Mycobacterium Indicus Pranii vaccine to multidrug therapy in newly diagnosed leprosy cases for better treatment outcomes & immunoprophylaxis in contacts as leprosy control measures

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Policy Brief

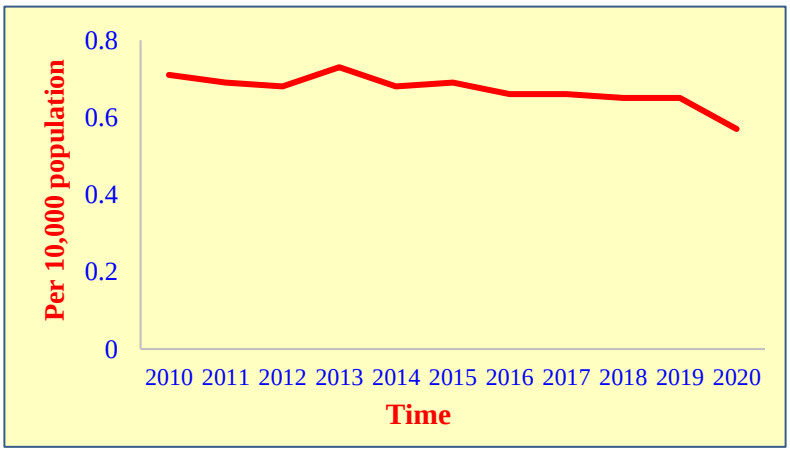
Summary

India is currently running one of the largest leprosy eradication program in the world, the National Leprosy Eradication Program (NLEP). However, the number of new cases reporting annually remained nearly the same during the last 10-15 years. Moreover, a substantial number of these new cases reported disabilities for the first time. Therefore, besides multidrug therapy (MDT), newer strategies with focus on effectively decreasing the number of new cases, optimizing the treatment of detected cases, averting disabilities and arresting the transmission of the disease are required.[1] Understanding this importance, we recommend to implement MIP vaccine in National Leprosy Eradication Programme (NLEP) for newly diagnosed leprosy patients as well as their contacts to arrest, decrease the transmission and occurrence of new cases.

Problem Statement

Leprosy is a chronic infectious disease caused by *Mycobacterium leprae* and it multiplies very slowly. The initial symptoms are spots on the skin, which later turn into skin lesions that are lighter than normal skin color and have a loss of sensitivity. Other symptoms are muscle weakness and numbness. Leprosy is curable with multidrug therapy (dapsone, rifampicin, and clofazimine), a combination that kills the pathogen, cures the patient, and halts transmission. In India, leprosy continues to be a public health problem in India. Though India achieved the leprosy elimination goal as a public health problem in 2005, it still has a high burden of the disease and reported 114,451 new leprosy cases in 2019-2020. The Indian National Leprosy Eradication Programme (NLEP) has scaled up campaigns for early case detection, implemented new initiatives and interventions to accelerate leprosy elimination goals at all sub-national levels reporting of a nearly stable incidence of new cases in the last 10-15 year and increasing reports of disabilities in new case.[1]

Prevalence of Leprosy



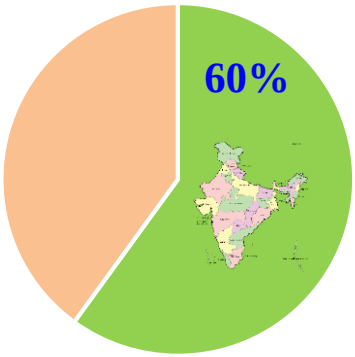
The current multidrug therapy (MDT) strategy alone may not be able to effectively control the disease and its transmission. Better treatment strategies, early diagnosis, care of reactions, reducing disabilities, sensory and motor impairments, preventing relapses and controlling the transmission of leprosy are required.[1]

MIP vaccine has been shown to have both immunotherapeutic and immune-prophylactic effects in multibacillary leprosy patients and their contacts.[2,3] Immunotherapy with MIP vaccine resulted in complete clearance of anti-phenolic glycolipid-1 antibodies in contacts that might otherwise have developed leprosy. Immunoprophylaxis was safe and without any serious side effects. Introduction of MIP vaccination in the NLEP appears to be a cost-effective strategy for India. Significant health gains were reduction in the number of new leprosy cases, decreased incidence and severity of reactions during treatment, and after release from treatment, prevention of disabilities, thus reducing the cost as well as stigma of the disease.[4]

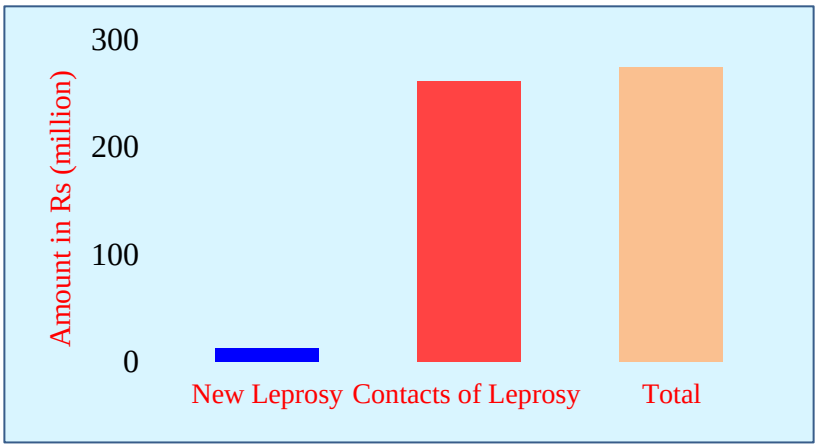
Key Messages

- Leprosy has a low mortality rate but is characterized by several complications in the form of reactions, impairment and loss of sensory and/or motor function, disabilities, social stigma as well as socio-economic implications.
- It is well established that household contacts are about seven times more likely to be infected, while social contacts are 3-4 times more likely to be infected, as compared to the general population.
- *NLEP* has to prioritize strategies to implement *MIP vaccine for newly diagnosed leprosy patients as well as their contacts to arrest/ decrease the transmission and occurrence of new cases*
- Regular awareness and proper treatment of patients with appropriate antibiotics stops the person from spreading the disease.
- MIP vaccine has been shown to have both immunotherapeutic and immune-prophylactic effects in multibacillary leprosy patients and their contacts
- Introduction of MIP vaccination in the NLEP appears to be a cost-effective strategy for India.

India accounts for 60% of new cases reported globally



Annual cost of nationwide implementation of incorporating MIP vaccination



Recommendations

- *NLEP has to prioritize strategies to implement MIP vaccine for newly diagnosed leprosy patients as well as their contacts to arrest, decrease the transmission and occurrence of new cases.*
- Strengthening surveillance and health information systems for programme monitoring and evaluation (including geographical information systems).
- Ensuring prompt start and adherence to treatment, including working towards improved treatment regimens.
- Strengthening patient and community awareness on leprosy and improving prevention and management of disabilities.
- Promoting interventions for the prevention of infection and disease.

Conclusion

The addition of MIP to newly detected cases for better treatment outcomes, reducing the morbidity of the disease, stigma of the disabilities, improving the quality of life of patients, together with reducing the incidence of new cases and is cost-effective for the programme needs. Hence, NLEP has to prioritize strategies to implement MIP vaccine for newly diagnosed leprosy patients as well as their contacts.

This policy brief is based upon the study on "Cost-effectiveness of incorporating *Mycobacterium Indicus Pranii* vaccine to multidrug therapy in newly diagnosed leprosy cases for better treatment outcomes & immunoprophylaxis in contacts as leprosy control measures for National Leprosy Eradication Programme in India".
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Budget impact analysis and net health benefit

The annual cost of nationwide implementation of incorporating MIP vaccination for newly detected leprosy patients and their contacts in the present NLEP was estimated. Based on the estimated incidence of leprosy, the incidence of leprosy among contacts, the expected number of contacts and the expected number of persons to be vaccinated, as well as the tentative budget required was calculated. However, the cost of administering single-dose rifampicin (SDR) to contacts of index case was not accounted for, in the comparator arm, as this strategy was recently introduced in the NLEP and that too only in endemic districts.

References

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