Guidelines for Post Exposure Chemoprophylaxis with Single dose Rifampicin

Background

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 done at Dadra and Nagar Haveli in 2015 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.

The surveillance of leprosy contacts is a priority action for control of the disease. Available evidence has indicated that: i) chemoprophylaxis with single dose rifampicin is efficacious in reducing the risk of developing leprosy and can be targeted to contacts , ii) across very diverse settings, contact tracing combined with chemoprophylaxis offers protection rates comparable to those reported in controlled trials; administration of PEP may be more optimal in high-incidence pockets ('hotspots') or remote or confined high-incidence populations ('hotpops'), iii) implementation of contact-tracing programmes is feasible and cost-effective, particularly in high-risk groups

Eligibility criteria for PEP

Inclusion criteria

1. A person who has been living/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. A diagnosed case of Tuberculosis on treatment and 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.

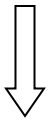
Post Exposure Prophylaxis with Rifampicin (Directly Observed Rifampicin Supervised DORS)

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

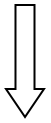
Paramedical worker/MPW will visit house of the confirmed case along with ASHA.

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

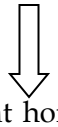
All contacts other than those suspected for leprosy will be screened for any exclusion criteria.



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 is a CHILD

In case the index case is a child (≥ 2yrs and <14yrs) everything will be done as in point 1 to 8. But on top of that the class mates of the child in the same locality will get a home visit to screen them for leprosy and checking eligibility for PEP.

In case contact is not available at home, the eligibility of the person will be checked by MPW/PMW from family member and medicine along with the eligibility format will be left with ASHA who will then ensure the consumption of Rifampicin by the absentee contact and return the eligibility form to MPW/PMW after consumption of Rifampicin.

Process after exclusion

In case a contact is suspected to have leprosy . This contact will be referred to the medical officer at the nearest health facility.

In case the contact is diagnosed with leprosy, the patient will be treated with MDT as per the national guidelines. If leprosy is excluded by the medical officer, the contact will be given PEP.

Safety/adverse event management

Adverse events following the administration of the single dose of rifampicin rarely occur.

Likely adverse drug reactions are upset stomach, heartburn, nausea, headache, drowsiness, or dizziness which will be managed as per standard treatment protocols.

This medication may produce a harmless, reddish coloration of urine, sweat, saliva, or tears.MPW will educate the persons about this side effect during her visit.

Procedure in the case of an Adverse Event

Adverse Drug Reaction noticed by patient himself after medication

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In case of reaction

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Patient will report to MO

PHC who will either manage the case or refer

to the nearest referral hospital

Monitoring and supervision

The medical officers will be responsible for and regularly check that the contact screening for leprosy and checking the in- and exclusion criteria is done appropriately. The medical officer will approve and sign the contact form and will be responsible for adverse event management.

The state leprosy officer, as a leprosy expert with vast experience, will guard the integration of chemoprophylaxis into NLEP according to the guidelines.

Procurement

1) Procurement of rifampicin would be done by the state.
2) Firstly, calculation of the requirement based on yield of cases from LCDC and calculation of cost of the required quantity (assume 20 contacts /case).
3) Select the supplier based on the lowest bidder without compromising on the quality of stock.
4) Make a written request to supplier.
5) Check the quantity,expiry of drug stock received.
6) Maintain record of stocks.
7) Distribute the drug to the district.

Training Plan

Target group	**Purpose** To learn about	**Duration**	**Trainer**
SLOs and DLOs	Implementation, management, supervision, recording and reporting	1days	NLR & GLRA,WHO partners in coordination with NLEP
PMW/MPW/NMS	Leprosy, contact examination, PEP, counseling for adverse reaction, data collection	2 days	State Leprosy Officer and DLO
ASHAs	Leprosy, contact examination, PEP	1 day	PMW/MPW/NMS

Reporting

Field level data collection will be conducted by PMW/MPWs .Every day filled forms will be transported from field/ Sub Centre to corresponding PHC, where the medical officer will verify the forms (continuous random check) and ensure the completeness of the forms. Also, he will confirm the diagnosis of suspect cases. All the forms will be dully signed by the medical officers, and further transported to the district. The whole process will be coordinated by the NMS/PHN. Data from the paper forms will be compiled in excel format by DEOs at state level. Further, SLOs, Consultant NLEP will again check the data accuracy and completeness by 10% random checks. Further, the data will be transmitted to CLD under the following heads:

1) Total no. of index cases
2) Total no. of contacts examined
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

Operationaldefinitions:

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	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 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

	Staff Involved	Roles and Responsibilities
1	MPW/PMW/ASHA in rural area MPW/PMW/USHA in urban area	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 neighbour 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.	MO PHC /MO UHC	a. See contacts suspected of leprosy or TB b. Have medical responsibility for distribution of rifampicin: signs all index and contact forms c. In case of any adverse reaction, MO will manage the case at PHC or refer to RRT or hospital
3	NMS/PHN	a. Accompany all house visits to children and around 10% of house visits to adults b. Work with MPW/PMW/ASHA during house visits and check the procedures c. Check data on index case form d. Check data on contact form
4	DLO/State Leprosy Officer (NLEP)	a. Leprosy expert supervision of field level staff and Mos. b. Give training

ANNEXURE III

	Index case form	• Registration number • Diagnostic date • DOB and gender • Disability grading • Type of leprosy (PB-MB) • Date of start of MDT
	Contact listing register	• Date of contacts listing • Registration number of index case • Registration number for each contact • Type of contact: household/neighbor/social contact
Contact form	**Contact form general part**	• Registration number of index and of contact • Date of contact screening • DOB and gender • BCG scar • Type of contacts: relative/neighbour/social/temporary
	Contact form negative screened part	• Inclusion criteria for rifampicin • Exclusion criteria • Date of Rifampicin swallowed – dosage received • Adverse event – type of adverse event
	Contact form positive screened part	• Number of skin lesions with definite loss of sensation • Weakness and deformity of hand, eye, foot. • Referral Y-N • Date seen by medical officer • Diagnosis confirmed Y-N • If confirmed start date of MDT

ANNEXURE IV

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:

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 swallowed – dosage received

Sign of MPW/PMW

Name: