Leprosy/Hansen disease: Contact tracing and post-exposure prophylaxis

Technical guidance





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Abbreviations

GPS	geographic positioning system
IEC	information, education, communication
LPEP	Leprosy Post-Exposure Prophylaxis Programme (study)
MB	multi-bacillary
MDT	multidrug therapy
M. leprae	Mycobacterium leprae
M. tuberculosis	Mycobacterium tuberculosis
NCDR	new case detection rate
NGO	nongovernmental organization
NLP	National Leprosy Programme
NNN	NTD NGO Network
NTD	neglected tropical disease
PB	pauci-bacillary
PEP	post-exposure prophylaxis
ROM	rifampicin, ofloxacin, minocycline
SDR	single-dose rifampicin
ТВ	tuberculosis
WHA	World Health Assembly
WHO	World Health Organization

Foreword



Early detection and prompt treatment have been the basic tenets of leprosy control for several decades. When this was combined with multidrug therapy, which was introduced in the 1980s, leprosy became a curable disease.

As more patients were cured, the number of patients on treatment – known as the "registered prevalence" – rapidly decreased. However, the detection of new cases reduced more slowly, at a rate of 2% per year. Visible deformities at the time of diagnosis as well as childhood leprosy continue to occur, highlighting the need for high-impact preventive initiatives to bend

the case-detection curve and reduce leprosy-associated disabilities.

Prolonged contact with untreated leprosy patients is known to spread infection. Contacts at home, in the neighbourhood or in the community, are considered at greater risk of being infected and subsequently developing the disease. The screening of contacts and the provision of prophylactics are crucial to break the chain of transmission.

Based on available evidence, prophylaxis with single-dose rifampicin, administered to both household and social contacts, prevents leprosy. The protective effect is around 55%-60%, with a higher efficacy when combined with BCG vaccination at birth. Consequently, the WHO Guidelines for the diagnosis, treatment and prevention of leprosy (2018) recommends post-exposure prophylaxis with single-dose rifampicin for all contacts.

This document addresses *how* to undertake contact screening and chemoprophylaxis under routine programme conditions. It also elaborates on the need for persons affected by leprosy to be counselled on disclosing their disease status and having their contacts traced. Counselling is also important for motivating healthy contacts to reduce their chances of developing leprosy through chemoprophylaxis. The document elaborates on the components of screening and chemoprophylaxis in leprosy. Maximizing the coverage of both interventions is required to achieve the necessary impact, which can be further accelerated by introducing post-exposure prophylaxis – a new, simple and promising intervention.

I am hopeful that this document will help national programmes and partners to sustain and accelerate the implementation of high-impact leprosy preventive initiatives, and to secure additional investments from both governments and partners for achieving a leprosy-free future for all.

Phitapol

Dr Poonam Khetrapal Singh Regional Director WHO South-East Asia Region

Executive summary

Leprosy or Hansen disease is known to mankind since ancient times. In the early 1980s, introduction of multidrug therapy (MDT) brought a lot of hope. Goals were set to achieve 'elimination of leprosy as a public health problem'. This goal was achieved at the global level in 2000 and by most countries in 2005. The data of the last ten years, however, show that the number of new cases detected globally hovers above 200 000 each year. An increase is even reported in several countries where special efforts were done to search actively for cases hidden in the community. Contact tracing is one modality of such active case detection.

Research and field observations indicated that significantly more cases are detected among contacts of a leprosy patient compared to the general population. With no major decline in new case detection over the years, it was clear that passive case detection and treatment with MDT alone will not be sufficient to interrupt transmission.

Different medicines or combinations of medicines have been tried for prophylaxis of leprosy: dapsone; acedapsone; rifampicin, ofloxacin and minocycline (ROM); and rifampicin alone. They were found to be effective but the evidence was not enough to introduce it as a routine programme component. A randomized controlled trial with single-dose rifampicin (SDR), given once, demonstrated a reduction of 57% of new leprosy patients among contacts. Subsequently, studies in different countries have proven that chemoprophylaxis with SDR can be implemented as part of routine leprosy control activities, is effective and highly acceptable.

Leprosy control programmes in several countries – e.g. Morocco, India, Indonesia, Nepal, the United Republic of Tanzania – introduced contact screening and post-exposure prophylaxis (PEP) as routine programme activities and found it to be effective in bringing down the number of new cases. If implemented effectively in other countries, it is expected to accelerate bringing down the number of new cases globally.

The two interlinked approaches are considered as major public health interventions: screening of contacts will detect otherwise hidden cases while PEP will reduce future leprosy among the healthy contacts. Household contacts are the low hanging fruits when it comes to detection of leprosy in contacts while PEP will have the highest impact at population level if a wide coverage of all types of contacts can be achieved. The involvement of family members, persons affected by leprosy and community leaders is paramount for maximizing coverage of both interventions.

Counselling is critical to obtain informed consent from the index patients to reveal their disease status to their household, neighbour or social contacts; and from the contact

persons to agree to be screened for leprosy or benefit from prophylaxis unless a wider coverage/blanket approach is applied, for which disclosure of the disease status of the index patient would not be needed.

This technical guide is meant to provide guidance to the readers on how to implement contact tracing and chemoprophylaxis under routine programme conditions. The guide will be helpful for national and sub-national programme managers, doctors, paramedical staff, partners and the community.

Glossary

This glossary deals with different definitions and terms which appear in this document. It will be most useful if the reader is acquainted with these definitions and terms.

Exposure: When a healthy person comes in contact with a leprosy-infected person able to infect others (i.e. before treatment or even before symptoms occur), the healthy person is considered to be exposed.

Infection: When the leprosy bacillus enters the human body and multiplies, the person is said to be infected. The organism may or may not cause disease, depending on the immunity (the resistance in the body) of the host.

Prophylaxis: administration of a drug or vaccine to prevent disease.

Chemoprophylaxis: Prevention of an infectious disease by the use of chemical agents/drugs.

Post-exposure prophylaxis (PEP): Administration of drugs (e.g. rifampicin) to prevent leprosy disease in a person who is or has been in close contact with a leprosy patient as there is a higher probability that the person may have been infected.

Leprosy case: A patient having one or more of the following: (i) hypo-pigmented skin lesion with definite loss of sensation; (ii) Impairment or involvement of the peripheral nerve as demonstrated by a) definite loss of sensation or b) weakness of hands/feet or face or c) autonomic function disorders such as anhidrosis (dry skin); (iii) presence of visible deformities; (iv) signs of the disease with demonstrated presence of bacilli in slit-skin smear or histopathological confirmation; AND in need of leprosy treatment as decided by a clinician (1).

Index case: Any person diagnosed with leprosy for the first time.

Source case: An untreated patient who may have infected or may still infect other persons. Index case and source case are often used interchangeably, though it is not always sure that the index case is indeed the actual source of infection.

Secondary case: subsequent case, likely infected from a known source case. Due to the variable and often long incubation period, the above-mentioned definitions of index/source case and secondary case are only conventionally used while it may never be possible to determine which patient is the true source or secondary case.

Contact: a person having close proximity to a leprosy patient for a prolonged duration. Such persons are considered "exposed" to leprosy and may or may not have been infected. "Prolonged duration" is typically defined as having been in contact with an untreated patient for 20 hours per week for at least three months in a year, e.g. family members, neighbours, friends, school children in same class; co-workers in same office, etc. (2,3).

NOTE: A person whose exposure with a leprosy patient only starts after the patient has been treated for four weeks is not considered a contact.

Household contact: contact living in the same dwelling or sharing the same kitchen with an index case. This includes family members but also domestic staff or aids or co-workers or others sharing the same accommodation. A family member living elsewhere should not be considered as a household contact.

Neighbour contact: a person living in the neighbourhood of an index case, typically defined as an adjacent household or living within 100 metres (4). Because of geographic proximity, these persons have a higher probability of being exposed and/or infected.

Social contact: other persons having prolonged contact with an index case and who are not classified as household or neighbour contact. These may include friends, persons sharing workplace (e.g. factory workers, office colleagues) or school (students and teachers) or leisure venue (e.g. sports club).

Blanket approach: situation where the entire population of a defined geographic area (e.g. district, island, village, hamlet) is provided with an intervention such as a prophylactic drug. In case of drug distribution, this is sometimes also called "mass drug administration".

Early diagnosis and prompt treatment have been the main strategy to halt transmission of *Mycobacterium leprae* (*M. leprae*) and avoid disability. Tremendous efforts were made to reduce the prevalence which was defined as 'number of patients on treatment'. The World Health Assembly (WHA) target of reducing the prevalence rate to less than one case per ten thousand population was reached globally in 2000; and in most endemic countries at the national level by 2005. When this global target was achieved at the national level, policymakers, support organizations, even health workers became complacent. As a result, active case detection was no longer considered effective and gradually all active case detection methods were discouraged. Screening of contacts was no exception. Leprosy services were integrated into general health care services to enhance the reach of services through primary health care, improve cost-effectiveness and promote inclusion.

1.1 Importance of active case detection and contact examination

As highlighted in the *Global leprosy update, 2018: moving towards a leprosy-free world,* a decline – albeit very slow – in case detection has been observed: from 244 796 new cases detected in 2009 to 208 641 in 2018; the decline in case detection was about 2% per year. The decline in childhood leprosy was also only modest: from 10.6 per million children¹ in 2014 to 7.9 per million children in 2018. The proportion of children among new cases ranged from 9.0% in 2014 to 7.6% in 2018. The continuing high child rates and proportions point to ongoing transmission (*5*). The same publication documents a higher case detected cases in several countries is attributed to operational reasons rather than an actual increase in incidence, as these countries through active case detection campaigns (including contact examination) were able to detect many cases that were hidden for a long time. Annual screening (for five years) of all contacts of leprosy cases was proposed in the WHO Global Leprosy Strategy 2016–2020 as one of the key interventions of the leprosy programme along with MDT services in low burden settings (*1*).

The importance of contact examination can also be concluded from the following studies. A longitudinal study was conducted in Karonga district, Malawi, and found that household contacts of multi-bacillary (MB) leprosy patients have a five- to eight-fold increased risk of developing leprosy, compared with individuals not living in such dwellings;

¹ A child with leprosy is defined as being 0-14 years old at the time of diagnosis

while the likelihood of developing leprosy in household contacts of pauci-bacillary (PB) cases was almost double than the general community (6). A survey conducted in Puttalam district, Sri Lanka, concluded an increased risk of developing leprosy among household contacts (odds ratio: 6.69; *p*-value < 0.001) (7). In a study conducted in Bangladesh, it was concluded that contact examination should be completed at the earliest opportunity after the index case is diagnosed (8). Studies conducted in the Comoros and Bangladesh indicated an increased risk of leprosy among contacts beyond households and recommended that contact examination be extended to neighbours (2,9).

Contact tracing is also explicitly mentioned under Pillar 2 of the WHO *Global Leprosy* Strategy 2016–2020 "Accelerating towards a leprosy-free world" (Stop leprosy and its complications) promoting active case finding and contact management (10).

1.2 Chemoprophylaxis efficacy

Many efforts have been made to find a preventive treatment in the form of a drug. Several studies have been conducted including dapsone and acedapsone but references related to rifampicin are used here:

In 1988, chemoprophylaxis using SDR was studied in the Marquesas Islands of French Polynesia. Follow-up was done for ten years and the overall reduction in new cases was 35%-40% (11-13). Chemoprophylaxis was tried in different Pacific islands. Adults were given ROM while children received rifampicin. Though a substantial reduction in new cases was observed in 1999, subsequent data and follow up could not establish that the reduction was attributable to the chemoprophylaxis (14). Rifampicin was used in five highly endemic islands of Indonesia. The cumulative new case detection rate (NCDR) in the 'control' islands was 39/10 000 population while in islands using the blanket approach the NCDR was found to be around three times lower. (15).

A major break-through came with a double-blind, randomised controlled trial named COLEP carried out in Bangladesh between 2002 and 2007. The overall risk reduction was found to be 57% (16,17). A meta-analysis by Smith et al. of 127 published papers on chemoprophylaxis – using dapsone, acedapsone, ROM or rifampicin alone – found that chemoprophylaxis provides 60% protection to contacts of leprosy (18).

The WHO *Global Leprosy Strategy 2016–2020* promotes interventions for the prevention of infection and disease (10). The WHO *Guidelines for the diagnosis, treatment and prevention of leprosy (2018)* recommends prevention of leprosy through chemoprophylaxis. In the editorial note of the WHO Weekly epidemiological record nos. 35/36, 2019, 94, 389–412, it is stated that "the gradual reduction in new cases seen already would be boosted by the introduction of SDR chemoprophylaxis, and the decreasing trend in new cases raises the question of whether the case detection curve has taken a bend towards a leprosy-free world" (19).

1.3 Feasibility and acceptability of chemoprophylaxis

Feasibility and acceptability of PEP using SDR, given once, administered under routine programme conditions, have been assessed in several studies. A qualitative study was carried out in Bangladesh. It concluded that chemoprophylaxis for household contacts of leprosy patients is an effective and socially acceptable addition to leprosy programme activities (20). A feasibility study of administration of SDR was carried out in Selaru Island, Indonesia. It concluded that with adequate planning and some additional investment, blanket approach of chemoprophylaxis is feasible (21). Acceptability of the implementation of PEP was assessed in the Union Territory of Dadra and Nagar Haveli, India, concluding that SDR-PEP has been very well accepted by the main stakeholders with compliance rate of 99.0% among leprosy patients and 98.6% among contacts (22). In Brazil, a study was conducted for acceptability of PEP along with the *PEP-HANS project*, in which participants acknowledged the relevance of PEP, based on the possibility of interrupting the transmission, prevention of new cases and improved quality of life (23).

In a multi-country study named *Leprosy Post-Exposure Prophylaxis Programme* (LPEP), SDR was given once as PEP. The study was conducted in Brazil, India, Indonesia, Nepal, Myanmar, Sri Lanka and the United Republic of Tanzania between 2015 and 2018. It assessed the feasibility of PEP under routine programme conditions and concluded that the tested approach of contact tracing followed by screening and the provision of SDR is generally feasible, with contact definition adapted to local conditions and programme resources. Once contact tracing has been established, PEP can be integrated into the routines of leprosy control programmes with minimal additional efforts. It is generally well accepted by patients, their contacts and the health workforce (24).

The cost–effectiveness of SDR-PEP was also assessed as part of LPEP in Dadra and Nagar Haveli, India. It was concluded that the provision of SDR-PEP is a cost–effective strategy in leprosy control in both the short (5 years) and long (25 years) terms (25).

Till date, no vaccine or preventive tool has established itself to be implemented in routine leprosy control programmes.

With the facts mentioned above and the available evidence, it is clear that health systems should be geared towards adding contact examination as an important component of leprosy control. Examination of contacts and special interventions such as chemoprophylaxis with SDR, given once, is feasible, acceptable, cost-effective and will be useful in reducing the risk of developing leprosy and slowing the transmission of leprosy. Research is going on to find a 'preventive vaccine', combination of vaccine and chemoprophylaxis, more potent combinations of prophylactic drugs, etc., which may eventually replace SDR-PEP.

This technical guide is meant to provide the readers with different aspects of contact tracing and chemoprophylaxis used under routine programme conditions. It includes eligibility criteria, obtaining consent, administration, monitoring, supervision, drug procurement, supply management, adverse events monitoring and reporting. The guide will be helpful for national and sub-national programme managers, doctors, paramedical staff and partners.

2.1 Contact tracing and screening

Identification of index case(s), including address* at the time of diagnosis or from the treatment register for cases detected earlier		
Counselling of the case about the disease, its curability,		
spread and possible prevention		
Consent of the case for disclosure (not needed in a blanket approach)		
(if no consent, then no contact examination)		
↓		
Line-listing of contacts*		
↓		
Meet the contacts (home visit or by invitation to the health facility)		
↓		
Counselling of the contacts		
★		
Examine the contact (physical examination)		
↓		
Encourage self-reporting of contacts who could not be checked during the screening,		
especially those who may have lesions suspect of leprosy		

*wherever feasible Geographic Positioning System (GPS) may be used

2.2 Post-exposure prophylaxis



Roles and responsibilities **2**

3.1 Managerial responsibilities

The table below lists activities, with possible roles and responsibilities, which will be required to adapt and implement these guidelines effectively. Countries may adapt these guidelines as per the local policy and circumstances.

Activity/task	Responsible person
Developing of national guideline on leprosy contact tracing Developing of national guideline on	National Leprosy Programme (NLP) manager/Ministry of Health
chemoprophylaxis	
Printing and distribution of guidelines, forms, reporting formats, information-education- communication (IEC) materials	NLP manager, intermediate or peripheral level per the policy
National-level dissemination meeting on contact tracing/PEP	NLP manager and relevant stakeholders
Coordination with all stakeholders for smooth (routine) implementation of contact tracing and/or PEP	NLP manager
National-level training of identified trainers on contact tracing and/or PEP	NLP manager
Dissemination meeting on contact tracing/PEP at intermediate level	Leprosy programme manager (intermediate level) involving local stakeholders
Coordination with stakeholders at intermediate level	Leprosy programme manager (intermediate level)
Intermediate-level training of identified trainers on contact tracing and/or PEP	Leprosy programme manager (intermediate level)
Training of staff at peripheral level	Responsible officer at peripheral level
Procurement (or donation) and distribution of rifampicin	Leprosy programme/Ministry of Health
Data entry	Designated staff at national, intermediate and peripheral level (as per the country's information system)

Activity/task	Responsible person
Compilation of reports and reporting from different levels	Designated staff at national, intermediate and peripheral level (as per the country's information system)
Monitoring and supervision (may be part of overall leprosy programme or integrated supervision)	Leprosy programme manager (national, intermediate or peripheral level)
Conducting IEC on contact tracing and/or PEP (can be part of routine leprosy or health IEC activities)	Leprosy programme manager or health education focal point (national, intermediate or peripheral level)

3.2 Technical responsibilities

The table below contains an outline (checklist) while details for each activity are provided in subsequent chapters.

Activity/task	Responsible person	Remark
Identification of new (index) case	Medical officer or in-charge of health facility	At the time of diagnosis; if not done due to any reason, retrieve from treatment register
Recording of address, phone number and other details	Medical officer or in-charge of health facility or designated health staff	Retrieve from treatment register or ask directly to patient
Wherever feasible GPS coordinates may be recorded		
Counselling for consent of index case	Medical officer, counsellor or designated trained staff.	Requires conducive environment.
	Counselling can be done by a professional or a trained peer counsellor including a person	Counselling may be repeated after 3-6 months, depending on the need.
	affected by leprosy	Counselling may require one or more sessions.
Line-listing of contacts	Medical officer or designated staff	To be passed on to field staff who will undertake home visit
	Designated field staff	In case not done during consultation at the health facility
Visiting contacts at home, counselling, consent taking and emphasizing on early presentation of disease	Designated field staff, if needed with the help of a community health volunteer (or sensitized household/ family member). Counselling can be done by a professional or a trained peer	First visit to be carried out ideally within the first two to three months of treatment of the index case.
Wherever feasible GPS coordinates may be used		Counselling may be repeated after 3-6 months, depending on the need.
	counsellor including a person affected by leprosy.	Counselling may require one or more sessions.

Activity/task	Responsible person	Remark
Counselling and consent taking of contacts reporting at the health facility	Medical officer, counsellor or designated trained staff. Counselling can be done by a professional or a trained peer counsellor including a person affected by leprosy.	Index case, family member, field staff or volunteer motivate contacts to visit the health facility
Examination of contacts at their home	Designated field staff or sensitized household/family member	To be repeated yearly for 5 years; Counselling, contact examination and taking consent being the key component, to be implemented considering local context. Use the checklist for identifying leprosy suspects as well as SDR exclusion criteria
Examination of contacts at the health facility	Medical officer or designated staff	Same as above
Advocacy with local health or civil authorities, religious leader, etc.	District health officer	In case of a blanket approach
Advocacy with community members	District health officer, designated field staff, civil society representatives	In case of a blanket approach
Administration of SDR at	Designated field staff	Carry sufficient rifampicin;
home (for contacts) or at home/in the community facility (blanket approach)		Check for exclusion criteria; Record name of contact and/or
facility (blanket approach). If a case is detected among contacts, his or her contacts who have already received rifampicin in the past two years, should not received		community member and date of PEP administration;
		Counsel the contact/community members for potential side effects;
SDR again.		Determine appropriate dosage and supervise rifampicin intake
Administration of SDR at a	Medical officer or designated	Check for exclusion criteria;
health facility. If a case is detected among	staff	Record name of contact and date of PEP administration;
contacts, his or her contacts who have already received rifampicin in the past two years, should not received SDR again.		Counsel the contact for potential side effects;
		Determine appropriate dosage and supervise rifampicin intake
Follow up of all referrals	Designated field staff	Coordinate with different departments or programmes

4 Counselling

Many definitions of counselling are available, given by different authors, for application in different settings. Most suitable for leprosy is the definition provided by Pepinsky and Pepensky (1954) (26):

"Counselling is that interaction between two individuals to find a solution to the problems, which have an emotional angle, of one individual. Such a solution usually includes the behavioural change in the individual whose problems are being discussed".

Many people don't know that leprosy can be cured and each cure means that the patient is no longer infectious. Some still believe that leprosy is a dreadful disease. Many more don't know that prevention of leprosy is possible even after the infection has occurred and that prevention of (worsening of) disabilities is possible.

Counselling of the index case should be done at the time of diagnosis and may be repeated after three or six months. Counselling may require multiple sessions. Counselling can be done by a professional or a trained peer counsellor including a person who has experienced leprosy. The patient should be properly informed about the facts of leprosy, risk of infection for others, treatment, prevention and management of disabilities.

With regard to contact tracing, it is imperative that consent of the index cases is obtained to disclose their identity and permission is sought to screen their contacts. If an index case refuses to disclose his/her status, then this is to be respected. In this case, no contacts will be screened on an individual basis. Sometimes the index case may agree to disclose his/her identity to family members only and not to neighbours and social contacts. Health education should also be conducted in the community of the index case.

Consent of contacts is required before undertaking leprosy screening or offering SDR. In case of blanket approach, consent of community leaders is to be obtained before initiating a PEP campaign and of every community member before offering SDR. In case consent is not provided, SDR should not be enforced on the contacts or the community members.

4.1 Counselling of the index cases

Guide 2 on stigma and mental wellbeing (ILEP/NNN Toolkits) (27) describes the first encounter with a leprosy patient after confirmation of the diagnosis as the "golden hour". During this golden hour, the patient may be anxious to get the treatment and get cured right away. The diagnosis of leprosy may be received as bad news as the person may need

to disclose this diagnosis to family members and contacts. The patients and their families may fear to lose their social status or – worse – become ostracized and kicked out of their communities.

The degree of social loss depends on several factors, including the way the patient is addressed during this golden hour. Counselling during this encounter is considered a very effective intervention.

During such counselling session, the focus areas should include: "Leprosy is curable", leprosy treatment (early start, full duration), possible reactions, possible disabilities, when to report to the health centre for follow-up, and need for contact surveillance (33). Index cases should be informed that they may have infected other persons and that these persons have a lower risk of developing leprosy by administering SDR. Counselling will also help in obtaining consent of the index cases for revealing their identity and proceeding with tracing their contacts.

4.2 Counselling of contacts

Counselling of contacts (and community members in case of blanket approach) will help in obtaining consent for screening (i.e. undertaking physical examination) as well as administering SDR. The overall majority of contacts will be healthy persons with only very few leprosy cases among them.

Contacts need to be explained about: transmission, their possible risk of developing the disease, prevention of leprosy with SDR, one-time administration of SDR, safety of rifampicin, limitations of PEP, and early signs of leprosy. Contacts who agree to take SDR should be explained about common side effects of rifampicin (e.g. temporary red colouration of urine, saliva and tears) and rather rare adverse drug reactions (including possible stomach upset, flu-like syndrome or jaundice) in which case they should report to the health facility.

Good communication and counselling skills are needed by the health staff for counselling of index cases and contacts (family members, neighbours, social contacts). Ideally, professional counsellors should be involved but counselling can also be provided by community health workers, nurses, rehabilitation workers, general practitioners, community volunteers and peer counsellors. Peer counsellors are persons who themselves have experienced leprosy and have been successfully treated (cured). All persons provided counselling should have been adequately trained for this purpose.

Good counselling practices, as described in the WHO *E-module on counselling in leprosy* (28), include:

- Being well informed and giving correct information about the disease;
- Giving correct information about leprosy to the community;
- Being friendly, reassuring and encouraging;

- Answering questions and resolving doubts;
- Maintaining confidentiality;
- Avoiding unnecessary investigations;
- Advising patients to start treatment at an early stage and complete the full treatment for total cure.

Following is an example of how a patient (*Sam*) is counselled by a health worker (*Amy*). The same principles can be applied to contacts with information and facts relevant for them. This story serves as an example and does not aim to be complete or to be followed word by word. Care must be taken to keep in mind the education, social, cultural and religious background of the patients and their contacts. The simplest possible local language should be used and jargon avoided.





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Identification and recording of index cases 5

All new leprosy cases should be considered as index cases. The index case is generally considered the source of infection of contacts. Exceptions can be children and others where the source is often another patient in the same household, in the vicinity or the school. Hence, identification of the index case or detection of a new case forms the basis for contact tracing and PEP. A date from which the index cases are to be enrolled for PEP should be decided by the country e.g. date of start of the reporting year or including the previous year(s). As soon as the diagnosis is confirmed, they should be counselled as described in Chapter 4. Involvement of family members helps in improving acceptance of examination of all contacts. Following counselling of the patient, consent of the patient should be taken for disclosure of the diagnosis to household members, as secondary cases have the highest probability to occur among them. If there is no consent, disclosure should not be made.

If consent is not obtained, tracing of contacts could still be undertaken without disclosing the identity of the index case. Experience from studies and implementation of SDR has shown that the message "a leprosy case has been identified in your community, which places you at higher risk of also developing leprosy" does work. It results in acceptability of screening community members for leprosy as well as providing PEP.

Once consent is obtained, the index case should be recorded and considered as enrolled for further activities. A "consent box" can be ticked on the treatment card of the index case. The registration of the index cases should be linked to the treatment register, i.e. their registration number should be the same in all records and reports. Addresses and phone numbers of index cases should be recorded in such a way that it facilitates the visit to their houses. The list of index cases should be maintained by the reporting year, i.e. a 12-month period, in most (but not all) countries corresponding to the calendar year. This list is to be consulted every year the programme plans to screen the contacts, as per the country's policy. It is recommended to screen all contacts annually for a period of five years to ensure good follow up.

Counselling of the index case ideally should be done at the time of diagnosis as well as during any follow-up visit. If counselling was not done then, a special session can still be planned at a later date in the health facility or the house of the index case. Counselling should not be done in the workplace or a child's school, as this may create additional stigma and may prevent the index case from cooperating. Any person who has been in contact with an untreated index case for at least 20 hours per week for at least three months during the past one year is considered a contact for the purpose of contact tracing. Enlisting of household contacts, neighbour contacts and social contacts can be facilitated with the rapport developed with family members. These cut-off points (20 hours per week, 3 months per year) are not absolute but based on the higher probability that such contacts may have been infected or have the disease.

Different types of contacts can be distinguished:

- **Household contacts:** contacts living in the same dwelling or sharing the same kitchen as the index case. These include family members but also domestic staff or aids or co-workers or others sharing the same accommodation. A family member living elsewhere should not be considered as a contact.
- Neighbour contacts: A person living in the neighbourhood of an index case, typically defined as an adjacent dwelling or within 100 metres. Because of geographic proximity, these persons have a higher probability of being exposed and/or infected. For pragmatic reasons, programmes may also define neighbour contacts as the residents of the 5 to 10 houses surrounding the house of the index case (depending on local housing density).
- **Social contacts:** other persons having prolonged contact with an index case and who are not classified as household or neighbour contact. These may include friends, relatives, persons sharing workplace (e.g. factory workers, office colleagues) or school (students and teachers) or leisure areas (e.g. sports club).

Note: A person whose exposure with a leprosy patient only starts after the patient has been treated for four weeks is not considered a contact.

All contacts including household, neighbours and social contacts of an index case should be line-listed with their details. A sample of such line-listing format is provided in Annex 1.

Tracing of contacts **7**

This is one of the important components for identifying new leprosy patients as well as for administering PEP. Contact tracing protocols can be used not only for active leprosy case finding, but also to investigate other common diseases where active case detection may be indicated, such as tuberculosis (TB), yaws, other skin diseases or diabetes mellitus. All personnel involved in contact tracing should be properly trained in suspecting leprosy, TB or other health problems. Through the application of standard questions and, in case of doubt, further investigations, the risks of missing contra-indications can be minimized.

Approaches for contact tracing

- Household contact approach: When an index case is detected, all household contacts are listed and traced. Tracing can be undertaken by inviting the contacts to present in the health facility, at the next planned visit or separate from such visit; with or without the index case. Alternatively, a health worker or trained volunteer (male and female, depending on the cultural context) can visit the house of the index case. If this is the case, it is important to give advance notice so that maximum (ideally all) household members are present during the visit. Obtain consent of index case in advance to avoid that the visit itself breaches the confidentiality by disclosing the diagnosis of leprosy to family members or neighbours. Sensitized and motivated household/family members need to be identified for improving contact tracing, screening and coverage.
- Neighbour contact approach: This usually requires one or more visits by a health worker or trained volunteer (male and female, depending on the cultural context). Depending on the country's policy, it may include an arbitrary number of houses (e.g. five) around the house of the index case or all houses within a range of e.g. 100 metres around the house of the index case. The expected number of neighbour contacts is variable, typically between 25-50 contacts (an average of 5 per household).

Tracing of household contacts can be undertaken at the same time as tracing of neighbour contacts.

• **Social contact approach:** In this approach, social contacts are traced. Tracing social contacts at their home ensures the best way to maintain confidentiality but often involves complex logistics. Sensitized household/family members contribute to the enlisting of social contacts. Exceptionally, they may also be traced at their work place, school or other convenient location. Or they could be invited to come to the health facility.

• **Mixed approach:** All contacts – household, neighbour and social contacts – are line-listed. They can be invited to present in the health facility at a convenient time or visited their houses or other convenient location. Household members can be approached together. Neighbour contacts can be approached house-by-house; while social contacts should be approached individually.

The mixed approach is likely to yield the highest number of contacts traced. It should be kept in mind that maximizing coverage – both for active case detection as well as for PEP – is paramount.

- Blanket approach: This is mainly recommended for small, defined populations with relative high leprosy burden. The circles of contacts are overlapping so much that it is more practical to consider the entire community as contacts of the index cases. A defined population can apply to a district, an island, an urban pocket area (e.g. slum), a village or even a smaller cluster.
- **Self-screening approach:** In this participatory approach, the persons affected and their families enlist and register themselves as contacts. Leaflets showing symptoms and signs of leprosy are distributed to the contacts. They are asked to examine themselves (or be examined by a family member) and, if leprosy is suspected, report to the health facility for confirmation of (or ruling out) the diagnosis. In this approach, a lot of motivation on the part of the index cases and contacts is required.
- **Skin camp approach:** This approach helps in detecting new cases and registering their contacts simultaneously. In this approach, skin camps are organised in an endemic area with the primary purpose to detect leprosy cases and consequently their contacts. Other common skin diseases are also detected and treated.

Special situations:

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• Contact tracing if the index case is a child

If the index case is a school going child, disclosing his/her diagnosis and labelling him/her as a cause of potential spread to others may lead to stigma and discrimination. Though a child may spend typically more than 20 hours per week in school, it is not advisable to trace classmates or teachers in the school. The only exception would be if a regular school health programme or a campaign with physical examination is scheduled. This could be an opportunity to investigate leprosy in the school, otherwise the school may be informed and either the school health programme may be roped in or the principal or teacher could be requested to provide the home addresses of the contacts of a child case. Classmates and teachers of a child case need to be traced at their homes. While visiting the family, the identity of the index child case should not be disclosed to the contact or his/her family. The home visit is an opportunity to reach out to all family members of the contact. Household/family members play a key role in giving consent for examination and facilitate completing the

examination of all members. Proper counselling of the family of the child – about leprosy but also about the advantages of PEP – should be done before the screening.

• Migrants as contacts

If persons move in into a family, city or even country, but have themselves no history of exposure to a leprosy patient, then they should not be considered as contacts.

For migrants, the history of contact of each individual, with an index case in their native place, must be explored.

If persons have been in contact with an index case for more than 20 hours per week for 3 months in a year but have now moved out, they should still be considered as a contact. All efforts should be made to find out about their whereabouts. The public health authorities in charge of the area to which such persons have migrated should be informed and tracing pursued.

• Death or migration of an index case

If an index case, who has lived with his family members or neighbours or social contacts, for around 20 hrs per week for 3 months in a year and dies or migrates out, the contacts should be screened and given SDR, if eligible.

Timing and frequency of contact tracing

Tracing of contacts can be done as soon as possible after diagnosis, or periodically in a defined geographic area or annually in a special campaign or through a mixture of such approaches. Important is that efforts are undertaken to maximize (ideally aim for 100%) coverage.

The timing or frequency of contact tracing and the approaches used will depend on operational factors of the programme, infrastructure and geographical setting in a particular country or setting. This could be:

- Contacts of every new case are traced shortly after the index case is diagnosed (e.g. in programmes where address verification is routinely done);
- For every single case after four weeks of starting treatment by the index case;
- In waves, when there are sufficient index cases diagnosed;
- In waves, periodically (e.g. every 3, 6 or 12 months) for all new cases in the previous 3, 6 or 12 months as well as index cases identified in the past five years;
- When outsourced to community outreach workers, whenever it fits in their schedule.

The purpose is to ensure that maximum number of contacts are traced.

8 Screening of contacts

Screening of contacts may be done at the health facility, at their homes or a designated place. Efforts should be made to maximize the number of contacts traced and screened. Repeat visits may be planned to ensure maximum coverage. Family members of persons affected by leprosy help enhancing coverage of contact screening.

Screening is a synonym of examining a person for signs and symptoms of leprosy (with the purpose of detecting leprosy), examine for other conditions (e.g. TB) or identify other exclusion criteria for PEP.

Before examining the contact, rapport must be established and counselling should be done. Contacts must be explained about the facts of leprosy (curability, transmission), importance of early detection, and possibility (with limitation) for reducing the risk of developing leprosy through PEP. The examination procedure must be clearly explained. Consent from the contact for physical examination should be obtained as well as for administering PEP as appropriate.

Physical examination of the body must be done from head to toe in good light (preferably day light) but with full respect for privacy. The cultural context should be respected, requiring usually that female contacts are examined by women and male contacts by men. If the health worker or community volunteer is of the opposite gender, it may be necessary to explain carefully and/or to utilize the services of a sensitized male/female household/family member or volunteer and let this person do the physical examination. If this is not possible, explanation can be given for self-examination.

History of tingling, numbness in hands and feet, fever, cough, loss of appetite, weight loss, nausea, yellow colouration of urine or pale coloured stool should be explored. Possibility for pregnancy should be discussed. Observation should be made for any swelling under the eyes or swelling over the face, yellow colouration of eyes, any hypopigmented patch or patches over the skin. If a patch or tingling numbness exists, presence of anaesthesia over the patches or the limbs should be assessed. Contacts with lesions suspicious of leprosy must be referred to a trained health staff for confirmatory examination of leprosy.

Care must be taken to identify the following:

 A person with signs of leprosy: hypo-pigmented skin lesions with loss of sensation; impairment or involvement of the peripheral nerves as demonstrated by a) definite loss of sensation or b) weakness of hands/feet or face or c) autonomic function disorders such as anhidrosis (dry skin) or d) presence of visible deformities; if any of these are present, or in case of doubt, refer the person for further investigation;

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- A person showing signs and symptoms of TB: chronic cough (more than two weeks), loss of appetite, loss of weight, evening rise of temperature. If any of these symptoms are present, refer the person for further investigation;
- Pregnancy: this could be confirmed by the history of missed menses or positive pregnancy test. If in doubt and the person is otherwise eligible for PEP, refer the case for ruling out pregnancy;
- Liver disorder: early signs of liver involvement are: loss of appetite, loss of weight, nausea, distaste for smoking. Other signs are yellow colouration of urine, yellow colouration of eyes (conjunctiva), pale coloured stools. If any of these are present, refer for further investigation.
- Kidney disorder: early signs of kidney involvement are an alternate pattern of oliguria (less urine) and polyuria (excessive urine), weakness, earthy look over the face, fullness below the eyes or swelling over the face, history of high blood pressure. Refer the case for further investigation.

If a contact person is screened, this should be recorded with the date against the contact name. The result of the screening should also be recorded.

Contact Tracing & Screening





* Wherever feasible Geographical Positioning System (GPS) may be used.
Administration of PEP

Post-exposure prophylaxis for leprosy is given as chemoprophylaxis i.e. a medicine (rifampicin) is given, only once, to healthy persons to reduce the risk of developing leprosy. It is important that the beneficiary provides consent before taking the medicine. This requires that the person is adequately informed about the benefits (reduced probability of getting leprosy) but also about common side effects (such as discolouration of urine) as well as less common or extremely rare adverse reactions.

SDR should be given to contacts only after the index case has taken treatment at least for four weeks. The reason is that this is the time required to make most patients non-infectious. There is thus always a (small) chance of infection occurring during the initial weeks of treatment of the index case. However, if coverage with SDR would be much compromised by delaying administration, it could be given earlier.

Care must be taken to exclude leprosy, TB and other ailments before administration of SDR. Inclusion and exclusion criteria are as follows:

- Inclusion criteria
 - Being identified as a contact, i.e. a person who has been in close contact with the index case for 20 hours or more per week for more than 3 months. Exception is blanket approach where no link with an index case needs to be established.
 - Age: more than 2 years; if younger than 2 years, the child can be given SDR at the age of 2, in follow up visits of contacts (if meeting all other inclusion criteria).
 - Consent of the contact obtained. Depending on the country situation, this can be written or a verbal consent. In case of children, consent should be obtained from the parent or guardian, and sometimes an assent from the grown-up children.

• Exclusion criteria

- Persons with possible signs and/or symptoms of leprosy;
- Persons with possible signs and/or symptoms of TB or confirmed with TB;
- Persons with a history of liver or kidney disorders;
- Pregnancy; SDR can be given after the delivery;
- Persons who have received rifampicin in the last two years e.g. as treatment of TB, leprosy or as prophylaxis (e.g. contact of another index case);

- Persons with history of allergy to rifampicin;
- Refusal to take SDR.

Contacts with signs or symptoms of leprosy should be referred to confirm (or rule out) leprosy. In case of confirmation of the diagnosis, a full treatment with MDT is to be provided. The patient should then be treated as another index case and his/her contacts listed as per guidelines. In case leprosy is ruled out, chemoprophylaxis with SDR can be administered (unless another exclusion criterion is present).

Contacts with signs or symptoms of TB should be referred to confirm (or rule out) TB. In case of confirmation of the diagnosis of TB, a full treatment is to be provided. In case TB or other ailments are ruled out, chemoprophylaxis with SDR can be administered.

Questions and doubts were raised about the possible risk of inducing resistance to rifampicin in case SDR is administered to a person in whom active TB may not have been recognized. It was concluded by experts in antibiotic resistance, TB and leprosy that SDR given to contacts of leprosy patients, in the absence of symptoms of active TB, poses a negligible risk of generating drug resistance in *Mycobacterium tuberculosis (M. tuberculosis)* in individuals and at population level. The benefits of prophylaxis with SDR in reducing the risk of developing leprosy in contacts of new leprosy patients far outweigh the negligible risks of generating drug resistance in *M. tuberculosis (29)*.

Table 1 provides the recommended dosage for SDR. Rifampicin is generally available in capsules of 300 mg or 150 mg. For children, rifampicin syrup may be indicated. The dosage is generally based on age and/or body weight.

Age / body weight	Rifampicin single dose
15 years and above	600 mg
10-14 years	450 mg
Children 6-9 years (weight ≥ 20 kg)	300 mg
Children 6-9 years (weight < 20 kg)	150 mg
Children 2-5 years	10-15 mg/kg

Table 1: Dosage of rifampicin given as SDR for leprosy prophylaxis

SDR as PEP is generally a well-tolerated intervention. So far, no serious adverse event has been reported from any research study or programme implementing PEP with SDR. Nevertheless, side effects and the possibility for (rare) adverse events should be adequately explained to the recipients, monitored and followed-up. The most common side effect of rifampicin is the red colouration of urine, saliva, tears or sweat. Though common, this is transient and gets cleared in four to six hours. Possible adverse events of rifampicin include fever, body ache, weakness (i.e. flu-like syndrome) and – rarely – jaundice. Recipients of SDR should be explained clearly that, if they notice or feel any kind of sign or symptoms, apart from the harmless colouration of urine, they should contact the nearest health facility.

Supply chain management with regard to rifampicin

The crucial component of PEP using SDR is having sufficient rifampicin stock to be able to make it available to eligible persons. Ideally, the country should develop a policy for acquiring rifampicin for this purpose. This involves forecasting drug needs, procurement (unless donated), storage and distribution. All these elements come under supply chain management, which can be taken care of in an integrated fashion (together with MDT or other medicines) or as a special project. The latter approach may be more appropriate when there are only a handful of index cases and contacts while the former approach may be more cost-effective and sustainable.

10.1 Forecasting

In leprosy control programmes of several countries and research projects, cases detected in previous years were counted as index cases; their contacts were traced and given SDR. This practice was based on the assumption that cases detected in previous years might have infected their contacts, who remain in a sub-clinical stage or undiagnosed.

A date from which the index cases are to be enrolled for PEP should be decided by the country e.g. date of start of the reporting year or including the previous year(s). For the calculation of rifampicin requirements, the number of cases detected (or anticipated to be detected) in a year should be determined. The number of cases detected in the previous year can be considered for estimating the number of cases that will be detected in the prospective year, with some adjustments to be made if there are changes in operational conditions (such as active case detection campaigns). Estimation of rifampicin needs should be determined in three steps: (1) calculation of the total requirements of rifampicin doses for one year; (2) disaggregation of the total doses according to age-wise requirements; and (3) finalization of indent to be placed.

• Step 1: Calculate the total requirement

To calculate the total requirements of rifampicin doses needed for one year, the following data will be needed:

- Number of new (index) cases detected in the area in a (reporting) year;
- The highest number of listed contacts. If not known, 40 contacts per index case may be considered. This would mean that for each index case, we would need rifampicin to treat 40 contacts. This is an arbitrary

number presuming 5 household contacts, 25 contacts from 5 neighbouring houses and 10 social contacts. This number may be modified based on the contact tracing strategy and more refined data available, especially at the local level.

The calculation can be done using the following formula:

total doses of rifampicin required = number of index cases x number of contacts per index case

An example is provided in Table 2.

Table 2: Calculation of rifampicin needs for next year, country "ABC"

Number of cases reported in previous year	Number of contacts expected per index case	Total contacts expected
[A]	[B]	$[C] = [A] \times [B]$
847	40	33 880

A special situation is the blanket approach, where the number of eligible persons is estimated as the total area population above two years of age. If this figure is not known, it can be (arbitrarily) derived from the total area population.

Buffer stock

It is generally not possible to give rifampicin to all contacts (or the entire population): some may not be traced, some may refuse or need to be excluded for not fulfilling the inclusion criteria. A buffer stock may, therefore, not need to be added. A coverage of 85%-90% of the target population is considered as very good. If the calculation of rifampicin needs is done based on 100%, the balance of 10-15% can be considered as buffer stock.

• Step 2: calculate the age-wise requirements of rifampicin

After the total required doses have been calculated, the age-wise disaggregation should be determined. This may be done by assessing the percentage of the population in the different age groups in the community as the contacts will be drawn from the community. The following data are required:

- % population of adults (15 years and above);
- % population of children (10-14 years old);
- % population of children (6-9 years old); e.g. approximately one-third of them will have a body weight of ≥ 20 kg;
- % population of children (2-5 years old).

The age-wise requirement can be calculated with the following formula:

rifampicin needs for age group = $\frac{\% \text{ population of age group x doses required}}{100}$

An example of calculation is provided in Table 3.

	Percentage	Total contacts	Rifampicin needs fo	or age group
Age group	in population	expected	Calculation (formula)	Result
\geq 15 years	52%	33 880	52 x 33 880 / 100	17 618
10-14 years	12%	33 880	12 x 33 880 / 100	4 066
6-9 years (≥ 20 kg)	5%	33 880	5 x 33 880 / 100	1 694
6-9 years (< 20 kg)	10%	33 880	10 x 33 880 / 100	3 388
2-5 years*	10%	33 880	10 x 33 880 / 100	3 388

Table 3: age-wise requirements for SDR for one year, country "ABC"
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* As the proportion in the population of the age group of 2-5 years may not be known, half of the proportion in the population of the age group 0-5 years (21%) is used instead

• Step 3: calculation of indent

Rifampicin is available in capsules and tablets of 300 mg and 150 mg.

Table 4 shows how the drug needs are calculated.

	Number		Number	Total capsules	Total	needs				
Age group	of contacts	Capsule	of capsules	per age group	150 mg capsule	300 mg capsule				
	[A]		[B]	$[C] = [A] \times [B]$						
≥15 years	17 618	300 mg	2	35 236	-	35 236				
10 14 1000	4 066	300 mg	1	4 066	-	4 066				
10-14 years	4 066	150 mg	1	4 066	4 066	-				
6-9 years (\geq 20 kg)	1 694	300 mg	1	1 694	-	1 694				
6-9 years (<20 kg)	3 388	150 mg	1	3 388	3 388					
Total capsules (exac	ct)				7 454	40 996				
Total capsules (rou	Total capsules (rounded) (to be ordered)8 00041 000									

Table 4: Calculation of rifampicin needs, by type of capsule, one year, Country "ABC"

In the example above, country "ABC" would order 41 000 capsules of rifampicin 300 mg and 8000 capsules of rifampicin 150 mg. Though injectable rifampicin is also available, this should not be used for prophylaxis.

Rifampicin is also available in syrup form, which is the preferred form for younger children (2-5 years old). Most convenient for the purpose of chemoprophylaxis is to use 60-ml bottles of 100 mg/5 ml.

10.2 Drug supply management

The distribution and supply chain should be maintained as for other medicines. The forecasting may be made for the annual requirement of the area (district, region, province, country). Indenting and distribution may be done quarterly, twice or once a year, taking into account the need of the area, shelf life of rifampicin, mode (wave or case-by-case), distance, accessibility, availability of transport, the time required to dispatch the consignment and travel time to the destination.

Following the norms of good storage, care must be taken to store rifampicin also in a cool and dry place away from direct sunlight and children. The principle of "first expiry/ first out" (FEFO) should be followed in the maintenance of the supply chain.

Post-Exposure Prophylaxis





11.1 Maintaining records for contact tracing and PEP

Contact tracing and PEP implementation should be routine components of the national leprosy programme. Records should be kept to the minimum and record keeping should not be too labour intensive and align with routine data recording and reporting.

The following records should be maintained:

• Patient treatment card

This card normally contains all information pertaining to a leprosy patient. There is no need to develop a stand-alone "Index case card".

With regard to contact tracing, the *Patient treatment card* must contain the following information: "Consent provided for contact tracing: \Box YES / \Box NO". Of course, the complete address and phone number of the patient should also be mentioned.

• Contact list or Contact register

Though contacts could be mentioned on the Patient treatment card, they may be too numerous to be included there. Strictly speaking, information pertaining to contacts is not relevant for the clinical management of the index case. It is therefore advisable to introduce a contact list (one list per index case) or even Contact register (one page per index case). Instead of paper record, the list or register can also be maintained electronically with good back-up. The PEP-HANS project in Brazil has demonstrated amalgamation of PEP data into their routine web-based information system (*30*).

This record will be useful in recording data pertaining to contact tracing, contact screening (including referral) and PEP administration. Reports can be generated from this record. It can also be used for follow up after screening or administration of SDR e.g. a cohort follow up may be made. A sample of the form (list or register) is shown in Annex 1.

The Contact list (or page in Contact register) should include the following elements:

- Index case: name and treatment number (e.g. 2020/32);
- Contact: contact number, name, age, gender and type. The *contact number* can be same as the treatment number of the index case, followed by the contact

serial number (e.g. 2020/32/01, 2020/32/02, etc.); with "type" is meant: household ("H"), neighbour ("N") or social ("S") contact.

- Date contact traced (leave blank if not traced);
- Consent obtained for screening: tick if done;
- Date contact screened (leave blank if not screened or put reason for not screening in the remarks column, e.g. due to absence of female health worker);
- Consent obtained for PEP: tick if done;
- Date SDR administered (leave blank if not given); mention reason in remarks column
- Remark: mention information, such as refusal, exclusion criteria, etc.

11.2 Reporting related to contact tracing and PEP

Data collection, compilation and reporting – related to contact tracing and PEP – should be part of the routine reporting system of the national leprosy programme. The country's recording and reporting formats may need to be revised to accommodate information related to contact tracing and PEP.

The collation of data related to contact tracing and PEP should be done at the same level(s) as where other leprosy reports are collated. Reporting for leprosy is typically done on a quarterly basis, but some countries maintain monthly reporting while some other countries compile leprosy reports twice or once a year. Few countries even require reporting of leprosy in real-time. The same frequency for reporting on contact tracing and PEP can be maintained.

If the leprosy reports are prepared at the health facility level, then the report on contact tracing and PEP should also be compiled at that level. However, if the reports are generated at the district level, then reports on contact tracing and PEP can be generated there. Aggregated reports can be forwarded as paper-based reports or electronically through the existing channel of reporting in the country. Ideally, they should be foreseen from a brief narrative commentary.

If leprosy recording is done electronically and is case-based, then the additional information related to contact tracing and PEP should be added to the index case information while a separate mechanism should be designed for blanket approach.

The following indicators are useful to give meaning to the performance of the contact tracing and PEP components of the national leprosy programme:

- Number of index cases enrolled during the period (month/quarter/year): [A]
- Number of contacts listed against these index cases: [B]
 - Number of household contacts: [B₁]

- Number of neighbour contacts: $[B_2]$
- Number of social contacts: [B₃]
- Average number of contacts per index case: [C] = [B] / [A] (benchmark: ~40)
- Number of contacts screened: [D]
- Proportion of contacts screened: [E] = [D] / [B]
- Number of contacts who have received SDR: [F]
- Proportion of contacts who have received SDR: [G] = [F] / [B]
- Number of leprosy cases detected among contact screened: [H]
- Proportion of leprosy cases detected among contacts = [H] / [B]

Implementing contact tracing and PEP 12

12.1 Preparation at the national level

For successful implementation of contact tracing and/or PEP (using SDR), considerable preparation will be required. This will include:

- Adaptation of this technical guidance document to the national (and subnational) context. Recording and reporting formats will need to be tailored: patient treatment card, contact list or register, referral slip. This could be done by forming a task force/team or assigning this job to a group of individuals.
- The country-specific guidelines, recording and reporting formats need to be printed and distributed (alternatively, they can be made available online). The documents may also need to be translated into local languages before printing and distribution.
- Contact tracing and PEP are primarily public health interventions, even if they are linked to individual patients. Hence it is important that both the policy makers and the community are informed about them and have agreed with these strategies. Especially if the two interventions are new in the country or at the sub-national level, advocacy should be undertaken. A budget (for advocacy, training and implementation) will also need to be identified.
- Once agreed at the policy level, actors need to be identified to implement the interventions. The primary responsibility lies with the health service providers, but other stakeholders may need to be involved, e.g. nongovernmental organizations (NGOs), persons affected by leprosy, community-based organizations, community health volunteers, religious leaders, teachers. At the national level, key representatives of these stakeholders can be brought together in a national workshop to obtain their support. They should also be informed that SDR PEP significantly reduces the risk of developing the disease.
- To build capacity for undertaking contact tracing and/or PEP, a national-level training of trainers should be organised so that they could be involved in the cascade training of health staff and volunteers at the lower levels. This may also be integrated in another training.
- Obtaining rifampicin for prophylaxis purpose, through donation or procurement. If procured, the country policy should be followed, which could mean central or local procurement. If obtained through donation or centrally procured, it

may be most efficient to organize distribution together with the regular MDT supplies. This requires detailed planning.

- To inform the community at large about the benefits of contact tracing and/or PEP, appropriate IEC materials need to be developed and disseminated.
- The (annual) national leprosy plan should incorporate contact tracing and/ or PEP; this would be preferred over developing a stand-alone plan for these interventions. It should be possible to monitor overall progress in implementation of contact tracing and/or PEP as part of leprosy control activities.

12.2 Preparations at the intermediate level

Preparatory activities to implement contact tracing and/or PEP at the intermediate level – state, province, region – will differ from country to country, but may include the following:

- Representatives of different stakeholders programme managers, doctors, health care staff, politicians, partners, persons affected by leprosy, local NGOs, village leaders etc. – may be invited in a meeting held at the intermediate level. In this meeting or workshop, the details of contact tracing and/or PEP may be explained so that all stakeholders understand the benefits for the community and are convinced to support them. They should also be informed that SDR PEP significantly reduces the risk of developing the disease.
- To build capacity for undertaking contact tracing and/or PEP, a formal training of identified trainers should be organised at the intermediate level, using the centrally-trained trainers as key resource persons. The trained persons at the intermediate level can then be further involved in a cascade training at the more peripheral levels.
- The roles and responsibilities of health staff and community health volunteers for different actions should be defined and cascade training planned accordingly.
- If rifampicin is to be procured at the intermediate level, it should be done according to prevailing policies.
- The community at large needs to be informed about the benefits of contact tracing and/or PEP as public health interventions. Appropriate messages should be incorporated while developing IEC materials at intermediate level.
- The (annual) leprosy plan for the intermediate level should include necessary activities for implementing contact tracing and/or PEP: training of staff, obtaining and distribution of rifampicin (ideally together with MDT drugs), planning for contact tracing, supervision. It is preferable to have contact tracing and PEP embedded in a regular leprosy control (or even disease control or health) plan than developing a stand-alone plan for this purpose. It should be possible to monitor overall progress in implementation of contact tracing and/or PEP as part of leprosy control activities.

12.3 Preparations at the peripheral level

Preparatory activities to implement contact tracing and/or PEP at the peripheral level – district or sub-district, community – will differ from country to country, or even within countries. They may include the following:

- Representatives of different stakeholders programme managers, doctors, health care staff, local politicians, partners, persons affected by leprosy, local NGOs, village leaders, religious leaders, etc. – may be invited in a districtlevel meeting. In this meeting or workshop, the details of contact tracing and/ or PEP may be explained so that all stakeholders understand the benefits for the community as well as the individual patient and are convinced to provide support for implementation. They should also be informed that SDR PEP significantly reduces the risk of developing the disease.
- The roles and responsibilities in implementation of contact tracing and/or PEP by doctors, health staff and community health volunteers should be explained.
- To build capacity for undertaking contact tracing and/or PEP, a training or orientation of peripheral health staff and community health volunteers should be organised (typically at the district or sub-district level), using the intermediate-level trainers as key resource persons.
- Procurement of medicines is generally done at a higher level. In case rifampicin is procured at the peripheral level, it should be done according to prevailing policies.
- The community at large needs to be informed about the benefits of contact tracing and PEP. The community should also be informed that SDR PEP significantly reduces the risk of developing the disease. Local advocacy and relevant IEC activities should be undertaken periodically (in case of contact tracing or PEP being done throughout the year) or few weeks before actual implementation (in case the activities are undertaken in a campaign fashion). This is to maximize coverage.
- Any additional activity to be decided at the local level.
- The (annual) leprosy plan for the district/community level should include necessary activities for implementing contact tracing and/or PEP: local advocacy, training or orientation of staff and volunteers, obtaining and distribution of rifampicin (ideally together with MDT drugs), identifying a referral system, planning for contact tracing, monitoring and supervision.
- It is preferable to have contact tracing and PEP embedded in a regular leprosy control (or even disease control or health) plan for the district than developing a stand-alone plan for this purpose. It should be possible to monitor overall progress in implementation of contact tracing and/or PEP as part of leprosy control activities.

13 Monitoring and supervision

Monitoring and supervision are mostly dealt with together as both are programme management tools, meant to keep track of progress in implementation of planned activities or assess the programme's or project's performance.

Monitoring consists of a assessing the continuous flow of information up and down in the programme chain, and through (periodic or ad-hoc) progress reports, to other units and beyond. It relies on a set of indicators that are based on planned – SMART² – objectives. Only indicators that can be collected with relative ease should be used. The information that is generated through monitoring is used at every management level (national and sub-national) to assess progress, identify problems and institute remedial measures (1).

The purpose of supervision, on the other hand, is to ensure and improve the quality of services. It is mainly focussed on assessing and improving the performance of staff. Supportive supervision encourages improvement through a spirit of collaboration by setting uniform standards, identifying and solving problems, identifying needs and providing opportunities for development. More information on monitoring and supervision can be found in the WHO *Global Leprosy Strategy 2016–2020, Monitoring and Evaluation Guide (1).*

This chapter focuses on monitoring and supervision elements relevant to contact tracing and PEP. In reality, this can be undertaken as part of overall leprosy programme assessment or even assessment of community outreach activities across public health interventions.

Monitoring of implementation of the planned activities and supervision of the performance of health staff and community health volunteers can be undertaken by accompanying them using a checklist and observations. The following checklists may be used.

• Checklist for enrolment of index cases

- The identified index cases match with the recorded cases in the treatment register
- All index cases have been counselled on the basic facts of leprosy as well as on the benefits of contact tracing and PEP

² SMART objectives: Specific, Measurable, Achievable, Relevant and Time-bound

A sample of index cases may be interviewed to check their knowledge. A sample of counselling sessions could be observed to ascertain quality. If the knowledge of index case is unsatisfactory, or the quality of counselling is not up to the mark, counselling may be demonstrated by the supervisor to the person doing counselling.

Checklist for contact listing and contact tracing

 Consent of the index cases is obtained about disclosing their disease during contact tracing. This implies that the index case also agrees that contact tracing is undertaken.

The index cases may have agreed to "partially" disclosing their disease, e.g. to household contacts but not to neighbours or social contacts. This may be cross-checked with a sample of index cases.

 The list of contacts is as complete as possible. Names and other details of contacts are recorded correctly in the contact form/register.

Household and neighbour contacts can be confirmed during a homevisit to the house of the index case. It is not generally possible to check if all social contacts are listed.

 Visits have been made by the designated health care worker or community health volunteer to the listed contacts.

This could be cross-checked by visiting houses of few listed contacts. While visiting contacts, the following points need to be cross-checked:

- > Details of the contacts are correctly recorded
- Counselling is done related to the possible transmission and prevention of the disease.

• Checklist for contact screening

- The importance and steps of screening has been properly explained to the contacts and consent for screening (physical examination) was provided by the contact. This can be cross-checked by interviewing a few contacts.
- The screening of contacts was properly done, screening could be observed, or the supervisor can request the contact to describe how the physical screening was done. This is preferable than subjecting the contact case for a new physical examination.
- Referral, if any, has been made and was followed up;
- Contacts who reported by themselves after screening to be enlisted.

• Checklist for PEP

- The contacts were adequately counselled about the benefits and limitations (limited efficacy but also possible side effects) of PEP with SDR.
- In case SDR was provided, evidence was available that exclusion criteria were checked.
- In case SDR was not provided, evidence was available that the inclusion criteria were checked.

The above criteria can be ascertained by interviewing a sample of contacts or observing the procedures.

In case of refusal of PEP, efforts should be made by the supervisor to convince the contact for acceptance of PEP.

Checklist for drug management

- Availability of rifampicin (in different dosage) is adequate as per anticipated need of the area/campaign.
- Indent for rifampicin is made timely.
- Storage of rifampicin is done as per the standard guidelines.
- Expiry date to be checked. "First expiry-first out" principle is adhered to.

• Monitoring of records and reports

- Patient treatment card, contact list or register is complete and properly maintained.
- Stock-in/Stock-out record (Bin card) or drug register is correctly maintained.
- Reports are correctly compiled.
- Reports are timely submitted to the next level.
- Feedback, if any, is received and action taken accordingly, if required.

The following indicators can be used to assess implementation of contact screening and/or PEP. The indicators can be collected monthly, quarterly, or yearly for a given area and aggregated at a higher level.

- Number of index cases enrolled during the period (month, quarter, year)
 [A]
- Number of contacts listed against these index cases [B]
- Average number of contacts per index case [C] = [B] / [A]. Benchmark: ~40
- Number of contacts screened [D]
- Proportion of contacts screened $[E] = [D] / [B] \times 100 (\%)$
- Number of contacts who received SDR [F]

- Proportion of contacts who received SDR $[G] = [F] / [B] \times 100 (\%)$
- Number of leprosy cases detected among contacts during the period [H]
- Total number of leprosy cases detected during the period [I]
- Proportion of leprosy cases detected as part of contact tracing [J] = [H] / [I] x 100 (%)
- Rate of leprosy case detection among listed contacts = $[H] / [B] \times 1$ million

The indicators described above may have been collected as part of routine implementation of contact tracing and PEP. If these data are available, the supervisor can compare her/his findings with what was collected/reporting and assess in this way the quality of routine reporting.

14 Information, education and communication

Information, education and communication – also known with its abbreviation "IEC" – is a very important component in any public health programme. An informed community will foster demand for services while a patient or affected person who is well informed and has understood the basic elements of leprosy will be more compliant and cooperative.

Along with other IEC activities, simple messages such as "Now leprosy can be prevented", "now risk of developing leprosy can be reduced significantly" or "a single dose of rifampicin can significantly reduce the risk of developing leprosy", etc. should be highlighted. Such messages should be phrased in a language understood by the beneficiaries. Medical jargon should be avoided. These messages will give hope to patients, their family members, contacts and the community at large.

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Annexes

Indey	Index case Name:							Age:		ye	years		Reg. No.:	0	
	Phone:							Dise	ase ty	Disease type: \Box MB	MB	DB Da	Date treatment started:		
Contacts	acts														
				Sex	×		Type	Ŭ	Counselled		Consent obtained	d t			
No.	Name	Phone	Age	٤	щ	plonsuoH	Neighbour	laisoe	Screening	8DR	Screening	ם sD8	Date(s) screened	Date SDR given	Remark
-															
2															
3															
4						_									
5						_									
9															
7															
8															
9															
10															
1															
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13															
14															
15															
16															

Annex 1: Contact List

Technical guidance

	Remark																								
	Date SDR given																								
	Date(s) screened																								
Consent obtained	SDR																								
Con obta	Screening																								
Counselled	SDR																								
Coun	Screening																								
	Social																								
Type	Neighbour																								
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Sex	٤																								
	Age																								
	Phone																								
	Name																								
	No.	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40

Annex 2: Consent by index case

(to be informed by counsellor / medical officer / health worker)

"Leprosy – like many other infectious diseases – is a disease caused by a germ. If not treated, it may lead to disability and disfigurement. Leprosy is curable with a full course of multidrug therapy (MDT).

Leprosy is typically transmitted by being in close contact with an untreated patient. When the patient sneezes or coughs, germs are spread in the air which can then be inhaled by another person. Most persons have natural immunity, but some may develop – often after many years – leprosy.

After starting treatment with MDT, you are going to be cured.

But those who are or have been in close contact with you, e.g. your family members, neighbours, colleagues, etc. for longer time (20 hours per week, 3 months per year) may also have been infected. Rifampicin is an effective drug to kill germs in the body before disease develops. Research has proven and WHO recommends that a single dose of rifampicin (SDR), if given to contacts, (who may have germs in their body but not showing signs or symptoms), may prevent them from developing leprosy.

Based on these facts, we recommend that we screen your contacts for signs and symptoms of leprosy. If they have no signs or symptoms, they can be given rifampicin to prevent them from developing leprosy. A single dose of rifampicin is sufficient to prevent leprosy.

Now since you have started treatment, you will no longer be infectious and you will get cured. But to prevent leprosy in your family, neighbours, colleagues or friends, do you agree that we tell them you have leprosy so that we can check them also and offer them rifampicin?

If you agree, please sign this form that you agree that we disclose that you have leprosy and we can trace your contacts.

If you do not agree, we will respect your decision also."

I agree that you disclose my identity to:

□ my family members	other people living in my house						
□ my neighbours	□ my colleagues / friends / others						
Index case Reg. No	Counsellor / medical officer / health worker						
Name:	Name:						
(in case of minor) Guardian:	Designation:						
Signature:	Signature:						
Date:	Date:						

Annex 3: Consent by contact

(to be informed by counsellor / medical officer / health worker)

"Leprosy – like many other infectious diseases – is a disease caused by a germ. If not treated, it may lead to disability and disfigurement. Leprosy is curable with a full course of multidrug therapy (MDT).

Leprosy is typically transmitted by being in close contact with an untreated patient. When the patient sneezes or coughs, germs are spread in the air which can then be inhaled by another person. Most persons have natural immunity, but some may develop – often after many years – leprosy.

Since you are living in an endemic area or have spent ample time with a patient, you might have been infected. In case you would be infected – and there is currently no test to confirm this – there is a chance that you may also develop leprosy, even after many years.

One of the drugs named rifampicin is an effective drug to kill germs in the body before leprosy develops. We offer you rifampicin to prevent leprosy. This is only a single dose, one time. It reduces the chance that you would develop leprosy with more than 50%. However, before that, we will need to examine your body to rule out leprosy and also ask you some questions to find out if you would have other contra-indications for rifampicin.

Rifampicin given as single-dose is very safe. It only causes red colouration of urine, which goes away after a few hours. Other adverse events such as stomach upset, flu-like symptoms or even jaundice, can occur but these happen very rarely. In that case, you should immediately report to the nearest health facility where you will be given appropriate treatment.

If you agree that we examine you for signs or symptoms of leprosy and offer you rifampicin to prevent leprosy, please sign this form.

If you do not agree, we will respect your decision also."

I agree: \Box to be screened for signs and symptoms of leprosy

□ to take rifampicin as a single-dose to reduce the chance of getting leprosy (if I am found to be eligible for this intervention)

Contact case Reg. No	Counsellor / medical officer / health worker
Name:	Name:
(in case of minor) Guardian:	Designation:
Signature:	Signature:
Date:	Date:

"In order to bring down the case detection among leprosy contacts from Point A to Point B, programmes can choose to treat 100 contacts with leprosy and nobody with chemoprophylaxis **or** provide chemoprophylaxis to all contacts and treat only 43 leprosy patients". The latter choice is the most obvious for many programmes.

This document provides guidance on **how** to implement contact screening and chemoprophylaxis with single-dose rifampicin. The contents are logically ordered: counselling and obtaining consent, identification and listing of index case, listing of contacts, tracing of contacts, screening of contacts, administration of prophylactic drugs.

Managerial aspects to undertake contact screeninig and chemoprophylaxis are also elaborated, including planning, training, supervision and drug management.



