सत्यमेव जयते

National Leprosy Eradication Programme
Post Exposure Chemoprophylaxis

2019

Operational Guidelines

Central Leprosy Division
Directorate General of Health Services
Ministry of Health and Family Welfare
Government of India

NATIONAL HEALTH MISSION
राष्ट्रीय स्वास्थ्य मिशन

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FOREWORD

The National Leprosy Eradication Programme (NLEP) was started in the year 1983 and has achieved considerable success in controlling leprosy. India achieved the elimination of leprosy as a public health problem, less than 1 case per 10,000 population at the national level in 2005. Although the disease has been eliminated, it was observed that new cases are continuing to occuras per the situation analysis done in year 2016. The trend of two important indicators of NLEP, India i.e. Annual New Case Detection Rate (ANCDR) and Prevalence Rate (PR) are almost static since 2005 – 2006.However, the percentage of the percentage of Grade II Disability (G2D) amongst new cases detected has been increased from 1.87% (2005-06) to 4.60% (2015-2016). In view of the same, in addition to the routine activities, several innovations were introduced to address the issues being faced by the programme in a phased manner, including Post Exposure Prophylaxis (PEP) for the prevention of leprosy among contacts.

As a result of all these innovations, the Grade II Disability has been reduced to 2.65 case per million in the year 2018-19 and percentage of G2D among new leprosy cases has also gone down from 4.48% in the year 2014-15to 3.05% in 2018-19.

Recently,in the year 2018, World Health Organization (WHO) has also recommended Single Dose Rifampicin (SDR) chemoprophylaxis for the contacts of leprosy cases as PEP. Feasibility of PEP has been documented in the recent study conducted in Dadra and Nagar Haveli (DNH) during 2015-2018 in collaboration with Netherlands Leprosy Relief (NLR) and Central Leprosy Division (CLD).

Based on the evidence generated under PEP in DNH, and subsequent endorsement by WHO, under NLEP, PEP has been launched nationwide w.e.f. October 2018. This PEP operational guideline will enableprogramme officers and health care staff understanding their role in the implementation of PEP. This guideline will provide directions for systematic implementation of activities pertaining to PEP i.e. planning, coordination, implementation and monitoring.

I would like to acknowledge all experts who helped in bringing out this guideline. I would also like to acknowledge the support of NLR in revising this guideline.

Anil Kumar

Dr. Anil Kumar

Contents

Abbreviations:

ANM	Auxiliary Nurse Midwife
ASHA	Accredited Social Health Activist
CDR	Case Detection Rate
CHC	Community Health Centre
DH	District Hospital
DLO	District Leprosy Officer
MB	Multi Bacillary
MDT	Multi Drug Therapy
MO	Medical Officer
MPW	Multi-Purpose Health Worker
NLEP	National Leprosy Eradication Program
NMS	Non-Medical Supervisor
NRHM	National Rural Health Mission
OBC	Other Backward Class
PB	Pauci Bacillary
PEP	Post-Exposure Prophylaxis
PHC	Primary Health Centre
PMW	Para Medical Worker
RFT	Released from Treatment
SC	Schedule Caste
SDR	Single Dose of Rifampicin
ST	Schedule Tribe
TB	Tuberculosis
TOT	Training of Trainers
UT	Union Territory
WHO	World Health Organisation

INTRODUCTION

Hansen's bacillus (*Mycobacterium leprae*) is considered a microorganism of high infectivity and low pathogenicity and virulence. It is transmitted via nasal oropharyngeal secretions and breaks in the skin of infected patients. Therefore, the main form of transmissibility is inter-human and the greatest risk of contagion is cohabitation with these patients.

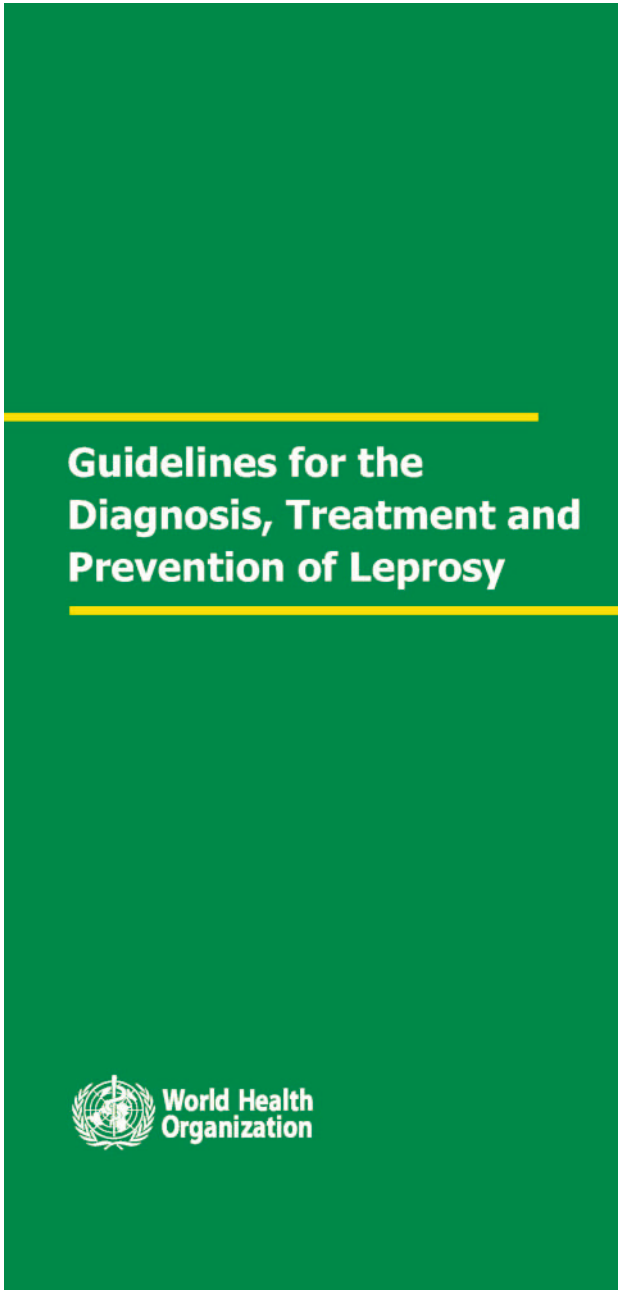
It is estimated that most individuals have a natural resistance to *Mycobacterium leprae* (*M. leprae*) and that some are prone to developing a severe form of the disease, the multibacillary forms. Studies on exogenous reinfection and endogenous reactivation in chronic diseases, such as tuberculosis and leprosy, show that susceptible individuals become infected by the bacillus through contact with multibacillary patients.

The number of new leprosy cases has remained constant over the past years (since 2005), indicating that transmission of *Mycobacterium leprae,* the causative agent of leprosy, is ongoing. The basic intervention is multidrug therapy (MDT) given to newly found leprosy cases, but this seems to be insufficient to decrease the number of new cases.

The main risk of exposure to *M. 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 neighbours and social contacts is between three and five-fold . Therefore, contacts should be the main focus of a future leprosy control strategy.

Post Exposure Chemoprophylaxis is any preventive medical treatment started immediately **after exposure** to a pathogen, in order to prevent infection by the pathogen and the development of disease. In leprosy, the preventive strategy consists of employing medications to prevent the infection by *M. leprae* in people with a higher risk of exposure to the disease, i.e. those in contact with the patient. Trials with rifampicin used as chemoprophylaxis for contacts of leprosy patients have shown it to be effective.

In view of the above and as per the recommendation of expert committee formed by Indian Council of Medical Research (ICMR), chemoprophylaxis administration to contacts was introduced under the National Leprosy Eradication Programme (NLEP) in year 2016, specifically in Districts conducting Leprosy Case Detection Campaign (LCDC).



Further, in view of the recommendation given in “Guidelines for the Diagnosis, Treatment and Prevention of Leprosy”, 2018, WHO the PEP administration activity will be implemented at Pan India level under National Leprosy Eradication Programme, India.

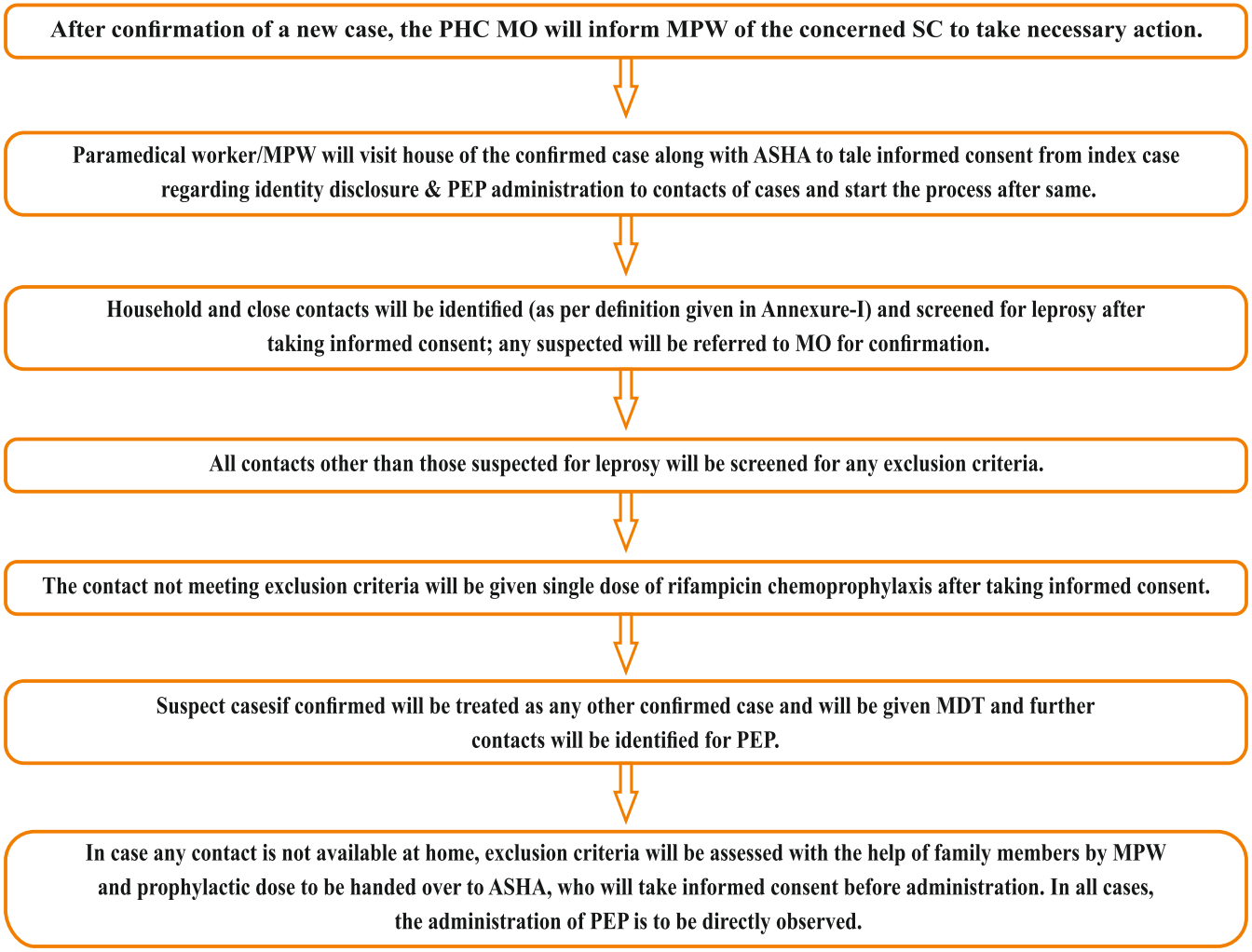
Preparatory activities for Post Exposure Prophylaxis (PEP)

Necessary preparatory activities need to be undertaken before starting single dose administration of rifampicin in the target population.

Sensitization/ orientation meetings need to be conducted for Medical Officers, PHN, NMS, MPW, PMW and ASHA etc. Necessary IEC activities must be carried out at least one week before starting the activity to generate awareness and ensure acceptability of same in community. Single dose rifampicin chemoprophylaxis should be administered in the motivated community members willing to accept prophylactic dose.

District Leprosy Officers should supervise all the preparatory activities with the support from Medical Officers.

Post Exposure Prophylaxis with Single Dose Rifampicin: Flow Chart



Eligibility criteria for PEP

Inclusion criteria

1. A person who has been living/working/having social activities for more than three months and 20 hours/week with a newly detected case of leprosy in the last 1 yr.

2. Age > 2years.

Exclusion criteria

1. Pregnant women (PEP can be given after delivery).

2. People receiving rifampicin therapy for any reason in the last two years (e.g. for tuberculosis [TB] or leprosy treatment, or as a contact from another index case).

3. People with a history of liver disorders (ask for H/o jaundice, right sided abdominal pain and swelling, swelling in legs and ankles, pale coloured stool) or renal disorders (ask for H/o decreased urine output, swelling in legs and ankles, H/o high BP).

4. People who have possible signs and/or symptoms of leprosy.

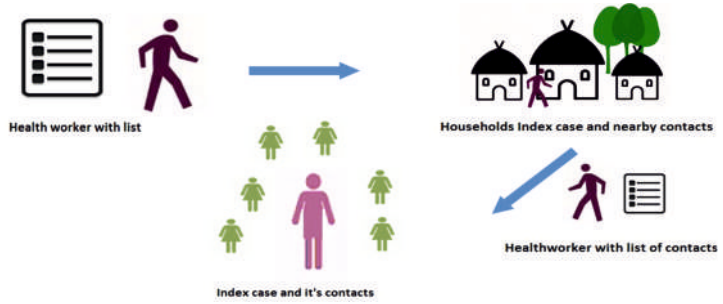
5. People who have possible signs and/or symptoms of TB (patients having any of the these symptoms should be screened for TB: cough for more than two weeks, night sweats, unexplained fever, weight loss).

6. Person with acute febrile illness.

However, patients with signs and symptoms of other diseases including leprosy may be referred to nearest health facilities for further confirmation and management.

Contact Tracing and screening:

The health worker visits the contacts on the list, informs them about the LPEP and screens them for leprosy, exclusion and other eligibility criteria.



Contact Screening, in case the index case is a child:

In case the index case is a child (>2yrs and <14yrs) everything will be done as in point 1 to 8. In addition to the above home visit to the class mates of the child living in the same locality must be done to screen them for leprosy and checking eligibility for PEP.

In case of non -availability of all or any contact at home during visit of the worker, the eligibility for PEP of all or same must be checked by MPW/ MW through enquiry with other family members. Afterward, Rifampicin and eligibility formats for the persons not checked for eligibility, must be handed over to ASHA with the responsibility to ensure the consumption of same by the absentee/s contact after checking for the eligibility. The filled in format (Annexure IV) for eligibility must be submitted back to MPW/ PMW.

If during screening of contacts a suspected case of leprosy is identified the referral of same may be done to the Medical officer of the nearest health facility for confirmation. If the suspect confirmed as a leprosy patient same may be treated as per the standard guidelines, if not the post exposure prophylaxis i.e., rifampicin to be given.

PEP – administration:

After screening the contacts using exclusion criteria, eligible contacts are given Single Dose of Rifampicin (SDR). Depending on age / weight, the dose of Rifampicin is likely to be as follows:

600 mg (age ≥15 year),

450 mg (age 10–14 years), and

300 mg (age >6–9 years and weight≥20 kg).

Children under 20 kg (≥2 years) should be given a dose of 10–15 mg/kg body weight

The oral intake of rifampicin should be supervised by health staff. In case of child index case, his/her contacts/classmates are to be examined at their houses (not in the school) after collecting their addresses from the school. PEP could be given to these contacts after taking consents from their parents.

Safety/adverse event management

The adverse events following administration of single dose of rifampicin rarely occur. However, likely adverse drug reactions are upset stomach, heartburn, nausea, headache, drowsiness, or dizzeness which will be managed as per standard treatment protocols. In addition the persons may be educated by MPW during the visit only about that this medication may produce a harmless, reddish coloration of urine, sweat, saliva or tears.

Procedure in the case of an Adverse Event

In addition to the above mentioned symptoms, if any adverse drug reaction is noticed by the person/ contact himself/herself after administration of Rifampicin. The case must be referred to to Medical Officer of PHC for further management or referral to the nearest hospital.

Monitoring and Supervision

The Medical Officer of the PHC is responsible for ensuring screening of all the contacts of each and every leprosy patient. The MO has also to ensure that the guidelines specified for inclusion and exclusion criteria are being followed while screening of contacts. The MO PHC will also be responsible for adverse event management.

Procurement

1) Procurement of rifampicin would be done by the state/district.
2) Calculation of the requirement based on yield of new cases and calculation of cost of the required quantity (assume 20 contacts /case).

Reporting

The data collection has to be done by PMW/ MPWs and filled forms have to be submitted from field/ Sub Centre to corresponding PHC . MO PHC must verify the completeness of the forms through random selection. The data from District has to be sent to State. The data will be transmitted to CLD under the following heads (as per Annexure V):

1) Total no. of index cases
2) Total no. of contacts screened
3) Total no. of contacts diagnosed as leprosy
4) Total no. of contacts found eligible for PEP
5) Total no. of PEP administered
6) No. of contacts given SDR developed serious adverse event.

Annexure I

	Operational definitions
Chemoprophylaxis	Post-exposure prophylaxis with one or more antibiotics given to contacts of an infectious disease case. A single dose of Rifampicin is used to reduce the risk of developing leprosy in contacts of leprosy patients (index cases).
Contact	Someone who had prolonged regular or interrupted contact with an index case during the last one year. The time period of contact will be 3 months (cumulative) and 20 hrs /week.
Contact category	This is based on physical proximity to the index case. The categories are family contacts, household contacts, neighbour contacts and social contacts.
	Family contacts comprise of all family members. However, if a family member has been away due to reasons e.g. work or education during the last 1 year, then he will not be included among contacts.
	Household contacts are people living in the same house as the index case.
	Neighbour contacts would compriseof are all people living in 3 houses oneither side and 3 houses across thestreet from the index case.
	Social contacts are all people withwhom the index case is in contact for more than 20 hrs per week for a cumulative of 3 months or more.
Contact screening	Examination of a contact having been in physical proximity to the index case to determine if they have signs or symptoms of leprosy.
Leprosy patient	A leprosy patient is defined as someone who has one of three cardinal signs.
Single-dose rifampicin prophylaxis	Post-exposure prophylaxis, in which a single dose of Rifampicin, with dosage based on weight/age is given to contacts of an index case. In this document single dose Rifampicin prophylaxis is referred as Post-Exposure-Prophylaxis (PEP).
Index case	Any confirmed case diagnosed for thefirst time as leprosy case

Human Resources: Roles and Responsibilities

Annexure II

S. No.	Staff Involved	Roles and Responsibilities
1.	MPW/PMW/ASHA	a) Find index leprosy patient b) Carry out house visit c) Confirm the start of MDT for index case d) Inform about leprosy prevention and chemoprophylaxis e) List 11 neighbourhood contacts on contact form f) Collect data on contact form g) Screen for leprosy h) Bring contacts suspected for leprosy to M.O. I) Record referral in contact form j) Check eligibility for PEP (PMW/MPW) k) Give PEP if eligible (PMW/MPW) l) Record eligibility and SDR in contact form Refer to PHC in case of adverse event
2.	NMS/PHN	a. Supervision of field activity of MPW/PMW/ASHA
3.	MO PHC	a. Examine contacts suspected of leprosy or Tb. b. Responsible for distribution of Rifampicin. c. Management of adverse reactions.
4.	DLO/StateLeprosyOfficer (NLEP)	a. Leprosy expert supervision of field level staff and Mos. b. To provide training.

Annexure III

SAMPLSE FORMATS

INDEX CASE INFORMATION:

Name: Date of Birth/Age:

Gender:

Date of Diagnosis:

Registration Number:

Type of Leprosy (PB-MB):

Disability: Y/N

Date of start of MDT:

Annexure IV

CONTACT FORM

Name: DOB:

Informed Consent taken: Y/N
Gender:
Registration No. of contact:

Registration number of index case:

Date of contact screening:

Type of contacts: relative/neighbour/social/temporary

Inclusion criteria for Rifampicin:

1.Person has been living/working/having social activities for more than three months. Y/N

2.Age > 2 years. Y/N

Exclusion criteria:

1.Pregnancy Y/N
2.Rifampicin therapy for any reason in the last two years (e.g. for tuberculosis [TB] or leprosy treatment, or as a contact from another index case) Y/N
3.History of liver disorders (ask for H/o jaundice, right sided abdominal pain and swelling, swelling in legs and ankles, pale colour stool) Y/N
4.History of renal disorders (ask for H/o decreased urine output, swelling in legs and ankles, H/o high BP) Y/N
5.Possible signs and/or symptoms of leprosy. Y/N
6.Presence of Acute febrile illness. Y/N
Whether eligible for chemoprophylaxis: Y/N
Date of Rifampicin administered ----------

Name: _____

Sign of MPW/PMW: _____

PEP: Monthly Report Form

Annexure V

Name PHC/CHC : ……

Name District : ……

Name State : ……

Report of Month : ……

S. No.	Name of PHC/	CHC/ DistrictNo. Index cases approached	No. contacts examined/screened			No. of new leprosy cases among contacts	No. of contacts found eligible	No. contacts given SDR	No. of persons given SDR reported adverse event
			Family	Neighbours	Social				

until
No Leprosy Remains

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