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Letters to the Editor

MULTIDRUG THERAPY

Editor,

Thank you for the editorial and commentary in the June 1998 issue of *Leprosy Review* regarding the new shortened multidrug therapy (MDT) regimen.

I think all of us working in the field of leprosy are agreed that the introduction of fixed duration MDT has been the single most significant development in the history of leprosy control and elimination. I am sure we also agree that the shorter the regimen can be the better, both for patient compliance and overall public health management. I do hope, however, that we would all hold equally to a commitment to proven treatment efficacy.

I was particularly interested that it was Dr Ji who wrote the editorial on this subject and was surprised by his contention that studies show a low rate of relapse. Dr Ji was co-author of the Institut Marchoux Study which appeared in the June 1995 issue of the International Leprosy Journal[1] in which he and the other authors conclude that: 'Relapses occurred late (at least 5 ± 2 years) after stopping MDT.' 'Relapse rate closely correlated with the bacterial load of the patient, occurring far more frequently among patients with a BI of ≥4·0 before MDT.' 'To avoid the alarmingly high relapse rate, it is proposed that the duration of MDT be doubled to 4 years in patients with an average BI of ≥4·0 before MDT.'

In this study, patients were analysed on two occasions with a gap of 2½ years (after 41·9 ± 12·1 months and 72·7 ± 17·3 months). It was found that in the intervening 2½ years, there had been a significant increase in the number of relapses. This led the authors of the study to a call for a 48-month regimen for high BI cases (while recognizing the operational difficulties). It is ironic that after a further 2½ years, one of the principal authors of that study is now arguing for a quartering of the regimen they proposed in 1995 (48 months to 12 months). It is also ironic that in both articles, Dr Ji refers to the WHO/CTD/LEP/94.1 document, which points to a low rate of relapse after MDT. In the most recent article, he uses the information as one of his main points for justifying 12 months MDT, whereas in the previous article we were being warned to interpret the findings of this document with 'great caution'.

Furthermore, in the June 1998 *Leprosy Review* article, we are advised that patients with a BI ≥4·0 are 'relatively scarce in the field'. In Nepal, where the bulk of patients are identified in the field and where there are generally no facilities for taking skin smears, it is not possible to say with certainty that the proportion of MB patients with BI ≥4·0 is low. Furthermore, nationally Nepal registers a far higher proportion of MB cases than in other countries. The Nepal Leprosy Trust in its centre at Lalgadh, Dhanusha District recorded almost one quarter of all the new Nepali cases registered during the 1997/98 fiscal year. The proportion of MB cases to PB cases was 60% to 40%, and of the MB cases registered, almost 10% had a BI ≥4·0. (This is 1 out of every 10 MB patients being put at an 'alarmingly high' risk of relapse.) On the basis of Dr Ji's comments regarding the overdiagnosis of MB leprosy, the actual percentage would be much higher.

On the basis of the 1995 article recommending longer chemotherapy for high BI cases and taking into account other factors, the Leprosy Control Division of His Majesty's Government Nepal agreed to shorten the regimen for MB–MDT to 12 months in the field, and that Referral Centres should continue

to offer 24 months MDT to patients with a confirmed BI $\geq 3{\cdot}0$ at start of treatment. This group accounted for 15% of MB cases registered last year at Lalgadh (not figures that could be described as being relatively scarce).

There is still no conclusive evidence to show that shortening regimens will not lead to higher rates of relapse. It is probably fair to say that even amongst the proponents of the new regimen, there is recognition of a possible increased risk of relapse. At the very least, therefore, it is not unreasonable to expect leprosy control programmes to address this issue actively. Shortening regimens without providing sufficient safety nets to those in danger of relapse seems both shortsighted and dangerous. Apart from the personal tragedy for those who do relapse, there is the negative impact of such an 'advertisement' on the control programme. In a programme like NLTs, where 65% of the 1500 new patients annually come as a result of recommendations from other patients, this is not an insignificant consideration.

I think the Nepal model of recognizing the risk to those with a high BI is a good one at the current time. I would propose one major development to this. Until such time as we can empirically prove that the shortened regimen does not significantly increase the risk of relapse, patients treated in the field where BI cannot be measured should be given 24 months MDT and only patients for whom a low BI can be confirmed (i.e. in a referral centre) should be given the shortened regimen.

Given the contents of Dr Ji's most recent article, I do not see any significant development in Dr Ji's information, only a different interpretation of the same data.

In the light of Dr Waters' commentary and in particular of his timely reminder that we are still a few years away from conclusive evidence that the relapse rates from the 12 months regimen will be minimal, I recommend we take a more measured approach to shortening regimens.

The year 2000 is our target, but elimination is the real goal. Let us ensure the year 2000 remains our slave, not our master.

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Reference

[1] Pierre Jamet, Baohong Ji and the Marchoux Chemetherapy Study Group. *Int J Lepr*, 1995; **63**: 195–201.