

## EDITORIAL

*Editorial opinions expressed are those of the writers.*

## Leprosy Program in India at the Crossroads

No country in the world can be more concerned about leprosy than India, as India represents nearly 76% of the global burden of the disease<sup>(1)</sup>; India alone represents 87% of prevalence<sup>a</sup> and 90% of new detected cases in the South East Asian Region. This clearly indicates that India is a key country in efforts to eliminate leprosy.<sup>(2)</sup>

The year 2005, which is the extended date for global elimination of leprosy, has brought new challenges to Indian leprosy workers and administrators. In their efforts to reach targets many steps are being taken by leprosy authorities of the Government of India, most of them with the support of the international agencies and NGOs. The Government of India, in its efforts to eliminate leprosy through its National leprosy elimination program (NLEP), has constantly been in consultation with organizations such as the World Health Organization (WHO), Global Alliance for Elimination of Leprosy (GAEL), and Non Governmental organizations (NGOs) such as the International Federation of Anti-Leprosy Associations (ILEP), and others.

India being the seventh largest and second most populated country in the world, the organization of leprosy services reaching to many distant parts of India was an enormous task. The WHO MDT program, which was initially introduced in India in 1983, could only be extended to all parts of the country by the end of 1995.<sup>(3)</sup> In the region of Jharkhand, for example, which is highly endemic for leprosy, MDT was in-

roduced in only 1994–1995.<sup>(4)</sup> Thus, since the WHO in 1991 had declared its intention to reach the global elimination target by 2000, program managers were already planning for the elimination of leprosy even as the complete coverage of leprosy in all parts of India had barely been achieved, and infrastructure had just been put in place. As noted, however, this goal was extended to 2005 as WHO observed that 12 countries would not be able to achieve the elimination target by the year 2000.

Meanwhile, the MDT therapy in itself has undergone significant modifications with respect to the duration of therapy and also to the criteria for inclusion of patients into MDT-PB and MDT-MB groups.<sup>(5)</sup> Various methodologies were adopted in the leprosy program with the belief that they would benefit the patient and at the same time bring about rapid reduction in the prevalence rates of leprosy in India along with the rest of the world. Two such examples were the introduction of single-dose ROM (rifampicin, ofloxacin and minocycline) therapy for single skin lesion leprosy (SSL –PB)<sup>(6)</sup> and initiation of the Leprosy Elimination Campaigns (LECs) all over India.

The rationale for ROM therapy was always controversial as it was based on a single multi-centric double blind field trial study whose results actually showed that ROM therapy was marginally less effective than MDT-PB in treating SSL-PB patients.<sup>(7)</sup> These results notwithstanding, ROM was introduced in India probably because single skin lesions comprise a significantly high proportion (up to 60%) of leprosy patients in this part of the world.<sup>(8)</sup> For reasons not detailed, ROM therapy was dis-

<sup>a</sup>The author has followed the WHO convention in using “prevalence” and “incidence” of leprosy to refer to the total number of registered cases, and the number of new cases, respectively. Ed.

continued five years after its introduction. However, the names of the patients who received ROM-single day therapy were removed from registers, as they were considered to have completed their treatment.

During the same time, Modified LECs (MLECs) were being conducted all over India and the state machinery participated with enthusiasm. There have been five MLECs between 1997 and 2004. Four nationwide MLECs have been conducted in the country as special efforts towards early detection of leprosy cases and their prompt treatment with MDT. The Fifth MLEC was conducted in eight high priority States during 2003–04.

In September 2003, with only one and half years to go to meet the deadline of leprosy elimination in India by 2005, the Government of India and the WHO organized a meeting in Goa of health secretaries of India's major leprosy-endemic states. It was in part a follow-up to a meeting held in Tokyo in June, 2002. Several important NGOs also participated in this meeting. The Goa meeting recommended that the seven states in India where the prevalence rate of leprosy was between 1–2/10,000 would work hard to achieve the elimination target by March, 2005. These endemic states and union territories were advised carry out the Strategic Plan of Action discussed during the meeting in specified areas during the next one-year period. (8)

After the Goa recommendations, further meetings were held at various state headquarters and leprosy directorates of India to encourage these program officers to reach the elimination target by March, 2005. To do this, new instructions were given by the health authorities of Andhra Pradesh to the field staff. These instructions are called the "Kathmandu recommendations." They are:

1. Stop all active search for case detection.
2. Do not register cases before reconfirmation by experienced staff.
3. Declare patients as released from treatment (RFT) and delete the names of these patients from registers as soon as they receive the last pulse of treatment.
4. Do not register single lesion cases for now.

The first three instructions were through official documents and office orders to the

field workers.<sup>9</sup> The last instruction was a verbal instruction; such verbal instructions were not limited to the state of Andhra Pradesh but were also given in other states of India.

Let us examine these directives. First, the first directive 'to stop all active case detection' is endorsed on the website of the WHO representative of India (2), which states that 'at present, the emphasis for detection is based on routine voluntary reporting, with no more routine active case detection'. The WHO document containing the plan for leprosy work for the period 2006–2010 proposes the use of case detection as the main indicator to monitor progress. (10) It states that the important component of the leprosy control program is timely detection of new cases, but it recommends that case-finding should mainly be focused on promoting self-reporting.

With falling prevalence rates and the goal of elimination in sight, the focus of the leprosy program has shifted from an active search for new cases to voluntary reporting. However, there are some who feel that leprosy elimination cannot be accomplished without full geographic and population coverage and without intensified effort to treat all patients. (11) It is true that intensifying case detection may lead to over-registration and over-reporting of cases, but this should not mean that we do away with active searching for new cases. Although WHO evaluators observed that the number of new cases detected in LECs included a significant proportion of wrong diagnoses, re-registration, and 'non-existent patients'<sup>b</sup> in programs (12), not all evaluators found LECs to be the cause of over diagnosis or re-registration. Some evaluation teams actually diagnosed additional new cases missed by the LEC teams. (13)

A balance needs to be struck between detecting all hidden cases and avoiding re-registration and wrong diagnoses. Intensive active case detection conducted through MLECs for the discovery of new cases proved to be one of the most successful health care interventions undertaken in India in recent years, particularly in the states of Bihar and Orissa. (14) It is only fair to say

<sup>b</sup>See also Editorial, *Int. J. Leprosy* 72: 501, 2004. Ed.

that in a vast and diverse country like India, a combination of strategies and methods is required to reach varied target groups. <sup>(15)</sup>

The second guideline, which is re-validation by an experienced health worker within one month of the diagnosis of leprosy could serve to delay the inclusion of new patients into the registers and hence to help keep the monthly new case detection rate and prevalence rate within limits until the elimination goal is achieved.

The third guideline also serves a similar purpose, by deleting the patient from case registers and advancing the RFT date by a month. In such cases the last month's therapy becomes accompanied MDT.

The fourth and important verbal instruction was confirmed with various health workers of Hyderabad, Andhra Pradesh. Issuance of similar verbal instructions was personally confirmed with health workers of one other state (Delhi) which is in the northern part of India, while Andhra Pradesh is in south India. It is not unreasonable to assume that such instructions may not be limited to these two states.

Single-lesion leprosy cases have always had a special place in leprosy. The percentage of single-lesion disease among leprosy patients in India is quite high. <sup>(7)</sup> Although single lesion leprosy is considered paucibacillary, multibacillary leprosy may also present as a single lesion. <sup>(16,17)</sup>

Generally it is believed that single-lesion leprosy cases have no transmission potential and are not of great significance from the public health point of view, as a high percentage of these case show a tendency for self-healing. <sup>(18)</sup> However, large numbers of single-lesion cases detected represent an exposure of the population to a reservoir of infection which may contribute to the number of new cases and hence cannot be ignored. On the whole it is believed that at least a proportion of single-lesion leprosy will, without treatment, progress to multi-lesion leprosy. <sup>(19)</sup>

Some workers wanted single-lesion cases to be excluded from the number of leprosy patients when calculating new case detection rates, arguing that they do not contribute to the spread of the disease. <sup>(20)</sup> However, many studies have suggested that untreated MB patients do not represent the sole source of infection and that household

contacts of PB patients have also been shown to be at a greater risk of developing the disease than non-contacts, although the risk is smaller than that of contacts of MB patients. <sup>(21)</sup> It is unwise and unethical to exclude single-lesion leprosy cases from the registers as new cases and to deny therapy. However, such non-registration/non-inclusion of single-lesion cases will substantially help the program managers to bring down the number of new cases and thus assist in reaching the elimination target in time.

What about the present leprosy statistics of Andhra Pradesh? The reported tentative average prevalence rate of leprosy in Andhra Pradesh state (with 22 districts) in mid 2004 <sup>(22)</sup> was 1.78/10,000, with 10 districts having rates of 1–2/10,000, 9 districts having rates of 2–3/10,000, and 2 districts with rates of 3–5/10,000. In the epidemiological indicators of new leprosy cases prepared for Andhra Pradesh up to March 2005, the percentage of child cases was 19.8% and of MB cases was 28.2%. Scheduled castes (SC) and Scheduled tribes (ST), who are the under-privileged of the society and live in areas with difficult access, constitute 33.5% of all new cases. A large proportion of children among the newly detected patients is a sign of active and recent transmission of infection, <sup>(21)</sup> especially when there is no active search or campaign for case detection. The large number of leprosy cases being detected among SC and ST populations indicates that focused health and communication campaigns are required to improve access to information and health services of these populations, particularly to those in remote areas.

In the neighboring state of Tamil Nadu, the leprosy prevalence rate was 1.4/10,000 in the year 2004. <sup>(23)</sup> On May 15th of 2005 the health ministry of Tamil Nadu has declared <sup>(24)</sup> that the present prevalence rate in Tamil Nadu is only 0.85/10,000, which means that it has already reached the elimination target. As other states are also encouraged to reach the targets, it is bound to happen sooner rather than later. It has already been reported in media that four southern states (Tamil Nadu, Andhra Pradesh, Kerala and Karnataka) have reached the elimination target of a prevalence rate of <1/10,000 population by May

of this year. <sup>(25)</sup> This was substantiated by a 'news and notes' report of a regional conference on leprosy held at Chennai, published by the Indian Journal of Leprosy. <sup>(26)</sup>

It will not be out of context here to consider the experience of the National Malaria Control Program of India, which was initiated in 1953—a story of failure. Initially it made rapid gains so that by 1961, the annual number of new cases registered was only 50,000. However, a resurgence of malaria was reported from 1962 onwards. By 1976, 6.4 million new cases were reported. Presently, the annual incidence is around 2 million. <sup>(27)</sup> Some of the important causes detailed for the failure of the National Malaria Eradication Program of India <sup>(28)</sup> were as follows: diversion of the work force, promoting newer priorities when greater effort was needed to root out the last pockets of endemicity, entrusting work to multi-purpose and basic health workers who were ill prepared for the task and, above all, laxity in national commitment and determination. It was also mentioned that the third world countries did not fully understand the epidemiological 'rules of the game'. In short, the present resurgence of malaria is due to the relaxation of effort.

Similar indicators already exist in present leprosy program of India. Added to these are newer national priorities such as HIV and a resurgence of tuberculosis. Dilution and relaxation in the efforts of the NLEP has already set in.

What is being presented here is common knowledge in India, and the government orders cited were circulated openly and were not privileged information. Most of the NGO's participating in NLEP in India would also be aware of these directives and figures, as they work very closely with the central and state governments of India and are participate in the national and international meetings and consultations. The credit for decreasing the leprosy prevalence and the efficacy of leprosy control program in India should be shared equally by GOI, WHO and NGOs. However, for reasons unknown, there seems to be a great hurry on the part of everyone involved with NLEP in India to reach the elimination target by the end of 2005 and to get on with a vision of leprosy beyond 2006.

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