

## Zero Leprosy Best Practices

### **Best Practice:** *Comprehensive Household Contact Examinations Preceding Offer of Post-exposure Prophylaxis Intervention*

#### **Subthemes**

- PEP / people at risk
  - Implementation phase, +/- preparation phase
  - Tracing and examining contacts
- Operational capacity
  - Health workforce/service delivery

#### **Target Audience(s)**

- Program managers
- Health staff
- Other partners such as NTD NGOs

#### **Contributors**

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#### **Key Messages**

High coverage of household contacts (HCs) with thorough individual assessments conducted by trained staff, after gaining consent of index case, are desirable both for early case detection and for correct identification of individuals suitable for single-dose rifampicin (SDR) prophylaxis.

In situations where resources are limited and for maximum output, priority for household contact examinations (HCEs) can be given to households where index cases are smear positive (or have multibacillary [MB] leprosy).

The effectiveness of SDR prophylaxis depends upon its being given to people with subclinical infection (i.e., those who have not yet developed overt disease) after the source of infection is controlled.

#### **Key Informant / Date Submitted**

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### Description of the Best Practice

#### Introduction

Compared to the general population, HCs of newly diagnosed leprosy cases are known to be at higher risk of developing leprosy. They are also an easily identifiable population. Hence, they are targeted for active case detection and also for post-exposure prophylaxis (PEP).

Assuming a new case detection rate of  $\sim 1.0/10,000$  population and an average household size of 5 people, only 4/10,000 cases are HCs. Despite their higher individual risk, HCs are a small proportion of the case population so the majority of new cases may still be found among non-HCs. Nevertheless, mathematical modelling has demonstrated that reducing incidence among HCs (by use of PEP) will ultimately impact the overall incidence of disease.

Offering any kind of PEP requires first identifying eligible individuals (i.e., considering their contact status and ensuring they do not have overt disease or other medical contra-indications to the administration of PEP) and receiving informed consent to administer it.

Properly conducted HCEs are essential. Requisite steps are outlined as follows:

- Request permission from the index case for a home visit
- Win confidence of household members by showing concern for their welfare and demonstrating professionalism
- Exclude overt cases and people previously treated for leprosy
- Identify suspected cases for further assessment
- Educate individuals to encourage future early reporting of signs and symptoms, whether or not they have received SDR
- In situations where resources for home-based HCEs are limited, for maximum output priority may be given to households of smear-positive or MB index cases.

If all actual cases are not excluded before PEP is offered to contacts at risk, then the intervention will be compromised: undiagnosed cases will not be cured by SDR, and other contacts will not be protected from later infection.

The definition of an HC is a person who has been a resident in the household for at least 3 months (i.e., one who shares a roof and/or kitchen facilities with the index case).

#### Objectives and Methodology

The first objective is to ensure that active case detection through education (about signs of leprosy) and physical examination(s) of HCs is offered to those who are at higher risk of developing leprosy because of their recent exposure to undiagnosed cases. Early diagnosis of any leprosy cases among these contacts can reduce the risk to the other HCs and to the general community. The second objective is to exclude actual cases from being inappropriately offered SDR as prophylaxis for leprosy.

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Over the past 30 years or more, in rural health programmes (RHPs) initial home visits for HCEs have been conducted within ~2 months of index case diagnosis. Repeat visits are conducted annually for 2 years for paucibacillary (PB) index cases and for 5 years for MB index cases. The project guidelines on HCEs are based on published evidence of higher incidence among HCs of newly diagnosed cases (compared with others in the local community).

We specifically target HCs rather than all contacts since HCs are a well-defined high-risk group and are easily identified and often trusted by the index case (hence the index case is more likely to give permission for HCs to know about his/her diagnosis). Neighbour and social contacts are less easily defined, at lower risk, and more likely to be outside the circle of people trusted by the index case to share his/her confidential information.

### Implementation of Practice

#### *Environment*

The work described here is being carried out in four districts of northwest Bangladesh (allocated to RHPs) where the national leprosy control programme has been supported by The Leprosy Mission International–Bangladesh (TLMI-B) over the past four decades. Good records are available back to 1995, when leprosy control was still conducted through a vertical programme.

The area is predominantly rural but has several large urban areas (Rangpur city, Thakurgaon and Saidpur towns). It is an underdeveloped area, with the economy based on agriculture and a high proportion of the population earning subsistence wages as daily casual labourers. Poverty and illiteracy are common. The area is prone to annual flooding and seasonal food shortages. The public transport network is weak and very few people own motorized vehicles, making it difficult for people to reach district/subdistrict-level health services when needed.

Without the additional input from TLMI-B, health and social services for persons affected by leprosy in this area (which has had prevalence rates higher than national averages since records began) would be very limited beyond dispensing of multidrug therapy (MDT) to known cases.

#### *Procedure*

1. Staff visit the homes of newly diagnosed cases only with their permission
2. At the initial home visit, all individuals who live there will be enumerated
3. At each home visit for HCEs, after the staff members have explained the purpose of their visit and described the signs and symptoms of leprosy that they are looking for (preferably using pictures), they should enquire if anyone was previously diagnosed with leprosy, and, if so, whether they completed treatment
4. Staff members will request permission for physical examination of individual household members

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5. They will do a physical examination (see below) of each person who gives permission and will record the information on the health card of index case
6. Suspected new leprosy cases are then re-examined (with skin smears) at a clinic as soon as possible
7. During the home visit, the index cases (and others who have been previously treated for leprosy) may also be re-checked (e.g., for disability problems)

### **Method of physical examination**

Good light and privacy are essential but are often difficult to achieve in a village/slum house. In rural Bangladesh, homes are often built around a relatively private courtyard, where male subjects are willing to undress far enough to reveal all skin in daylight. Females can sometimes be examined behind screens (e.g., a bedsheet held up by another woman) where there is daylight. A portable battery-powered lamp is useful.

The health worker should first ask the individual about any symptoms and signs noticed previously. Any immediately visible abnormality of hands, feet, or face should be noted (abnormal shape of hand/foot, loss of eyebrows, nasal collapse, etc.). Health workers should inspect as much of the skin as possible, keeping in mind the person's dignity while looking for diffuse infiltration and nodules as well as patches. Peripheral nerves should be palpated in sites of predilection, and a quick motor test done to identify weakness in commonly affected nerves. Sensation should be tested on any skin patches found (with a suitable tool such as a feather) and on palms and soles (with standard technique using a ball pen) (1). When any abnormality is found, the person should be asked about its duration and any action they may have taken (such as consulting a health worker).

At the end of the examinations, all household members should be reminded that if in the future they notice any early signs and symptoms of leprosy they should consult a health worker; they should also be told where and when that can best be done.

### **Follow up**

Persons with suspected leprosy should be asked to soon attend the nearest local clinic that has a professional capable of making a definite diagnosis of leprosy (2). There, a full clinical examination should be done and a skin smear arranged in most cases. For persons confirmed as having leprosy, their nerve function and disability grade will be assessed and recorded by a trained person and they will be allocated to a PB or MB regimen and registered for treatment. If the diagnosis cannot be immediately confirmed (or excluded), the suspect case should either be referred immediately for a second opinion by an expert or be reviewed at 1-3 months (1).

### **Training**

In our project, the majority of field staff have received a comprehensive 3-6 month long formal course of leprosy diagnosis training that includes (among other topics) signs and symptoms of leprosy, methods of physical examination, skin-smear taking, patient confidentiality, professional behaviour, and record keeping. In Bangladesh, government TB/Leprosy Control Assistants (TLCAs) should be capable of

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conducting HCEs but often cannot leave their clinics to do so. Qualified generic health workers (including nurses, health assistants, and similar health professionals) can be trained in 3 days to a satisfactory level for conducting HCEs. Training of volunteers (family members, representatives of affected peoples' organisations, and similar) or of lower level basic health services field workers to assist field staff in conducting HCEs can be done in a 1-day orientation.

In the current integrated programme in Bangladesh, TLCAs employed by the government are not expected to undertake home visits, so NGO staff support them in this activity. TLCAs record HCs or other suspects seen at clinic and implement the decisions about them (e.g., administering MDT if a new case is confirmed). If an index case refused a home visit, he/she would be advised to bring his/her HCs to the clinic for examination.

Lower level government health workers who are posted in the community are often able to assist with HCEs. Networks for persons affected by leprosy are often willing to assist with motivating families to be examined by providing chaperones and escorting suspects to clinics, as well as in other ways.

### **Ethical and cultural issues**

Index cases should be asked at the clinic (after suitable explanations) for their permission to do a home visit. Health workers need to be discreet even if permission is given, since individuals commonly involved in public education/advocacy activities may be easily identified by neighbours as "leprosy staff." For example, it is unwise to have conspicuously labelled vehicles arriving unannounced at the home of a newly diagnosed case.

It is essential to have a female health worker or trained volunteer available for physical examination of a female contact/suspect.

### **Provisos**

- During home visits: looking only for patches is not enough (1)
- In the clinic: criteria for diagnosis should be agreed upon (2)

### **Results—Outputs and Outcomes**

Only because such good practice was in place as part of routine work for field staff prior to the study was it possible to demonstrate the impact of SDR in the COLEP trial (3). In that study, before deducting actual cases, 24.72% of enumerated contacts were excluded from SDR administration because they were absent/refusing (9.09%) or had specified contra-indications (13.63%) (see Appendix 1).

HCE activities are constantly monitored by operational indicators for quality control and internal reports.

The outcomes of HCEs in terms of new case detection rate (NCDR) at each year after diagnosis of the index case are included in several recent publications in *Leprosy Review* (4-6).

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The percent of new cases found as contacts each year in RHPs ranged from 8%-20% during the past 22 years (see Appendix 2). It is not known how different this might be in a population where the overall NCDR was lower.

Outcomes of HCEs conducted in the past year are given in Appendix 3. These refer to routine work, so HCs examined are all those who were due to be seen because their index case was diagnosed within past 2 years (if PB) or past 5 years (if MB). In our area, there is an average of 4.25 HCs per index case and it takes about 1 hour to complete a home visit for an HCE (including health education), excluding travel time. In 2018, 1.67% of HCs were considered suspect cases and sent for a definitive examination at the clinic. The proportion of HCs identified as suspect cases was much higher among HCs of MB index cases compared to PB index cases. With our well-trained staff, about 70% of suspect cases were confirmed as new leprosy cases. If this percentage was very much less, one might consider the threshold for referral too low (undue anxiety caused to families), whereas if it was close to 100% one might wonder if there were many false negatives among the HCs classed as “healthy.”

### Lessons Learned

#### *Advantages of this practice*

- Good relationships with patients and their contacts are fostered and opportunities for follow up are facilitated
- Good output in terms of new case detection in relation to staff time spent, especially if staff concentrate on households of MB/smear-positive index cases
- New cases among contacts are found early, mostly before disability, and hopefully also before they infected others
- Those contacts who have been found healthy can be confidently offered PEP, after a further check for contra-indications to rifampicin (being a TB suspect, pregnancy, age below 5 years, etc.)
- If home visits for contact examinations are done only during the usual working day, some groups will be missed (predominantly children in school and men at work). It is necessary to do some visits in early morning, late evening, or on weekends.

### Replicability and Scalability

HCEs as described are usual practice in many TLM centres in various countries, including Nepal and India. They are done in rural and in urban settings, including in city slums. Initial HCEs should be a priority and ideally are done in the person’s home, with his/her permission. This might be arranged by delegation to field-based health workers. They can alternatively be done by inviting all HCs to attend the clinic where the index case is being treated (e.g., if the index case is attending a private clinic or a tertiary centre far from his/her home). Also, if the index case refuses permission for a home visit but is willing to bring his/her HCs to be examined at a clinic, this should be encouraged.

Public awareness campaigns could include mention of HCEs as a method of case finding. Organisations of persons affected by leprosy sometimes provide volunteers to assist with HCEs.

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It is preferable to continue annual HCEs where resources permit. However, the highest NCDR will be found at first examination (detection of co-prevalent cases). If it is not possible for health workers to conduct annual re-examinations, the leprosy cases and their HCs might be taught to examine each other, after the initial HCEs by a qualified person.

It is only safe and useful to do HCEs if quality can be assured (people may be falsely reassured that they do not have leprosy or given undue anxiety on being wrongly suspected). Supervision should include a review of a sample of those HCs declared “not leprosy-affected” as well as a review of a sample of diagnosed cases, to check on false-negative and false-positive rates, especially if less-trained people are undertaking the physical examinations (1).

It is advisable to first establish, as a routine part of leprosy control, good practice regarding HCEs before beginning implementation of PEP. Factors affecting this include the following:

- Staff should be competent to do the HCE well
- The increase in new case detection arising from the first rounds of HCEs will confuse data on prevention of cases through PEP
- The evidence from the COLEP study (3) on effectiveness of PEP by SDR relates to administration of SDR within 2 months of index case diagnosis (delay may impair its impact as subclinical cases may then have a higher bacterial load)

The manpower resources required for HCEs are trained staff (supported as necessary by volunteers) who are capable of

- Teaching about signs of leprosy recognizable by lay people,
- Discretely and courteously undertaking physical examinations,
- Reliably making a diagnosis of leprosy,
- Keeping accurate confidential records

If the examinations are to be done through home visits, staff need means of transport (in rural Bangladesh the ideal is a motorcycle), funds to cover travel expenses, minimal equipment such as a lamp, and permission to be out of their assigned office for enough time. They also need permission for flexible working hours in order to make home visits when more HCs are likely to be at home. Time allocation will depend on distances to travel; up to 1 hour may be needed at the home, for a household with 4 HCs.

In fully integrated programmes these resources should be available through the government service, but where they are not an NGO may offer supplementary resources (as in RHPs where work is financially supported by TLM).

Information on the Bangladesh government policy on HCEs is included in Appendix 4.



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### Conclusions

HCEs are a practice which has good face credibility (it is easy for the public to understand its rationale and value). Their impact can be easily monitored and tested (countable, observable output), and the practice is highly relevant to leprosy control as it targets a known high-risk group. It is compatible with either vertical or horizontal (integrated) leprosy control policies, whether run by government departments or by NGOs. It is also feasible to combine home-based HCEs for leprosy with screening for other NTDs (e.g., lymphatic filariasis) or TB, if staff are trained for this extra responsibility and appropriately supervised.

### Further Readings

#### References

1. World Health Organization. Enhanced global strategy for further reducing the disease burden due to leprosy 2011-2015, operational guidelines (updated). New Delhi: WHO SEARO/Department of Control of Neglected Tropical Diseases, 2009. Available at <https://www.who.int/lep/resources/B4322/en/>. (Extracts included in Appendix 5).
2. Butlin CR. Diagnosis of leprosy (Letter). *Lepr Rev* 2018;89:399–401.
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#### Other reading

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### Appendices

#### Appendix 1. Data from the COLEP Study (3)

Among 28,092 contacts of new cases identified as potentially suitable for inclusion in the trial, 2553 (9.09%) were absent or refused participation and 3828 (13.63%) were not eligible for SDR:

Reason	Number of Contacts
Absent	2217
Refused	336
Temporary resident	131
Under 5 years of age	2970
Pregnant	438
Liver disease/jaundice	51
On treatment for TB/leprosy	42
Contact of another index case	4
Reason not recorded	17
Leprosy suspect	16
Confirmed new leprosy case	159

#### Appendix 2. Data from Rural Health Programmes (4 districts) in Bangladesh

Year	NCDR/10,000	Total No. of New Cases	No. of Contacts Among New Cases	% of Contacts Among New Cases
1995	4.70	2754	346	12.56
1996	5.32	3116	395	12.68
1997	4.15	2507	313	12.49
1998	4.05	2486	351	14.12
1999	3.97	2471	263	10.64
2000	3.63	2293	202	8.81
2001	2.91	1866	195	10.45
2002	2.41	1568	174	11.10
2003	2.15	1417	166	11.71
2004	2.05	1371	163	11.89
2005	1.61	1095	154	14.10
2006	1.59	1098	109	10.00
2007	1.31	916	94	10.26
2008	1.26	894	84	9.40
2009	1.45	1043	171	16.40
2010	1.18	807	141	17.47

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2011	0.77	572	59	10.31
2012	0.86	651	88	13.52
2013	0.84	641	116	18.10
2014	0.99	765	124	16.21
2015	1.02	801	168	20.97
2016	0.84	666	126	14.62
2017	1.07	862	123	14.27

### Appendix 3. Output of Household Contact Examinations (HCEs) in 2018 in Rural Health Programmes

Index case group	Number of Index Cases	Household Contacts (HCs) Examined			Suspected Cases Identified during HCEs			New Leprosy Cases Confirmed Among Suspected Cases Reviewed		
		Total	Male	Female	Total	Male	Female	Total	Male	Female
MB	1064	4803	2134	2669	154	78(3.66%)	76(2.85%)	116	57	59
PB	1648	6720	3073	3647	38	12(0.39%)	26(0.71%)	25	8	17
Total	2712	11523	5207	6316	192	90(1.74%)	102(1.61%)	141	65	76

Mean, 4.25 HCs per index case. Mean suspected cases, 1.67% HCs examined. Approximately 70% of suspected cases were confirmed as new cases of leprosy

### Appendix 4. Government of Bangladesh Policy

Until recently, the only method of active case detection encouraged under the national programme was household contact examinations:

*Case detection: Voluntary reporting will be the most practical and feasible method of case detection in Bangladesh.... Among the different methods of active case detection, priority will be given to survey of family contacts. The contact survey should be undertaken immediately after the detection of any case in the family... Any form of active case detection such as whole population survey, school survey or slum survey will not be part of the routine programme.*

National guidelines and technical manual on leprosy, 4<sup>th</sup> ed., 2014, published by the Government of People's Republic of Bangladesh

The most recent guidelines have widened the scope of contact examinations. "Promoting early case detection through active case finding: Family contact tracing and extended contact surveys will involve examination of all significant contacts....." (Bangladesh leprosy control strategy, 2016-2020, accelerating

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towards a leprosy-free Bangladesh. Published July 2017 by the Government of the People's Republic of Bangladesh). Note: there is no definition given for *significant contacts*.

**Appendix 5. Extracts from *Enhanced Global Strategy for Further Reducing the Disease Burden Due to Leprosy 2011-15, Operational Guidelines (Updated)*** (<https://www.who.int/lep/resources/B4322/en/>)  
(Note: For words in **bold** type, emphasis is the author's [CR Butlin])

3.2. *What is the role of household contact examination in case detection?*

*Household contacts of leprosy patients are at significantly greater risk of developing leprosy than contacts who are not living in the same household. **When a new case is detected, household contacts of the patient should be examined for evidence of leprosy.** They should then be educated on the early signs of the disease and their significance and requested to return if any suspect skin lesions or motor or sensory changes occur*

4.1. *What is a case of leprosy and when should leprosy be suspected?*

**A case of leprosy** is a person with clinical signs of leprosy who requires chemotherapy (MDT).

Leprosy should be suspected in people with any of the following symptoms or signs:

- pale or reddish patches on the skin (the most common sign of leprosy);
- loss, or decrease, of feeling in the skin patch;
- numbness or tingling of the hands or feet;
- weakness of the hands, feet or eyelids;
- painful or tender nerves;
- swellings or lumps in the face or earlobes; and
- painless wounds or burns on the hands or feet.

*Although the majority of leprosy patients have skin lesions which are visible, experienced field workers are aware that there is a great variety of skin lesions that are manifest in cases of the disease. **Some skin lesions are very diffuse and difficult to distinguish from normal skin. In these cases the other symptoms and signs become important for diagnosis.***

4.4 *What should be done when leprosy is suspected but the diagnosis is uncertain?*

*Generally, the most difficult cases to diagnose are people who present with one or two pale patches without loss of sensation or other signs of leprosy. In these cases, there are three options:*

**-Know where to refer cases that are difficult to diagnose;**

*discuss cases with colleagues who have the experience of managing leprosy (Section 2.2).*

*-Consider the possibility of another skin disease and treat appropriately.*

**-Wait three to six months and review the skin lesions again;** *if it is a case of leprosy, loss of sensation may now be observed and MDT can be initiated.*

*If there is no loss of sensation in the skin lesions and no enlarged nerves but there are nevertheless suspicious signs, such as nodules or swellings on the face or earlobes, or infiltration of the skin, it is important to **try and get a skin smear test done.** In these circumstances a positive skin smear confirms*

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*the diagnosis of leprosy while a negative result (in the absence of other cardinal signs) would, in practice, rule out leprosy. An alternative diagnosis should then be considered.*

*In PB cases (where the skin smear will be negative), loss of sensation is almost always detected. **In MB cases, normal sensation may still be present in a proportion of cases, but these patients often have one or more enlarged nerves and a positive skin smear.***

*Signs of nerve involvement (enlarged nerves or signs of nerve damage such as numbness, tingling or weakness affecting hands or feet) may occasionally occur without any obvious skin lesions.*

*In such cases, known as neural leprosy, the disease can only be diagnosed by someone having experience in assessing nerve involvement in leprosy.*

### *4.5 How can the accuracy of leprosy diagnosis be ensured?*

*The diagnosis of leprosy is straightforward in the majority of cases. These cases should be diagnosed in clinics as near as possible to the patients' homes and treatment with MDT should be started immediately or at least within a few days of diagnosis.*

*In some cases, the diagnosis is more difficult. As stated above (Section 4.4), **the most difficult ones are early PB cases with one or two pale patches on the skin. Another difficult group (especially if skin smears are not available) of cases are early MB cases with very vague skin patches and no loss of sensation.***

*The following steps will help ensure accuracy in leprosy diagnosis:*

- (1) Adherence to the criteria for case definition (Section 4.2).*
- (2) Competent training about leprosy diagnosis for health workers (Section 9.8).*
- (3) Regular and effective supervision, with on-the-job training (Section 9.4).*
- (4) Clear lines of referral for suspect cases, when the diagnosis is uncertain (Section 2.2).*
- (5) Availability of appropriate training and reference material (Section 10.1).*

***The quality of diagnosis should be monitored as part of regular technical supervision.** If there are indications of substantial over-diagnosis, a validation exercise on a representative sample of cases can be conducted (Section 8.3) in order to understand the magnitude of the problem*