Letters to the Editor

COMMENT: BLISTER-CALENDAR PACKS FOR MULTIPLE DRUG THERAPY IN LEPROSY

Sir,

I have read with interest the article 'Further observations on MDT blister—calendar packs in vertical leprosy eradication programmes—a multicentre study (Phase II)' by Revankar et al. Lepr Rev (1993), 64, 250–4, in which no significant difference was found in compliance rates for self-administered doses between the 2 groups studied (blister—calendar packs versus loose drugs). Their observations prompt me to submit some information from a trial of blister—calendar packs (BCPs) which was set up some years ago in Thailand. Although for various reasons (described below) the trial was terminated without analysis or publication, the attempt was of considerable interest, not only in the context of the historical development of BCPs for leprosy in recent years, but also as an illustration of some of the inherent difficulties which are likely to be encountered in trials of this kind.

In association with colleagues in the Ministry of Public Health in Bangkok, the Medical Department of Ciba-Geigy, Basle, Switzerland, set up a comparative trial in Thailand in 1987 to assess: 1, regularity of attendance for monthly medication; 2, compliance to the ingestion of daily unsupervised medication; 3, the logistics involved in the distribution of anti-leprosy drugs to patients; and 4, attitudes, motivation and performance of patients and staff, with particular regard to the dispensing of antileprosy drugs. Emphasis was given to the use of both vertical (specialized) and horizontal (integrated) programmes in the belief (at that time) that the most useful long-term application of BCPs might be in integrated programmes, using the primary health care approach, with supervision at district level, when prevalence rates had fallen to low levels. Multibacillary patients, either new or under treatment, were included, with a proposed total intake of 480, subdivided into 4 groups of 120 (BCP and loose drug groups in both vertical and horizontal programmes). The area chosen was situated in the north-eastern part of Thailand, extending towards the border with Laos. Each case was to be followed in the trial for a period of 6 months and apart from routine clinical and administrative details, records were to be kept of attendance rates and compliance, the latter based on dapsone-creatinine tests of the urine for the presence of (self-administered) dapsone. A questionnaire was included to record ‘soft’ data on motivation and attitude of patients and staff to treatment, notably with regard to the use of BCPs versus loose drugs. Preliminary descriptions of the techniques used in assessment¹ and the methodology of the trial² were given at the 13th International Leprosy Congress in the Hague in 1988.

Despite a reasonably good intake of patients, with satisfactory participation and completion by the majority, numerous problems arose with regard to the final collection, analysis and interpretation of data from the field, which eventually proved insurmountable. These were partly related to protracted difficulties with the analysis of the urine specimens for the dapsone:creatinine ratio, but also to problems of communication with the trial ‘managers’ in Oxford, Basle, Bangkok and the field areas. In 1990, it was reluctantly concluded that no further
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progress could be made and the trial was therefore closed. In retrospect, it is in fact doubtful if the data collected would have been adequate to demonstrate a statistically significant difference between results in vertical (specialized) and horizontal (integrated) programmes, and it is also clear that the 'soft' data on attitudes and motivation would have been extremely difficult to analyse in objective terms. Furthermore, the overall value of the trial was considerably weakened, even before it got under way, by: 1, rapidly mounting evidence that many national and international agencies working in leprosy had already decided to use BCPs, in some cases on quite a large scale; and 2, numerous reports from WHO and other agencies of high levels of attendance and compliance to prescribed medication, using loose drugs for multiple drug therapy, in routine control programmes in different parts of the world.

In the years since the publication of the first designs and recommendations for the use of BCPs in leprosy by Winsley et al. it has become increasingly clear that they are unlikely, in most circumstances, to improve attendance and/or compliance figures above those which are frequently achieved using loose drugs. As indicated by Revankar et al. in the article referred to in Ref. 3, and in a detailed editorial account of the development and potential of BCPs in leprosy, other operational benefits may be of much greater importance. Their wider use in leprosy has, almost certainly, been impeded by the element of higher cost, compared with loose drugs. However, there have also been remarkable (and in some ways inexplicable) contrasts between agencies and control programmes which have accepted and used BCPs extensively (for example the Philippines and the DANIDA-supported districts in India), as having obvious advantages, without the need for formal trial or assessment, whilst others have been slow to see operational benefits or cost-effectiveness.

As far as India is concerned, the issue may now be resolved, for it has recently been reported that BCPs will be used for all the remaining districts in need of MDT in the National Leprosy Eradication Programme, with support from the World Bank. As this involves 143 districts with over 1·5 million cases in the next 5 years, inclusive of new cases likely to arise, this clearly represents a very high level of interest and confidence in the use of BCPs for this purpose. In addition to the information which is already available from the use of BCPs over a period of many years by the DANIDA-Assisted National Leprosy Control Programme, the opportunities to further assess the value of BCPs in leprosy (and their potential for other diseases, notably tuberculosis) are likely to be immense.

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References

TASK-ORIENTED SHORT-TERM TRAINING TO CONTRACT LEPROSY WORKERS IN A NATIONAL LEPROSY ERADICATION PROGRAMME

Sir,

To hasten multidrug therapy (MDT) coverage in difficult endemic districts in Northern India, the National Leprosy Eradication Programme (NLEP) authorities decided to launch a novel scheme involving contract leprosy workers who were trained to deliver MDT. A main obstacle in these northern states stopping rapid MDT coverage was inadequate infrastructural facilities, especially manpower at the field level able to operate vertical MDT programmes. To develop manpower to deliver MDT, leprosy workers are usually given 4 months conventional basic training in leprosy training centres. To achieve rapid MDT coverage, the NLEP recommended that 4–5 days training should be offered to these contract leprosy workers (who will work on a contractual basis). The Bombay Leprosy Project was entrusted to design a suitable training module and offer training in 10 districts in Madhya Pradesh and Uttar Pradesh.

The main tasks of these contractual workers are to detect leprosy cases, prepare patient treatment records after leprosy is confirmed, deliver MDT under the supervision of supervisory staff, report suspect reactions, toxicity and identify deformities, etc. To develop adequate knowledge and skills, a task-oriented, simple, practical and unstructured training programme was designed. No theoretical lectures on anatomy, physiology and epidemiology were included. All the sessions were held with demonstrations, discussions and actual fieldwork. Patients, records, clinical photographs, slides and simple notes were used as training materials. All the sessions were arranged according to trainees' needs and feedback. During training, the stress was on multibacillary case detection (skin smear positive), and their importance in leprosy control, MDT drugs, regularity, defaulter retrieval, etc. The village visits were arranged to demonstrate population surveys and to study suspect leprosy cases. To determine the immediate impact of training, the trainees were asked to undertake population surveys, to investigate suspect leprosy cases and prepare patients' records including charting, clinical details, etc.

The study group comprised of 446 contract workers from 2 districts in Madhya Pradesh and 8 districts in Uttar Pradesh, who were given task-oriented training. During the training, they detected 138 leprosy cases during survey and clinic exercise; 34 were new cases, out of whom 4 were smear positive. The rest were old, treated cases. These findings indicate that with 4–5 days' training, adequate knowledge and skills could be developed to detect leprosy cases. Feedback obtained from 2 districts from Madhya Pradesh (Satna and Khandwa) revealed that 71 contract workers suspected 838 new cases, of whom 811 (97%) were confirmed as cases, 366 were MB type, and 120 (33%) out of 366 MB cases were smear positive. They also recorded 96 (12%) patients with deformities, and 2586 active cases also received MDT, in their respective areas.