

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 neighbors 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.

A meta analysis summarized 7 RCTs with a total of 66 311 participants to conclude that Chemoprophylaxis is effective in lowering the incidence of leprosy in contacts of patients diagnosed with the disease. Chemoprophylaxis provided 60% protection against leprosy.

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 atleast one week before starting the activity to generate awareness and ensure acceptability of same, amongst 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.

Eligibility criteria for PEP

Inclusion criteria

1. A person who has been living/working/having social activities for more than three months and 20 hrs/wk with a newly detected case of leprosy in the last 1 yr.
2. Age ≥ 2 years.

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 following symptoms should be screened for TB: cough for more than two weeks, night sweats, unexplained fever, weight loss).
6. Person with acute febrile illness.

Post Exposure Prophylaxis with Rifampicin (Directly Observed Rifampicin Supervised DORS)

After confirmation of a case detected during LCDC, the PHC MO will inform MPW of the concerned SC to take necessary action.



Paramedical worker/MPW will visit house of the confirmed case along with ASHA.



Household and close contacts will be identified and screened for leprosy, any suspected will be referred to MO for confirmation.



All contacts other than those suspected for leprosy will be screened for any exclusion criteria.



The contacts not meeting exclusion criteria will be given single dose of rifampicin chemoprophylaxis.



Suspect cases if confirmed will be treated as any other confirmed case and will be given MDT and further contacts will be identified for PEP.



In case any contact is not available at home, exclusion criteria will be assessed with the help of family members by MPW and prophylactic dose will be handed over to ASHA for administration. In all cases, the administration of PEP has to be directly observed.

Contact screening, in case the index case is a child

In case the index case is a child (≥ 2 yrs and <14 yrs) 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/ PMW 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 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.

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 dizziness 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 report 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 is 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.
- 2) Calculation of the requirement based on yield of cases from LCDC 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 has to be submitted from field/ Sub Centre to corresponding PHC every day. MO PHC must verify the completeness of the forms through random selection. The data from District to State may be sent on weekly basis. The data will be transmitted to CLD under the following heads:

- 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 as DORS

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 has 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 / wk.
Contact category	<p>This is based on physical proximity to the index case. The categories are family contacts, household contacts, neighbour contacts and social contacts.</p> <ul style="list-style-type: none">• Family contacts comprise of all family members. However, if a family member has been away due to reasons eg 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 comprise of are all people living in 3 houses on either side and 3 houses across the street from the index case.• Social contacts are all people with whom 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 and has not completed a course of MDT. A new case of leprosy is defined as someone who has one of three cardinal signs and has not consumed even a single dose of MDT/started a course of MDT.
	This definition is in the national guidelines and based on the WHO definition.
Single-dose rifampicin prophylaxis	Post-exposure prophylaxis in which a single dose of rifampicin, with dosage based on weight, is given to contacts of an index case. In this document single dose rifampicin prophylaxis is referred as Post-Exposure-Prophylaxis (PEP).
	> 35 kg - 600 mg
	20 - 35 kg - 450 mg
	< 20 kg - 10-15 mg/kg
Index case	Any confirmed case diagnosed for the first time as leprosy case

Annexure II

Human resources: roles and responsibilities

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 10 neighborhood contacts on contact form f. Collect data on contact form g. Screen for leprosy h. Bring contacts suspected for leprosy to MO 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 m. Refer to PHC in case of adverse events
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/ State Leprosy Officer (NLEP)	a. Leprosy expert supervision of field level staff and Mos. b. Give training

Annexure III

SAMPLE FORMATS

INDEX CASE INFORMATION:

Name:

DOB:

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:

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 coloured 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: _____