6. LEPROSY CASE DETECTION TRENDS IN INDIA

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Introduction

In 1991, the 44th World Health Assembly resolved to eliminate leprosy as a public health problem by the year 2000.1 Elimination of leprosy as public health problem was defined as reduction in the registered prevalence of leprosy patients receiving MDT to less than 1 per 10,000 population. Subsequent to the worldwide implementation of multi-drug therapy (MDT) programmes, estimated leprosy burden declined from 10-12 million cases in mid-1980s to 1.5 million in 1997. During the 54th World Health Assembly held in 2001, WHO declared that the historic target of global leprosy elimination was attained.2 Globally over the last two decades, the registered leprosy prevalence has fallen by almost 90% and new case detection has fallen by about 50%. In terms of new case detection, the global decline is contributed entirely by India (Figure 1). In 1985, 122 countries in the world had leprosy prevalence of over 1 case per 10,000 population. By 2006, this number came down to six countries3. These countries are: Brazil, Democratic Republic of Congo, Madagascar, Mozambique, Nepal and United Republic of Tanzania. However, new cases would keep on occurring globally demanding sustainability of leprosy control programmes. In fact, even countries like United States of America continue to report new cases.4 On 30th January, 2006, the Ministry of Health, Government of India formally announced that India achieved the elimination target (leprosy prevalence as on 31st December was 0.95 per 10,000).5 (Figure 2) The elimination slogan has certainly contributed to develop international commitment for reduction in leprosy burden over the years. The focus of the programme should now shift from prevalence oriented targets to sustainable leprosy control and provision of good care for the patients.

With the fall in the load of infection, it is logical to expect a fall in the rate of occurrence of incident cases. Even if one accounts for the long incubation period, new case detection rates (NCDR) should show a decline after a lag phase, assuming that the programme coverage is consistently high. But, since 2002, fall in new case detected in India is very sharp (Figure 2) compared to other endemic countries, including countries in the South-East Asia. However, as observed from the global trends and trend in other endemic countries, sharp decline in prevalence is followed by a slow fall in new case detection over the years. This phenomenon requires careful analysis of the situation. It is also essential to concentrate on new case detection as a means for sustainability of control. In any disease control programme, based on secondary prevention, case detection and case holding are the two most important components. Hence, case detection will demand focused attention in leprosy control programme even beyond the elimination stage.

The objectives of this paper are to (1) review factors associated with case detection trends in the context of control strategies (2) discuss trends in new case detection in India and (3) suggest approach towards appropriate sustainable leprosy control measures.

Current leprosy situation in India

Figure 1 projects number of new cases detected in India, various countries other than India and the total global picture. As mentioned earlier, new cases detected in India essentially forms the global trend. It can be seen that leprosy case detection in various countries other than India, has been more or less stable during the period 1985-2005 with a small spurt in the year 2000. Contrary to the global picture, case detection in India, has shown lot of fluctuations. For the period 1985-1996, case detection has remained stable with only small changes. From 1997 onwards, dramatic changes have occurred and from 2002 there is a precipitous fall in new cases detected.
The second phase of the World Bank supported National Leprosy Eradication Programme (NLEP) was aimed at achieving the elimination target and integration of leprosy control activities within general health services in the entire country. As of March 2006, registered prevalence of leprosy in India was 0.84 per 10,000 population (Figure 2). While 22 states and five union territories reached prevalence levels below 1 per 10,000; six states (Bihar, Chhatisgarh, Jharkand, West Bengal, Orissa and Uttar Pradesh) and two union territories (Delhi and Dadra & Nagar Haveli) still continued to have prevalence above 1 per 10,000. As of March, 2006 national level new case detection rate was 1.42 per 10,000. Information with respect to new case detection is now collected and updated every month at the state and national levels.

We examined annual change in the new case detection as a percent change for the period 1986-2005 taking 1985 level as the base level. The annual change was highly variable during the period 1986-1998 (Range: -10% to +25%). Decline was observed for 1998-1999 and 1999-2000 by 15% and 12% respectively. However, for the year 2000-2001, a sharp increase was seen. Further the decline was dramatic during the last four years (23% in 2001-2002, 23% in 2002-03, 29% in 2003-04 and 38% in 2004-05 (Figure 3). This sharp decline is observed almost uniformly for the new cases detected at the state level for the period 2002-2005.

Examination of data for the period 1996-2004 from ten districts of Bihar, do not support the sharp decline observed at the national level. Damien Foundation India Trust (DFIT) had been continuously involved in case detection activities using fairly constant methodology in these ten districts. Further, data from Subarnapur district of Orissa, indicates a definite but gradual decline in the occurrence of new cases during 1991-2004. LEPRASociety of India has been entrusted with leprosy activities in this district from 1990 onwards.

Factors influencing new case detection rates

The number of newly detected cases is used as a surrogate measure for incidence. The detection rate could be a reliable indicator of trend of incidence rates if the delay in detection is constant over the years and case detection methods are the same or standardized. Some other indices namely proportions of MB patients, child patients, and patients with visible (grade-2) deformities among new patients may reflect leprosy trends. However, the argument for considering these parameters lies in constant and standard methodology adopted over several years.

New case detection should be analyzed in conjunction with other data. The interpretation should be aided by knowledge about activities in the area. Case detection is affected by multiplicity of factors as mentioned below:

**Specificity of the diagnosis:** It was observed that over diagnosis was 6-13% in NLEP. Over diagnosis was observed more in urban areas as compared to rural areas. Changing case definitions, different diagnostic criteria used over the years for leprosy, and lack of quality control checks affect both accuracy and comparison between the studies.

**Sensitivity of the diagnosis:** Cases could be missed on account of non-coverage of certain areas or population groups such as working men, difficult to reach areas, tribal population, people below the poverty line etc. Marginalization of some sections of the society on account of gender, and poverty, inaccessibility to health services, opportunity costs, disabilities and stigma associated with the disease were some of the known factors that influence case detection activities.

**Recycling:** Re-registration of old or cured patients as new patients has been observed during the modified leprosy elimination campaigns by the evaluation teams. The range was between 33-82%. This might be due to lack of supervision; non-adherence to national and international treatment guidelines to show an inflated disease burden in the area.

**Self-reporting behaviour:** It was observed that voluntary reporting in Tamilnadu was 25% in the post-integration period as compared to that of 14% in the pre-integration period.
Single-dose treatment for single skin lesion paucibacillary patients: Changes in the treatment criteria affect the case count. It was observed that among paucibacillary (PB) patients with single skin lesions treated with single-dose combination of Rifampicin plus Ofloxacin plus Minocycline (ROM) was almost as effective as standard six months PB-MDT. Single dose ROM was introduced for single-patch cases in the programme from January 1998 and was in vogue for about five years. Apparently these cases were never taken on record since prevalence was the main indicator for judging progress towards elimination. These cases would never come into prevalence since they received only a single dose treatment. They should have been counted as new cases, but it was not clear how these cases were accounted for. There was apparently a tendency to over-diagnose cases of single patches since the treatment was a single-dose and the patients were not counted in prevalence. Use of ROM was eventually discontinued.

Case detection methods and intensity: Operational modalities [School surveys, contact tracing, leprosy elimination campaigns (LEC), block level awareness camps (BLAC), health camps etc] do certainly affect case detection in magnitude as well as in quality. Wrong diagnosis chances increase during leprosy elimination campaigns and health camps, if diagnosis of leprosy is left to the poorly trained personnel. This has been observed in several leprosy endemic countries. Before launching of MDT programmes, intensive case detection activities were generally taken up in different regions. In addition to leprosy elimination campaigns, these special case detection programmes helped in clearing backlog of cases. These activities also showed sharp increase in new case detected and subsequently new case detection used to drop back.

Targets: Targets provide an inescapable sense of urgency among the health workers. This in turn places excessive, counter productive pressures and demands on them as well as others. Case detection rates are adversely affected by these kinds of administrative and managerial decisions. It had been observed that the target allocation obscures NCDRs both in the integrated set up (like Tamil Nadu) and elsewhere where integration has not taken place. Nevertheless, it is argued that target allocation generates political commitment in pushing the elimination efforts ahead and achieve results, which otherwise would not have been possible. In the NLEP, the targets were of two kinds. First one was to achieve at least a minimum specified number of cases and the other was with respect to march towards elimination by the year 2000, pre-fixing prevalence figures for the year. To achieve the goal of elimination by the year 2000 targets were prepared after committing to the goal of elimination and projections were made based on such targets. Finally, setting targets were considered counterproductive to the assessment of surveillance data. Incentive structure for annual targets and incentives for staff had been discontinued by the Government of India. Case detection trends should be assessed in the context of vertical and integrated setups and the policy of targets during particular periods. Although, the Government of India had discontinued the practice of setting targets to the peripheral level workers for case detection, targets are mentioned in the form of goals / expectations at the State and National level according the national action plan 2005-06 of NLEP (Table 1). Practice of monthly review and update of cases detected and number of cases released from treatment continues to put pressure on the state level programme to some how achieve elimination at the individual state level and beyond even the district / block level.

Operational factors: LECs and modified LECs (MLEC) were discontinued from 2002 onwards. It was observed in some states, continued MLECs did not continue to have high case detection. Using this as evidence, MLECs were discontinued. Further, it was realized that campaigns come in the way of general health services and various health activities conducted by general health workers. Thus, campaigns are not a sustainable approach in an integrated set up. Even though, it was expected that removal of MLEC would not affect case detection, in practice, number of cases came down sharply as could be seen from 2002 onwards.

In January 2005, in the South East Asia Regional meeting of National leprosy programme managers at Kathmandu, some decisions were made. Firstly, every leprosy case detected by primary health care
workers was to be confirmed as leprosy by a special team at the district level. This approach of 100% validation was adopted from 2005. Secondly, various methods of active case detection were to be discontinued and case detection was to be taken up as voluntary reporting. Both these decisions affected case detection enormously. 100% validation was rarely feasible and a significant proportion of cases would thus never get examined for confirmation. This approach of validation added to the pressure of somehow reaching elimination at sub-national levels.

**Sharp decline from 2002**

Both at the global and national level, the strategy to eliminate leprosy as a public health problem (using prevalence less than 1 per 10,000 population) has helped to reduce the burden of the disease. However, NCDR over the years had not shown a perceptible decline at the national level until a few years back\(^\text{12, 26, 27}\) as compared to the sharp decline in the recent years. The observed case detection trends need to be interpreted in the context of various factors that exist in a given area.

The annual decline is dramatic during the last five years and requires further analysis. We could possibly discuss few known factors.

The impact of MDT on prevalence and case detection trends across the country was earlier examined in a workshop conducted by the Indian Association of Leprologists in Chennai, in 1993.\(^\text{20}\) It was seen that in the face of rapid decline in prevalence following MDT, NCDR remained quite steady. NCDRs for several countries clearly demonstrated that MDT did not result in a precipitous decline of NCDR.\(^\text{21}\) Therefore, decline could not be attributed directly to MDT \textit{per se}.

It is generally felt that the unchanged level of new case detection could be on account of intensive case finding in certain states (particularly in endemic states). However, the examination of state-level data did not support such hypothesis.\(^\text{13}\) Hence, even in the absence of active case finding strategies such a level of decline is not convincing.

Simulation Model for leprosy (SIMLEP) is an epidemiological framework developed to predict leprosy trends over a period of time.\(^\text{28}\) This model was developed on the basis of data from a high endemic region in Tamil Nadu. It assesses key indicators like prevalence, incidence and case-detection. Also, it simulates trends over time under specific user-defined assumptions on leprosy epidemiology and control. The outputs produced by the model can readily be compared with the observed data. It is a deterministic macro-simulation population-based compartmental model. The model is age-specific. Gender was not considered. About 70 input steps are involved in this simulation model. Out of these, accurate information is not available for about 40 parameters. Through a series of experiments and field activities, specifically taken up for validation purposes, we presently have a fairly satisfactory epidemiological model for leprosy. This simulation model, though a complex one, had certainly reflected the present knowledge on leprosy to a great extent.

To examine the immediate application of the model, we conducted two experiments, one was with respect to immunoprophylaxis where we had imagined a reduction of about 65% leprosy incidence, irrespective of the infection status of given individuals. The model predicted a sharper decline in incidence of leprosy and strong possibility for achieving elimination of leprosy and even its eradication over two decades. The second experiment that we carried out was with respect to reducing the delay in case detection.\(^\text{29}\)

Assuming leprosy incidence to be 200 per 100,000 population in 1950s, SIMLEP predicts that cases would continue to occur in the community beyond year 2000 (Figure 4). This prediction is despite an estimated annual decline of 2 to 12% in incidence beyond 2000.\(^\text{29}\) Hence, a very high level of annual decline in new cases detected is inexplicable.

**Conclusions**

After adopting NLEP slogan for elimination by the year 2000, a dramatic fall in leprosy prevalence has been attained. Fixed duration treatment and leprosy detection and case management activities using standard procedures have made leprosy control more acceptable even for the integrated health services. There are now better opportunities for diagnosis, treatment, and disability prevention.
management as well as referral services. There is a need to sensitise and motivate general health services personnel and enhance quality of leprosy control programme for ultimate benefit of individual patients. We, therefore, recommend that national leprosy programme now should shift from elimination to control in a sustainable manner and provide quality services to leprosy patients. They need not focus on achieving elimination levels at the sub-national levels. Leprosy is a disease with long incubation period. There will be reactivation of hidden infection and some re-infection as well. The programmes have a social responsibility to leprosy patients and they should fulfill the same.

Table 1. Goals to be achieved by December, 2005, status as on March and December, 2004 and expected as on March 2006, NLEP, Govt. of India, 2005

<table>
<thead>
<tr>
<th>Key output</th>
<th>Status as on March 2004</th>
<th>Achieved as per reports received until December, 2004</th>
<th>Expected December, 2005</th>
<th>Expected March 2006</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prevalence rate per 10,000 (National)*</td>
<td>2.44</td>
<td>2.13</td>
<td>&lt; 1</td>
<td>&lt; 1</td>
</tr>
<tr>
<td>Prevalence rate &lt; 1 / 10,000 in districts</td>
<td>42%</td>
<td>-</td>
<td>60%</td>
<td>65%</td>
</tr>
<tr>
<td>Disability among new cases</td>
<td>1.4%</td>
<td>1.4%</td>
<td>1.2%</td>
<td>1.1%</td>
</tr>
<tr>
<td>Annual new case detection rate / 10,000 (National)</td>
<td>3.3</td>
<td>2.9</td>
<td>2.8</td>
<td>2.5</td>
</tr>
<tr>
<td>MB proportion among new cases</td>
<td>39%</td>
<td>39.3%</td>
<td>43%</td>
<td>45%</td>
</tr>
<tr>
<td>Female proportion</td>
<td>35%</td>
<td>36%</td>
<td>40%</td>
<td>44%</td>
</tr>
</tbody>
</table>

* It is expected that the goal (Prevalence rate < 1 / 10,000) of leprosy elimination at the National level will be achieved by the year end of 2005, even though a few states may continue to have prevalence rate more than 1 per 10,000 population

Figure 1. Trends in new case detection by global, countries other than India and India, 1985-2005
Figure 2. Prevalence and new case detection rates (per 10,000) for leprosy, NLEP, Govt. of India, 1985-2006

Figure 3. Annual change (%) in number of new leprosy cases detected taking 1985 as the base level, India, 1995-2005
Figure 4 Model predictions on leprosy incidence, case detection and prevalence (Assuming incidence 200/100,000 in 1950s)
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