEPROSY

Sir,

The comments made by Dr J Muliyil merit serious discussion, because they point towards a fundamentally different approach to the one we have taken.

Dr Muliyil argues that by a constant relapse rate, the median is determined by the truncation of the follow-up. In the artificial data set elaborated by him, the median is less than 1 year if the observation period is only 2 years; is between 1 and 2 years if the observation period is 4 years; and should be between 2 and 3 years if the follow-up is 8 years.

Thus far we agree with Dr Muliyil. But in fact this argument is not pertinent to our study: in a control programme that is running a long time, the relapse rate is exponentially distributed (as our data suggest).

It has to be kept in mind that the data do not come from a cohort study, but from a study in which the intake of patients was spread over many years. The Kaplan–Meier technique allows one to transform this study population into a study of cohort type. The underlying assumption of no cohort effect was made, and is necessary for the correct interpretation of this series.

The problem of truncation is thus virtually non-existent in our data. (We agree that we accepted the assumption of lack of selection bias of the relapsed cases, i.e. that the chance of a relapsed case being detected is not determined by the duration of the programme or by the time interval since the end of the specific antileprosy treatment.) Dr Muliyil suggests that we need to take into account the whole experience of all treated patients. We do not agree for two reasons:

1 The experience of non-relapsed patients does not contribute any information that is relevant to our problem, which is the average length of time between the end of treatment and the relapse. Figure 1 represents the experience of the relapsed patients only, while Figure 2 represents (hypothetically) the relapse experience of all treated patients.

As we are *NOT* interested in the relapse rate itself, Figure 2 is not relevant for our study.

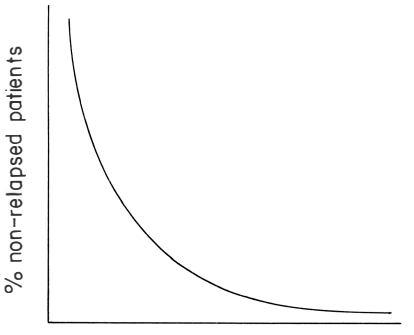

Figure 1. Relapsed patients.

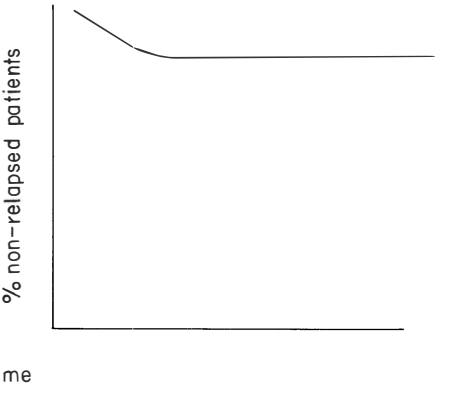

Figure 2. All patients.

2 The determination of the amount of person-years of exposure is NOT a measure of risk, but only of the incidence density of the force of relapsing.

We need the average cumulative incidence of relapsing (given by the median) and its time interval.

The MEDIAN is a good summary statistic of this time-series of relapsing and the determination of the 95% confidence intervals permits inference to a parent population that is similar to our study population. We are thus 95% sure that in any population, similar to our study population, the median relapse rate is not less than $1\frac{1}{4}$ years and not more than 3 years. The limits of the confidence bands would be narrower if the study population were bigger.

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