

Current Situation of Leprosy in India and its Future Implications

Abstract

The global leprosy situation has changed significantly over the last four decades after the introduction of multidrug therapy (MDT) in 1982 with a reduction in prevalence from over 5 million cases in the mid-1980s to less than 200,000 at the end of 2016. The programme in India also saw a reduction from a prevalence rate of 57.8/10,000 in 1983 to less than 1/10,000 by the end of 2005 when India declared to have reached the World Health Organization (WHO) target of elimination as a public health problem. Post 2005, major changes in the programme were made by the National leprosy eradication programme (NLEP) and the global leprosy programme, which may have affected the new case detection (NCD), disability, and child leprosy trends, which continue to show no appreciable regression. This article reviews the current global and Indian leprosy scenario to bring out its achievements and successes, including the impact of Leprosy Case Detection Campaigns (LCDC) on leprosy numbers. The basis and expected benefits of recent introduction of chemo and immune-prophylaxis in the programme are also discussed. It also discusses the shortcomings, the areas of concern, and the need for an inclusive strategy in the Indian leprosy programme that includes an intersectoral collaboration within the country for reaching the desired goal of leprosy eradication.

Keywords: Areas of concern, chemo and immune prophylaxis, global and Indian situation, leprosy

Introduction

Leprosy is one of the oldest diseases known to man. Despite advances in all spheres of medical science, leprosy continues to be a public health challenge in countries like India. This paper discusses the current situation of leprosy in India in the context of the world and includes the successes, new initiatives, challenges, and future implications for leprosy control in India.

Global Leprosy Situation

The WHO launched a 5-year ‘Global leprosy strategy 2016–2020’ in April 2016 titled ‘accelerating towards a leprosy-free world’.^[1] This was built on the earlier 5-year strategy 2011–2015 that focused on early leprosy detection to reduce disabilities. The document states that the agenda of eliminating leprosy at the subnational level is still unfinished in many countries and will therefore continue to be pursued in the coming years. Other challenges remain – continued delay in detecting new patients, persisting discrimination against people affected by leprosy, and limited impact on transmission of leprosy. Perhaps, for above-mentioned reasons, the strategy

for years 2016–2020 is built around three pillars: (i) to strengthen government ownership, coordination, and partnership; (ii) to stop leprosy and its complications; and (iii) to stop discrimination and promote inclusion. There is a special focus on women and children, strengthening referral systems, more effective contact tracing, assessing the value of chemoprophylaxis, and monitoring drug resistance.

The latest update from the WHO titled ‘Global leprosy update, 2016: accelerating reduction of disease burden: states that – although there has been a significant reduction in prevalence of the disease worldwide since the mid-1980s to elimination levels, new cases continue to arise indicating continued transmission.^[2] The global prevalence at the end of 2016 was 171,948 with a registered prevalence rate of 0.23 per 10,000 population, a decrease from that in 2015. The NCD in the year, however, was 214,783, a marginal increase compared to 2015 [Figure 1]. These global figures are based on the reports filed by 143 countries from different regions of the world. What makes these figures incomplete is that approximately 17 countries from the African region, 24 countries from the Americas, and

**P. Narasimha Rao,
Sujai Suneetha¹**

*Comprehensive Dermatology
Clinic, Masab Tank,
Codewell-Nireekshana,
Narayanaguda, Hyderabad,
Telangana, India*

Address for correspondence:
Dr. P. Narasimha Rao,
Comprehensive Dermatology
Clinic, Masab Tank, Hyderabad,
Telangana, India.
E-mail: dermarao@gmail.com

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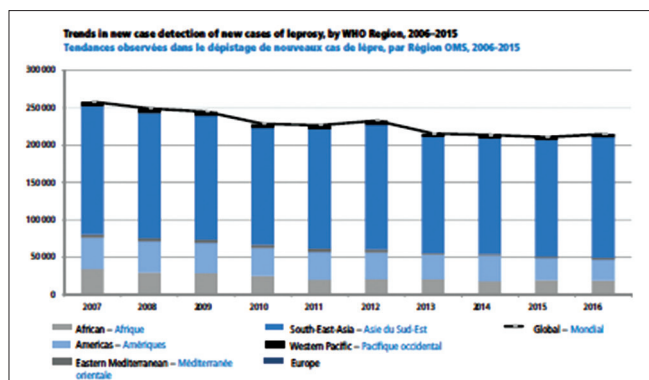


Figure 1: Trends in the new case detection of leprosy in WHO regions 2006–2016^[2]

2 countries from the southeast Asian region failed to send their data on leprosy.

Current Situation of Leprosy in India

In India, the National Leprosy Eradication Programme (NLEP) is the centrally sponsored health scheme of the Ministry of Health and Family Welfare, Government of India. While the NLEP strategies and plans are formulated centrally, the programme is implemented by states and union territories (UTs). The programme is also supported by WHO, ILEP, and few other nongovernmental organizations (NGOs). Due to their efforts, from a prevalence rate of 57.8/10,000 in 1983, India has succeeded with the implementation of MDT in bringing the national prevalence down to “elimination as a public health problem” of less than 1/10,000 in December 2005 and even further down to 0.66/10,000 in 2016. In addition to achieving the national elimination target by the end of 2005, India by the end of March 2011–2012 succeeded in achieving elimination at the state level in 34 states/UTs out of the total of 36 states/UTs. Only the state of Chhattisgarh and the UT of Dadra & Nagar Haveli were yet to achieve elimination. By the end of March 2016, 551 districts (82.36%), out of the total 669 in districts, in India had a prevalence of <1/10,000 population which is the target of elimination as a public health problem. The number of districts with prevalence between 1 and 2/10,000 were 76, number of districts with prevalence between >2 and 5/10,000 were 39, and those between 5 and 10 were 2.^[3]

Despite the above successes, the fact remains that India continues to account for 60% of new cases reported globally each year and is among the 22 “global priority countries” that contribute 95% of world numbers of leprosy warranting a sustained effort to bring the numbers down. In the year 2007, new cases detected in India were 137,685, and nine years later in 2016, the number remained almost the same at 135,485, a significant increase over the 127,326 new cases detected in 2015. This increase in new cases is attributed by NLEP to their recent strategy of innovative Leprosy Case Detection Campaign (LCDC), which resulted in the

detection of 34 000 new cases in 2016 from highly endemic pockets, which accounted for 25% of annual new cases.^[2] Of the total new cases detected, almost 50% were multibacillary leprosy and the child rate was about 8.7%, which was similar to the previous year’s figures, both indicating continued transmission of leprosy in the community. The LCDC also resulted in increasing the number of districts with a prevalence of >1/10,000 in the country, reminding us of the value of active case finding strategies.

NLEP annual reports of the last 4 years have consistently observed that the four states/UTs (Orissa, Chandigarh, Delhi, and Lakshadweep), which achieved elimination earlier in 2011–2012, have shown a prevalence of >1 per 10,000 population, which is a matter of concern for the programme.^[4] In addition, although the average national child leprosy rate is approximately 9%, the proportion of child cases was more than 10% of new cases detected in eleven states/UTs of India, with 6 of them (Tamil Nadu, Punjab, Dadra & Nagar haveli, Bihar, Mizoram, and Arunachal Pradesh) showing very high rates ranging from 14% to 23%. In a few of these states, the high multibacillary proportion, and in others a difficult to reach terrain could contribute to continued transmission.

Present and Future National Strategy for Leprosy

The NLEP in its recent evaluation have acknowledged that there are cases occurring in the community and detection capacity is not matching the level and intensity of disease occurrence. The office of the Dy. Director General for leprosy (India) in a directive in August 2016 drew attention to the following four alarming trends.^[5] One, there are pockets of high endemicity in the country where there is ongoing transmission. Two, here are many hidden cases in the community as revealed by the sample survey conducted by Indian Council for Medical Research (ICMR). Three, the new case detection rate has remained almost the same since 2005, and four, the disability rates in new cases has been rising due to a delay in diagnosis. To address these challenges NLEP advocated a three-pronged approach of (a) “leprosy case detection campaign (LCDC)” in highly endemic districts; (b) focused leprosy awareness campaign using ASHA and multipurpose health workers in “Hot Spots,” where new cases with Grade 2 Disability (G2D) are detected; and (c) area-specific plans for case detection in hard to reach areas. Given the importance of detecting missed leprosy cases in the community, the Indian Government initiated LCDCs, initially in 50 highly endemic districts of seven states – Bihar, Chhattisgarh, Jharkhand, Madhya Pradesh, Maharashtra, Odisha, and Uttar Pradesh, through active search methods.^[6] By the end of year 2016 a total of 163 highly endemic districts, which reported a prevalence rate >1/10,000 population in any of the last 3 years across 20 states/UTs, were identified for conducting case detection campaigns by NLEP.

It was felt that the major cause of hidden cases is low voluntary reporting in the community due to a lack of awareness as well as the continuing fear, stigma, and discrimination against leprosy. The SPARSH Leprosy Awareness Campaign (SLAC) was launched on 30th January 2017 and is a program intended to promote awareness and address the issues of stigma and discrimination.^[7] The anticipation of the present strategy is that, with increasing awareness and reducing stigma, more hidden cases will self-report for diagnosis and treatment. It is expected that the measures included in the strategy such as contact tracing, examination, treatment, and chemoprophylaxis will bring down numbers in the important vulnerable group of household contacts. The special emphasis on women, children, and those with disabilities is expected to flush out more hidden cases. In addition to continuing to administer MDT to patients, new preventive approaches such as chemoprophylaxis and immuno-prophylaxis are being considered to break the chain of transmission and reach zero disease status.

Chemoprophylaxis of contacts

Post-exposure chemoprophylaxis (PEP) is any preventive medical treatment started immediately after exposure to a pathogen to prevent infection by the pathogen and the development of clinical disease. The main risk of exposure to *Mycobacterium leprae* is in close contacts of new, untreated cases. Epidemiological studies have shown that the chance of finding a previously undiagnosed leprosy patient is ten times higher in household contacts of leprosy patients than in the general population, and the chance of finding leprosy among different categories of neighbors and social contacts is between three and five-fold.^[8] For this reason, assessing the value of chemoprophylaxis of contacts is the main focus of global leprosy control strategy.^[1] A randomized control study has shown that chemoprophylaxis with single dose rifampicin (SDR) has a 57% overall risk reduction in preventing the development of leprosy for household contacts during the first 2 years after its administration.^[8,9] However, the protective effect of SDR was seen only in the first 2 years, with no additional effect after 4 and 6 years.^[9,10]

Leprosy Post Exposure Prophylaxis (LPEP) was launched globally by various leprosy stakeholders and agencies in the year 2014.^[11] The overall aim of the LPEP programme is to evaluate the feasibility and efficiency of contact tracing and the provision of preventative treatment for leprosy under routine conditions in several countries and to determine the impact this has on leprosy incidence. The program has three prime components – contact tracing and screening and single-dose rifampicin (SDR) administration. Once a new patient has been diagnosed, health services actively screen household members and neighbours of the patient and examine them. Symptomatic persons are promptly referred for MDT and asymptomatic “contact persons” are offered

a post-exposure prophylaxis (single-dose rifampicin) to reduce their risk of developing leprosy by 50–60%. It is designed to complement and be integrated into the NLEP rather than operating vertically.^[12]

Contact of leprosy for this programme is defined as someone who has had prolonged regular or interrupted contact with an index case during the last 1 year. A single dose of 600 mg of rifampicin is advocated as LPEP to household contacts above 35 kg body weight, 450 mg to individuals of 20 to 35 kg weight, and for those with <20 kg body weight, 10–15 mg/kg of rifampicin as single dose.

A double-blind, randomized, placebo-controlled trial in northwest Bangladesh has observed that chemoprophylaxis with single-dose rifampicin given to contacts of newly diagnosed leprosy patients is a cost-effective intervention strategy.^[13] However, it also cautioned that implementation studies are necessary to establish whether this intervention is acceptable and feasible in other leprosy endemic areas of the world. In addition, there is a potential risk of rifampicin resistance emerging in community due to SDR. Nonetheless, a group of multidisciplinary experts in leprosy and tuberculosis after carefully reviewing the available evidence regarding the mechanisms and risk factors for the development of (multi) drug- resistance in *M. tuberculosis* with a view to the special situation of the use of SDR as chemoprophylaxis for leprosy^[14] concluded that SDR given to contacts of leprosy patients, in the absence of symptoms of active TB, poses a negligible risk of generating resistance in *M. tuberculosis* in individuals and at the population level.

LPEP is now operational in Indonesia, India, Nepal, Myanmar, Tanzania, and Sri Lanka and in a modified way in Brazil and Cambodia. As per the current planning, LPEP will continue until 2018 with ongoing data collection to generate evidence on the most efficient way to operationalize contact tracing with post-exposure prophylaxis and its potential to interrupt leprosy transmission. In India at present, a study is under progress in the union territory of Dadra and Nagar Haveli to assess the feasibility of administration and acceptance of single dose of rifampicin chemoprophylaxis.^[15] NLEP is also proposing to launch chemoprophylaxis with rifampicin in districts where LCDC is ongoing.^[7]

MiP Immuno-Prophylactic Vaccine

NLEP has introduced the *Mycobacterium Indicus Prani* (MiP) vaccine in a project mode in India from the year 2016. MiP vaccine has been shown to have both immunotherapeutic and immune-prophylactic effects in multibacillary leprosy patients and their contacts in both hospital and population-based trials.^[16,17] It also reduced the bacillary load, upgraded the lesions histopathologically, led to complete clearance of granuloma, reduced reactions,

and neuritis and reduced the duration of MDT in leprosy patients.^[18-21] In the new field project undertaken under ICMR and NLEP, the index leprosy patient will receive the MIP vaccine over and above the MDT. His family members and contacts would be immunized with MIP twice at an interval of 6 months with the expectation that their immunity is reinforced to evade leprosy on exposure to *M. leprae* from a patient.^[22] The utility of immunizing the index case is for rapid clearance of bacteria and clinical lesions. In contacts, MiP vaccination upgrades their immunity, thereby resisting the development of the clinical disease on exposure to *M. leprae* from those suffering from it.

Nikusth, a web-based reporting system for leprosy

For the ease of reporting and data management of registered leprosy cases, NLEP has launched “Nikusth,” a web-based reporting system in India.^[15] In addition, “Nikusth” will be helpful in keeping track of all the activities being implemented under the NLEP. NLEP is also planning to develop online training software for leprosy workers.^[23]

Areas of Concern

Despite all the initiatives mentioned above being taken by NLEP, there are many reasons why there is no decline in occurrence of new leprosy cases in India over last decade. When a disease is to be eliminated from a community, the efforts should be sustained and vigorous till the desired goals are achieved; the best example of success being the “national smallpox eradication programme.” Unfortunately, leprosy eradication from community appears to have been equated with the reaching of the WHO-defined target of elimination as a public health problem (prevalence of <1 per 10,000 population), which India reached by the end of 2005. In addition, the use of term “elimination” also leads to confusion among general public and to many even in the medical profession.^[24]

One more reason why attention from leprosy was shifted away in India was, while the nation was preparing for elimination of leprosy as a public health problem in 1990s, public health initiatives for HIV/AIDS were being rolled out in a phased manner in the country. To assist them, leprosy health workers were made multipurpose workers with additional responsibilities of HIV and tuberculosis control. Over the next decade, there was reallocation of resources and a gradual decline in funding for leprosy-related programmes. Later, the perceived drop in prevalence of leprosy paved the way for its integration into the general health care services, with a phasing out of the vertical leprosy programme. A study done in Odisha on the effects of integration of leprosy in to primary health care,^[25] highlighted the need for effective monitoring and evaluation of the integration process. It concluded that inadequate monitoring could lead to a reduction in early diagnosis, a delay in initiation of MDT, and an increase in disability rates, which in turn could reverse some of the programme’s achievements. The

wider reach expected in a horizontal programme needs to be evaluated and actualized. The lack of awareness, diagnostic skills and commitment to leprosy among general health personnel, and the ignorance about the disease in the community that continues to contribute to a delay both in diagnosis and patient self-reporting, need to be reversed.

Need for sustained efforts and increased support to the programme

Unfortunately, the WHO elimination target has no epidemiological or scientific basis or even significance to support the gradual decline or disappearance of the remaining cases of leprosy once it was achieved. Doing away with skin smear services, rapid merging of leprosy services into the general medical health services, efforts towards further reducing the duration of therapy, and reduced attention to research and funding of leprosy programme in general, are some of the direct results of such false interpretation. They need to be re-assessed for the sustenance of the programme. Many often wonder why the enthusiasm, zeal, and efforts of the first two decades of introduction of MDT were curtailed through repeated modifications of programme before the gains achieved were fully consolidated. In Brazil, which is similar to India in its economy and resources where leprosy is an important endemic disease, the investments made by the ministry of the health in leprosy have almost doubled, increasing from R\$ 7.7 million in 2004 to R\$ 13.1 million in 2005 in a scaling-up which was started in 2003.^[26] Another advancement presented by the ministry of Brazil was that the reduction in the incidence and number of cases was accompanied by the expansion of the leprosy diagnostic network. The results could be noted as the new cases in Brazil which were 39,125 in 2007, came down to 25,218 in 2016.

Basic investigations such as skin smear services need to be reintroduced in the leprosy programme of India, as this bacteriological test is often found as useful as advanced PCR techniques. In a study conducted in a leprosy research center to assess drug resistance, findings have shown the value of reintroducing skin smear examination for confirmation/classification of leprosy as it was found reliable in detecting bacilli in 43% of the patients, including 24% of paucibacillary leprosy patients.^[27] It may be learnt that re-introduction of bacteriological diagnosis indeed has changed the diagnostic landscape of tuberculosis, facilitating better case detection and control.^[28] Recognizing that blanket reintroduction of smears would mean training and significant resource allocation, a pilot strategy study in high endemic districts could be highly beneficial in assessing its value.

Disability in new cases and their continued occurrence

For global leprosy, G2D among newly detected cases, whose reduction is an important indicator for the success of

the program, was 5,245 (3.8%) for the reporting year 2016. When compared to the previous year 2015, the global disability rate reduced from 4.5% to 3.8%.^[2] In India, however, as per the NLEP website, the percentage of G2D among new cases detected has increased from 1.97% in 2005–2006 to 3.10% by 2010–2011 and were 4.61% for the year 2014–2015. NLEP report for year 2015–2016 noted 5851 patients with G2D (disability rate of 4.46%) among new leprosy cases, indicating a very marginal reduction. Continued high G2D rate among new cases indicates that leprosy is being detected late and there may be hidden cases in the community.^[29]

The G2D among child leprosy cases is also an important indicator, which is mentioned in absolute numbers. WHO global leprosy statistics for the reporting year 2016 states that information on child G2D cases was available from 210 countries, with 190 countries reporting zero child G2D cases and 14 countries reporting 281 cases, which does not include numbers from India. NLEP report for year 2015–2016 mentions that, out of the total 11,230 new child cases detected during 2015–16, the number of child cases with G2D was 162 (1.4%).^[3]

One of the key reasons for the rise in disability is a delay in diagnosis of leprosy and lepra reactions which lead to persistent neuritis and ultimately to disability. There is need for wider awareness about the signs and symptoms of leprosy and reactions among general health care staff as well as in the community to promote self-reporting, as well as early diagnosis and proper management of the disease and its complications in an integrated setting. “Care after cure” that includes management of trophic ulcers and other long-term complications cannot be ignored.

Need for New Drug Regimen

From its introduction in 1982 to till date, the same three drugs constitute MDT for leprosy, and with emerging resistance to these drugs, there is a need to expand the repertoire of drugs to treat leprosy. Clinical and laboratory studies suggest the emergence of secondary drug resistance in treated/relapsed patients to dapsone, and rifampicin.^[30,31] In 2016, India reported 536 cases of leprosy relapse, a slight increase over the 459 reported in 2015.^[2] Relapses can be due to treatment failure, inappropriate choice of regimen, and more often due to poor patient compliance. In 2016, India reported the largest number of retreatment cases of 6701 and cure rates of paucibacillary 95.4% and multibacillary cases 91.9%.^[2] Ofloxacin, minocycline, clarithromycin, rifapentine, and moxifloxacin are some of the drugs known to be effective in treatment of leprosy.^[32,33] However, there are no standard recommended/approved protocols to use them, except in cases of proven resistance to rifampicin. Absence of management guidelines is leading to their irrational use in various combinations and regimens that can potentially be detrimental to the programme in the long run. Hence, there is a need to design research

studies in this direction. One more reason why we need research proposal on their use is increasing reluctance from patients for using clofazimine due to skin pigmentation. The efficacy of pulse rifampicin, ofloxacin, and minocycline (ROM) as an alternative/additional regimen to treat multibacillary leprosy patients who refuse clofazimine needs to be evaluated.^[34] In addition, with increasing multibacillary leprosy load in the community and severe forms of lepromatous leprosy with high initial bacillary load being diagnosed across the country, there is an urgent need to review the current guidelines of “fixed duration therapy” (FDT) for all types of multibacillary leprosy. It is also important to recognize that leprosy can be associated with other comorbidities such as tuberculosis, HIV, and diabetes which could affect clinical manifestations and complications; hence, therapeutic management strategies need to be tailored to such situations.

Time to Reappraise the Priorities

There is tangible public apathy over leprosy, which struggles to stay high on the political agenda of countries. There is also an overall lack of a comprehensive approach towards battling the disease, which requires collaboration between different ministries and sometimes between countries.^[1] Integration without sustained and enhanced supervision and monitoring together with reduced funding has impeded some of the achievements. This has also posed questions regarding the quality and comparability of data and information collected on leprosy cases.^[1] In addition, with the integration there was a big void in expertise in recognizing and treating leprosy as well as managing complications over the last decade. The result is the present situation where disability percentages are rising because of a delay in diagnosis. There is now a realization that in the past there has been too much of an emphasis on “numbers” – a point prevalence of the disease and a new case detection rate rather than other more important indicators of grade 2 disability, leprosy in the younger age group, and multibacillary disease.^[7]

Need for an Inclusive Strategy

WHO in its document Global strategy for leprosy 2016–2020 acknowledges that in the programme the “meaningful engagement of all stakeholders, including private providers is still limited.” It also suggests “partnership with the private sector, including allopathic private provider for case detection/referral, care and/or social support” of leprosy patients.^[1] Moreover, there is a gap between the reported number of new cases and the actual number. In India, cases are being reported passively, as well as through active case detection for the past few years and around 130,000 new cases are recorded annually. However, the National Sample Survey (2010–2011) and surveys by other Indian leprosy institutes reported a gap between the number of reported cases and the number of actual cases in the community.^[23,35]

It is common knowledge that a good number of leprosy patients are referred to or seek treatment from dermatologists, both at government hospitals and private clinics in India. There are over 10,000 dermatologists in India with more than 9,000 being members of the Indian Association of Dermatologists, Venereologists and Leprologists (IADVL). These are the trained pool of medical practitioners who are the only remaining qualified leprologists in India, involved both in teaching leprosy to undergraduate and postgraduate medical students under university teaching hospitals of India, as well as managing leprosy patients, both new and post RFT in secondary and tertiary care institutions, as well as in private practice. There are significant number of leprosy patients in India managed by dermatologists who go unaccounted in NLEP statistics as they are not reported to government agencies. To test this claim, special interest group (SIG) leprosy-IADVL is planning a nationwide prospective survey to get an estimate of the number of unaccounted leprosy patients.

Leprosy is primarily a disease of the skin and nerves. Most often the first lesion to appear is a skin patch and patients often seek help or are referred to a dermatologist. Due to their in-depth study of leprosy as a part of their training and curriculum, dermatologists of India are capable of diagnosing and treating leprosy including its complications. From the number of research presentations by dermatologists at conferences and publications in journals like the IJDVL, IDOJ, PLoS and Leprosy Review, it is apparent that many dermatologists, both in the public and private sector, are fairly motivated and committed to managing leprosy. Such being the case, it is crucial that IADVL and its members are included by the NLEP of India as its “official partner” to infuse fresh impetus to the programme. What is surprising is that even Indian association of Leprologists (IAL), oldest leprosy association of India, is also not an ‘official partner of NLEP! Involving IADVL and IAL in national leprosy programme of India would be the best possible way of “promoting inter-sectoral collaboration within countries,” as suggested in the WHO strategy document for year 2016–2020.^[1] It is only by including and assigning an active role to this vast pool of dermatologists in the leprosy programme, who are well equipped to manage leprosy, that India can truly aspire to eradicate leprosy.

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Conflicts of interest

There are no conflicts of interest.

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