Editorial

Global leprosy strategy 2016-2020: Issues and concerns

P. Narasimha Rao

The introduction of multidrug therapy worldwide by the World Health Organization more than three decades ago was a seminal intervention in the fight against leprosy. This global leprosy policy brought down the number of leprosy patients in the world from 5.4 million in the early 1980s to a little over 0.21 million new cases for the year 2014. Over the last three decades, World Health Organization has been coming out with action plan documents periodically outlining areas of focus and strategies required, based on the global leprosy situation. The recommendations made by World Health Organization through these documents are of immense significance as these are followed worldwide in the campaign against leprosy. As India is the country with the highest leprosy burden worldwide, Indian leprosy agencies, both government as well as nongovernmental organizations, implement these directives in word and deed and also look to the World Health Organization for guidance in these efforts.

With all the countries with population of 1 million or more having achieved the elimination of leprosy as a public health problem at the national level by end of 2005, the last two operational guidelines for years 2006–2010 and 2011–2015 of World Health Organization elaborated on "strategies for further reducing disease burden" and "sustaining the leprosy activities" worldwide, as their titles suggested. In April 2016, World Health Organization came out with a document titled "Global leprosy strategy 2016–2020: Accelerating towards a leprosy-free world" which proposes to build on the momentum created in leprosy control at the global and local level.[1] Three key targets were defined for the global strategy which are (i) zero grade 2 disabilities among children diagnosed with leprosy; (ii) the reduction of new leprosy cases with grade 2 disability to <1 case/million population and (iii) zero countries with legislation allowing discrimination on the basis of leprosy. These are impressive and well-intentioned targets although they appear too ambitious and difficult to achieve in the next 5 years. Other goals mentioned include promoting early case detection through active case-finding campaigns in areas of high endemicity, strengthening surveillance for antimicrobial resistance including laboratory networks and taking steps to stop discrimination and promote inclusion of leprosy by society at large. The global leprosy strategy is also aligned with the "Roadmap for Neglected Tropical Diseases" to promote further integration at the country level between leprosy and other services at the primary and referral levels.

These are laudable targets and goals. However, there are areas of concern which need to be considered while proceeding with this action proposal. In this regard, let us first look at the latest global leprosy figures.[2] As per the data collected by the World Health Organization, by the end of 2014, a total of 174,608 leprosy cases were receiving multidrug therapy (point prevalence rate of 0.29/10,000 population), and there were 210,758 new cases detected. The Southeast Asian region accounts for 74% of the global new case load with India contributing more than 60% (127,326) of these patients. A slight increase in new cases

Department of Dermatology, Bhaskar Medical College, Yenkapally, Greater Hyderabad, Telangana, India

Address for correspondence: Prof. P. Narasimha Rao, B-48, Income Tax Colony, Mehdipatnam, Hyderabad - 500 028, Telangana, India.
E-mail: dermarao@hotmail.com

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detected was observed in African region, Southeast Asian region and India, attributed partly to the block level case detection campaigns in high endemic areas highlighting the importance of active search in uncovering hidden cases. It is important to note that the global leprosy figures for the year 2014 only encompass annual leprosy statistics received by World Health Organization from 136 countries and does not include leprosy statistics of 92 countries or territories of the world, including 26 African countries, from where no reports were received. Global leprosy planners need to take these unaccounted leprosy numbers, apart from hidden leprosy cases in high endemic and difficult-to-reach pockets of countries like India into consideration while implementing its strategy.

It is well known that the proportion of child leprosy cases is indicative of continued transmission of infection in the community while the percentage of patients with grade 2 disability reflects a delay in the diagnosis. Child cases which at present constitute about 9% of global and Indian new cases detected annually, showed no appreciable decline over the last decade. What is worrisome for India is that the proportion of child cases was 12% or higher of new cases detected in eight states/union territories with Lakshadweep reporting as a proportion of child cases as high as 75%; with 245 new child cases presenting with grade 2 disabilities for the year 2014–2015.[3]

In addition, the number of global new cases with grade 2 disabilities showed an increasing trend from 12,392 in 2006 to 14,059 for the year 2014 corresponding to a detection rate of 2.1 cases/million. This may be explained as being partly due to better reporting of disability status, but that cannot make it less relevant as a pointer to the hidden disability and disease in the community. Even in the Southeast Asian region, new cases with grade 2 disability showed an increase from 5791 new cases in 2005 to 8572 for the year 2014. These call for increased efforts to infuse new vigor into the program to detect and treat leprosy early, especially in children and those with reactions.

The World Health Organization currently uses a composite index for leprosy based on prevalence, new case detection, case detection rates, grade 2 disability rate and percentage of child cases for prioritizing countries that need attention. Based on these indices, 22 countries globally are now considered as having a "high burden for leprosy" including high transmission. This list includes all 14 countries that reported >1000 new cases for the year 2014 representing 95% of the global leprosy burden.

The global leprosy strategy 2016–2020 mentions the introduction of uniform shortened regimen as a key tenet under "vision, goals and targets." It envisions that the introduction of a uniform multidrug therapy regimen with shortened duration (in the case of multibacillary disease) would reduce transmission of infection as well as the number of new cases with grade 2 disability in children in the next 5 years but does not explain as to how a shortened therapy can achieve these objectives. However, in its executive summary, it is more cautious by stating that it would "promote steps to move towards the use of a shorter, uniform treatment regimen for all types of leprosy *based on a thorough review of available evidence on uniform* multidrug therapy and designing a global plan of action for its roll-out." In other words, although the proposal to introduce a uniform shorter multidrug therapy globally is very much alive, it is put on hold for now till the existing evidence is reviewed and probably till more evidence is gathered.

The proposal by World Health Organization in 2002 to introduce uniform multidrug therapy of 6 months duration globally within only 4 years of reducing the 24-month therapy for multibacillary leprosy to 12 months in 1998, has been controversial from the beginning as it was not evidence based.[4] Many leprosy workers questioned its relevance. Nonetheless, it was endorsed a few months after it was proposed and World Health Organization came out with a protocol for an open field trial with emphasis on follow-up for at least 5 years after completion of uniform multidrug therapy. This study proposal was criticized for flaws in the protocol and fears were expressed that it would not produce clear-cut conclusions and more seriously, would produce invalid conclusions in relation to the subgroup of patients with high initial bacillary index, as skin smear testing was not a part of the study design.[5] Nonetheless, World Health Organization went ahead with enrollment for this multicenter open labeled noncomparative study in 2004–2005 with eight centers in India and two in China to assess the efficacy of uniform multidrug therapy based on cumulative 5-year relapse rates. The results of the China uniform multidrug therapy study with 8-year follow-up comprising of 72 multibacillary patients that qualified for final analysis were presented at the International

leprosy Congress held at Beijing this year. Only one relapse was noted corresponding to a relapse rate of 0.05%.[6] The World Health Organization initiated uniform multidrug therapy multi-center Indian study appears to have been concluded, but final results are yet to be announced.

The global effort against leprosy, spearheaded by World Health Organization with the cooperation of all stakeholders, is at an important juncture with the battle against leprosy at a decisive phase while "accelerating towards a leprosy-free world" as envisioned by World Health Organization document for 2016–2020. Although there are matters and issues that need attention and renewed focus mentioned previously in this article, by and large, the state of global leprosy program has been healthy. At this stage, it is important to consolidate the gains already made rather than embark on new adventurous modifications in the program based on specious logic and poor evidence.[7] Further, shortening of the duration of multidrug therapy is one such endeavor, considered by many to be detrimental to the program. At present, multibacillary patients constitute 60.2% of new cases detected globally, and the current 12-month multibacillary-multidrug therapy is a robust regimen proven to treat multibacillary leprosy effectively. With continued reduction in global leprosy numbers, the reason for shortening duration cannot be budgetary constraints. In addition, there are no valid scientific or administrative reasons to shorten the duration of therapy for multibacillary leprosy by 6 months. While global leprosy numbers dwindle, the percentage of multibacillary leprosy cases, a proportion of whom with high initial bacterial load, is likely to rise further in coming years as is expected in the epidemiologic pattern of a waning disease. Hence, it is imperative to address and plan therapy for multibacillary leprosy carefully. It would be wise of the World Health Organization to examine evidence gathered in support of uniform multidrug therapy stringently and critically based on its quality keeping in mind the strengths and weaknesses of the study protocol. In addition, it should also carefully consider whether there is a real need for shortening the duration of therapy for multibacillary leprosy by half when the existing multidrug therapy program has proven to be robust and effective in bringing down the burden of disease globally.

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