NATIONAL GUIDELINE FOR LEPROSY MANAGEMENT

Health Protection Agency

World Health Organization
Maldives

National Leprosy Management Guideline

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National Guideline for Leprosy Management in the Maldives

Foreword

This is a technical guideline for the management of leprosy in the Maldives. This guideline with zero leprosy standard operating procedures (SOPs) has been developed to ensure that suspected leprosy cases are identified and diagnosed accordingly, and undergoes the prescribed referral channels for treatment and follow-up.

The National Guideline for Leprosy Management provides a brief situational analysis of leprosy in the Maldives, pathology, classification, physical examination, treatment options and record keeping. The zero leprosy SOPs further details the efforts to reach the zero-leprosy status in the country. This guideline and Zero leprosy SOPs are intended for all healthcare professionals across the Maldives who will be engaged with persons affected by Leprosy.

This guideline will ensure that leprosy is correctly reported, diagnosed, treated and managed nationwide. Compliance to this guideline will help gather data to further strengthen the current Zero Leprosy Programme.

Therefore, I urge all healthcare professionals involved to use this guideline with zero leprosy SOPs as an important resource in taking care for those affected by leprosy and reach attaining it purpose.

I extend my sincere gratitude for all those who have contributed and supported the development of this guideline.

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Acknowledgments

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The guideline underwent extensive technical review by the World Health Organization and partners from the Global Leprosy Program with additional support of detailing zero leprosy standard operating procedures.

The Health Protection Agency also pays respect to the valuable contributions of former National Leprosy Programme staff and appreciates the continuous efforts by working members in the Ministry of Health to ensure the continuity and integrity of the Leprosy Programme. We acknowledge the continuous support from the World Health Organization for their technical and financial assistance to the Zero Leprosy programme.

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List of Abbreviations

AFB	Acid fast bacilli
AH	Atoll Hospital
BB	Borderline Borderline
BI	Bacteriological Index
BL	Borderline Lepromatous
BT	Borderline Tuberculoid
CBC	Complete Blood Count
BCG	Bacille Calmette-Guérin
CBR	Community Based Rehabilitation
°C	Celsius
C	Clofazamine
CMI	Cell mediated immunity
D	Dapsone
DHS	Dapsone Hypersensitivity Syndrome
EHF	Eye Hand Foot
ENL	Erythema Nodosum Leprosum
G6PD	Glucose 6 Phosphate Deficiency
HC	Health Center
HPA	Health Protection Agency
ILO	International Labour Organization
LFT	Liver function test
LL	Lepromatous leprosy
M. leprae	*Mycobacterium* Leprae
MB	Multibacillary
MDT	Multidrug therapy
MI	Morphological Index
PB	Paucibacillary
RCS	Reconstructive surgery
RFT	Release from treatment
RH	Regional Hospital
R	Rifampicin
RR	Reversal Reaction
SDR	Single dose Rifampicin
SSS	Slit Skin Smear
TB	Tuberculosis
TT	Tuberculoid
UNESC	United Nations Educational Scientific and Cultural Organization
VMT	Voluntary Muscle Testing
WHO	World Health Organization
ZN	Ziehl Neelson

1. Introduction

The Maldives has made substantial progress in tackling leprosy. The Zero Leprosy programme was launched in 2019 with the core target of declaring the autochthonous population leprosy free. The National Guideline for Leprosy Management in the Maldives complements the targets set out in the Zero Leprosy Framework to declare the Maldives leprosy-free. This guideline underwent several phases of review and revisions based on expert and technical recommendations. It identifies the responsibilities and tasks at all referral levels. Upon endorsement, this guideline will serve four functions through standardized operating procedures:

1. Specifies how to classify leprosy in the Maldives
2. Instructions on clinical examinations and laboratory investigations for healthcare workers
3. Leprosy treatment regimens, complication management and rehabilitation
4. Referral system for reporting, treating and administrative tasks concerning leprosy cases.

1.1 Global and National Epidemiology

The first case of leprosy recorded in Maldives was in 1959. Patients were segregated into different islands through a government legislation. According to available data, 66 patients from 24 islands were segregated in Villivaru / Biyadhoo. Government collaborated with World Health Organization (WHO) and started leprosy control efforts in 1974 and the patients were given the opportunity to go back to their islands after treatment. The Maldives Leprosy Programme was initiated under the Department of Public Health with 896 cases from 53 islands on treatment.

Maldives was listed as a highly endemic country with a prevalence rate of 96.64 per 10,000 population until the introduction of multidrug therapy (MDT) in 1982. Subsequently, the Maldives achieved leprosy elimination status as per WHO recommendations with a prevalence rate of less than one per 10,000 population in 1987. For the past decade, an average of about 7 new cases per year have been reported. There has been no reports of grade 2 disabilities in any of the new cases due to high treatment completion rate.

Official figures from 159 countries from 6 WHO regions show the global registered prevalence of leprosy to be at 184,212 cases at the end of 2018. During the same year, 208,619 new cases were reported.

Elimination of leprosy as public health problem was achieved globally in the year 2000.

1.2New Global Leprosy Strategy

The Maldives has achieved all three targets set by the Global Leprosy Strategy 2016-2020: Accelerating towards a leprosy-free world. As a result, only 32 islands report cases sporadically with currently only 9 active cases nationwide.

As part of the new global leprosy strategy for 2021-30, an emphasis on post-exposure prophylaxis has been reiterated following several success stories in leprosy endemic regions. In addition, recommendations are in place for national leprosy programmes to scale up prevention via integrated active case detection. The strategy also highlights the importance of national programmes providing support services for counselling and psychological first aid for persons affected by leprosy. Furthermore, national programmes are recommended to incorporate monitoring of resistance to drugs used for leprosy treatment and any adverse drug reactions.

1.3 Zero Leprosy Programme

The Zero Leprosy framework was established in 2019 with the initial target of screening and declaring 100 islands leprosy-free by 2023. The programme draws strengths from previous successes on elimination of measles, malaria and lymphatic filariasis.

The zero leprosy programme aims to attain zero number of leprosy cases in the indigenous population in the Maldives. The programme considers an area eligible for Zero Leprosy status if no new cases of leprosy are found continuously for a period of ten years; that is twice the incubation period. The programme will also ensure that there is zero infection and disease, zero disabilities, and zero stigma and discrimination towards those affected by leprosy.

Nationwide, healthcare staff are well-versed with communicable disease control leprosy control mechanisms and an efficient referral system based on a patient-oriented software for follow-up and rehabilitation. With support from numerous stakeholders, persons affected by leprosy expressed an interest to participate in the programme.

2. What is Leprosy?

Leprosy is a chronic granulomatous infection, affecting principally skin and peripheral nerves, caused by the obligate intracellular organism *Mycobacterium leprae* (*M. leprae*). The etiologic agent, *M. leprae*, was identified by Norwegian physician Gerhard Armauer Hansen in 1873. Leprosy is also known as Hansen's disease. It can affect people irrespective of their sex, age and nationality.

The only known source of *M. leprae* is from untreated leprosy affected humans. Leprosy can be transmitted from an untreated leprosy affected person to a susceptible and/ or genetically predisposed person through droplets.

The bacilli mostly exits the body of an infectious person through the respiratory tract. Only a small proportion of those suffering from leprosy can transmit the infection.

Leprosy causes skin lesions and neuropathy with complications leading to deformities and disability. It is a highly stigmatizing disease with heavy socioeconomic burden.

M. Leprae belongs to the class Schizomycetes, order Actinomycetales, family Mycobacteriaceae, and genus *Mycobacterium*. *M. leprae* is a straight or slightly curved rod, with rounded ends, measuring 3-8 microns in length by 0.2-0.5 micron in diameter. It can be stained using Ziehl Neelsen (ZN) stain. *M. leprae* is different from other mycobacteria in terms of arrangement, since it is arranged in parallel chains, just like cigarettes in a pack, bound together forming the globi. The bacteria cannot be grown in artificial media and has been seen to grow slowly in mouse foot pads. It is viable in the environment for about 9 days. Human beings are the reservoir of *M. leprae*, but animals, such as armadillos, chimps, and other apes, the soil, and some arthropods are reported as natural reservoirs. *M. leprae* prefers growth temperature of less than 37°C which is the main reason for it to infect skin, nasal mucosa and peripheral nerves. It infects mainly macrophages and Schwann cells.

2.1 Incubation Period:

Leprosy has a very long incubation period which can vary between a few weeks to even 20 years with an average incubation period between five to seven years.

2.2 Transmission:

Transmission of leprosy is through contact with untreated leprosy patients.

2.3 Portal of Entry:

M. leprae enters the body through the upper respiratory tract and through the damaged skin.

2.4 Portal of exit:

The bacteria leave the body mainly through the nasal mucosa.

2.5 Age:

Leprosy can affect people of any age.

2.6 Gender:

Although leprosy is seen more in males, it can affect all the genders.

2.7 Pathogenesis

Leprosy pathogenesis has not been definitively understood. Leprosy disease and clinical manifestations are the result of a dynamic interactive process between *M. leprae* and the cell-mediated immunity (CMI) of genetically predisposed subjects. The vast majority (95%) of the exposed population is not susceptible to the disease; of the remaining 5%, the larger part successfully eliminates *M. leprae* through an efficacious immune response while only a relatively small percentage (1%) develops leprosy. M. leprae is the only bacterium with neurotropism. It is not cultivable in any known artificial media. Leprosy patients are the only reservoir of significance, despite the fact that leprosy-like infection has been reported in a few wild armadillos in the south of Texas and Louisiana.

Once *M. leprae* is inside the subject, it enters lymph and blood vessels to reach its target: the Schwann cells. The Schwann cells engulf *M. leprae* within their phagosomes, but cannot destroy *M. leprae* because Schwann cells lack lysosomal enzymes. Schwann cells are sanctuaries where the bacilli are protected from macrophages and can replicate slowly over years. Host genetic factors influence the CMI and have a partial effect on both the development of leprosy and the pattern of disease. The CMI determines either the elimination of the bacillus or the development of the disease. The spectrum of the disease is determined by the balance between CMI and bacilli: high CMI response means low number of bacilli (paucibacillary leprosy); low CMI response means high number of bacilli (multibacillary leprosy).

3. Diagnosis and Classification

The diagnosis of leprosy is based on the history and clinical examination. Very rarely laboratory and other investigations maybe needed to confirm a diagnosis of leprosy. An individual is diagnosed with leprosy if one of the following cardinal signs is positive:

1. hypo-pigmented patches with loss of sensation (touch, pain or temperature)
2. thickened or enlarged peripheral nerves with loss of sensation and or weakness of muscles supplied by that nerve
3. the presence of acid-fast bacilli in a slit skin smear

The first two cardinal signs can be identified by clinical examination alone while the third can be identified by examination of the slit skin smear in a laboratory

3.1 Classification

Classification of the person's disease is important to determine the treatment and prognosis of the disease and to know who are infectious.

3.2 WHO Classification

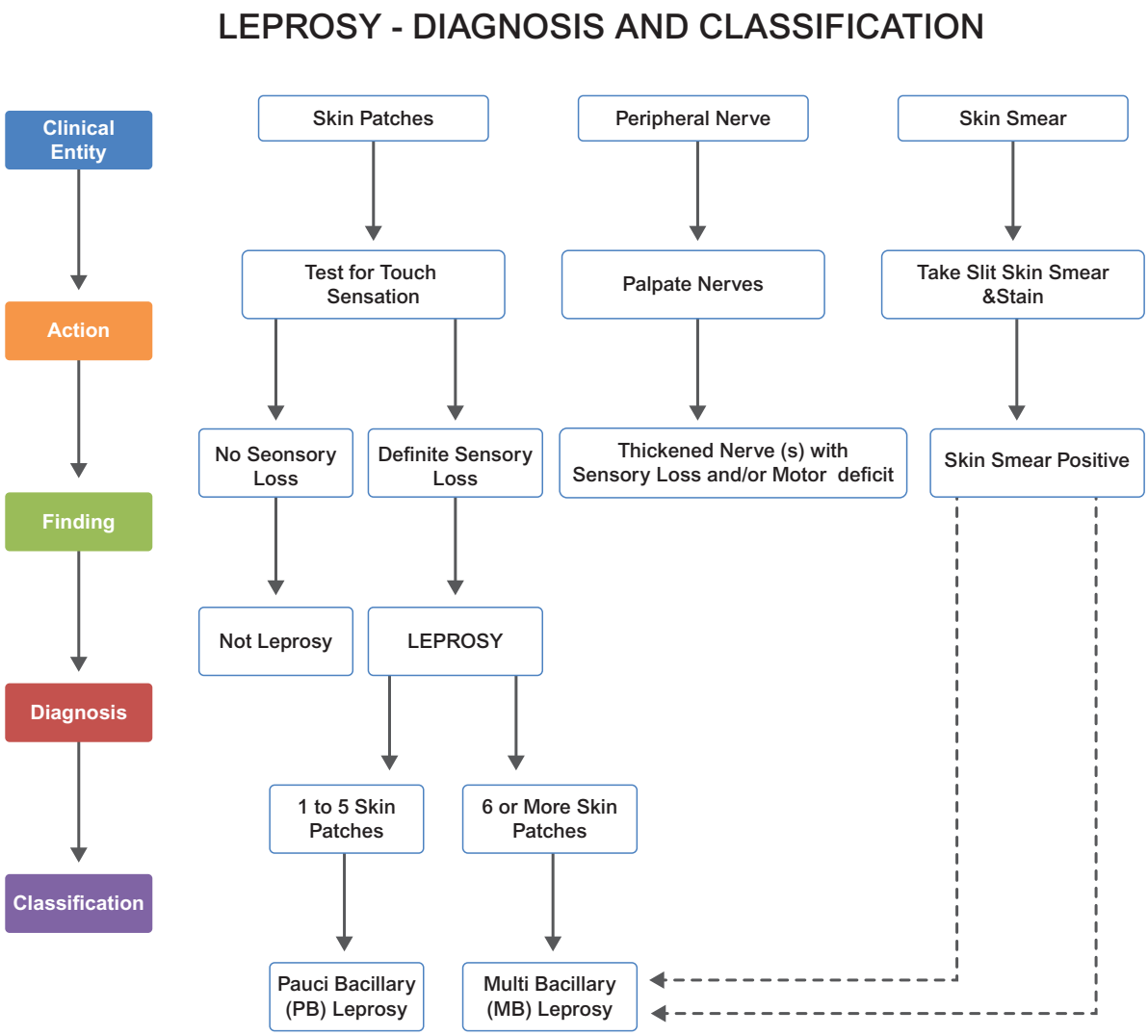
Paucibacillary (PB) cases have up to five skin lesions in total and skin smear is negative for Acid fast bacilli (AFB)

Multibacillary (MB) cases have six or more skin lesions or one or more nerve thickening OR skin smear is positive with any number of skin lesions.

Diagnosis and Classification of leprosy is presented in the following flow chart.

Fig. Flow chart – Leprosy Diagnosis and Classification

Figure 3.1



4. Clinical Examination

4.1 History

Proper history taking and collection of data is very important.

The following information must be recorded:

- General information: name, gender, age, address, phone number, occupation, Nationality
- Present complaints, date of onset, site of lesion, symptoms
- Any deformity, the time of its onset, and nature of its progress;
- Past history
- Treatment history and history of drug allergies
- Family history and contact history
- Any other associated illness

4.2 Physical Examination

A female patient should be examined preferably by a female health worker or in the presence of a female attendant if male health worker is examining.

Explain to the patient how the examination will proceed.

Examination should be carried out in adequate light (daylight).

Respect the patient's privacy. Examine the whole body.

General examination should be carried out. Look for Pallor, icterus, lymph nodes, oedema. Record vital signs.

Look for patches, nodules, discoloration, thickened nerves. Also check for dry skin, ulcers on the limbs, muscle weakness and deformity. Test for pain, touch and temperature sensation.

Slit skin smear test should be carried out

Some early lesions of leprosy may not have any of the cardinal signs but the lesions maybe suggestive of leprosy. Advice a skin biopsy for these cases.

The skin lesions should be examined for:

Table 4.1

Site	Anatomical position of the skin lesions
Appearance	Macule, papule, annular, diffuse infiltration, nodules, satellite lesions
Colour	Hypo-pigmented, Erythematous lesions
Number	Few (1to 5), 6 or more
Margin	Well defined, ill defined, sloping, Infiltrated
Distribution	Asymmetrical, symmetrical, areas of the body
Surface	Dry scaly, Smooth, Shiny, Central healing
Sensation	No loss, Impairment, absent
Hair growth	Present, absent
Tenderness	Present, absent

The skin lesion is usually hypopigmented, or maybe reddish or copper colored. Sweating maybe absent. There can be hair loss along with probable loss of light touch sensation and temperature sensation over the lesion. Peripheral Nerve enlargement maybe present with sensory loss or weakness of muscles supplied by that nerve. Leprosy could also present with different types of lesions including papules and nodules or infiltration, especially if patient is having leprosy reactions.

4.3 Testing for Sensation on Skin Patches

All the sensations should be tested. This includes temperature, light touch and pain. Light touch is detected by touching the skin lightly with cotton wool. Temperature can be tested using two test tubes with warm and cold water. Pain can be elicited using a pin.

Testing for touch

- Explain the procedure to the patient.
- Touch the skin with the tip of a ball point pen. Ask the patient to touch with one finger on the exact spot that is tested. Repeat over the normal and affected skin.

- Repeat the test with the eyes closed.
- Repeat the examination using a wisp of cotton wool for light touch.

Testing for temperature

- Explain the procedure to the patient.
- Fill two test tubes, one with warm water and the other with cold water.
- Touch the skin of the patient and ask to indicate to the point being tested. Ask the patient to describe whether it is warm or cold. Repeat over the normal and affected skin.

4.4 Nerve Function Assessment (NFA)

Leprosy affects sensory, motor and autonomic functions of peripheral nerves. Peripheral nerve involvement is demonstrated by thickening of the nerve, loss of sensation over the area supplied by the nerve with or without weakness of the muscles the nerve supplies.

NFA should be done

- At the time of diagnosis of leprosy
- Every month for patients on MDT
- If patient complaints of nerve pain, tenderness, development of new anesthesia, loss of function
- Every 2 weeks for those who are under steroid therapy
- At the time of RFT
- When patients come for annual checkup

NFA are done to assess the condition of function of peripheral nerves and to record condition of the patient during follow-up. This will help to detect any nerve function impairment early and prevent further damage.

After NFA any case eligible for surgery should be referred to a respective specialty in a referral hospital

4.5 Nerve Examination

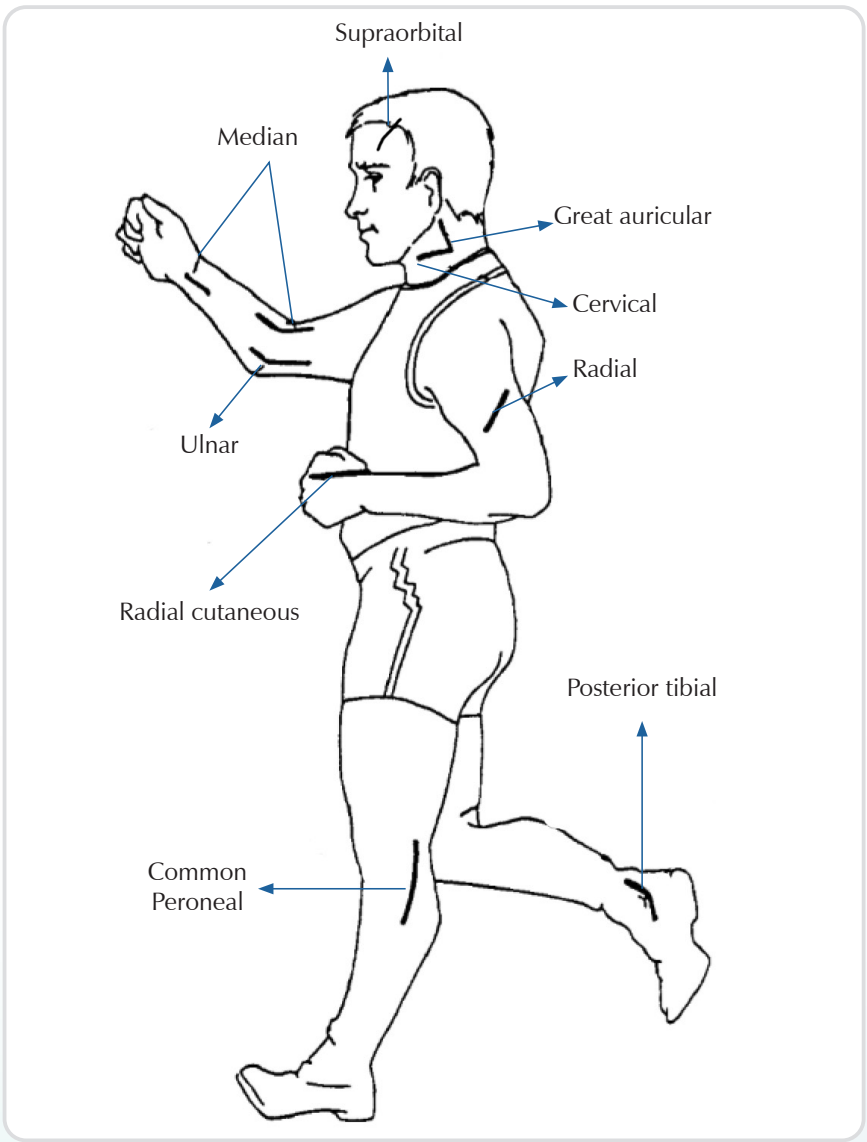
Palpation of nerves: Position the patient correctly. Palpate throughout the length of the nerve. Check for thickening of the nerve, tenderness. Both sides should be palpated and compared.

Peripheral nerve trunks: Facial nerve in face, Radial, Ulnar, median nerve in upper limb and common peroneal (Lateral Popliteal nerve), posterior tibial in the lower limb

Cutaneous nerves: Supra orbital, greater auricular, radial cutaneous nerves

Showing peripheral nerve trunks and cutaneous nerves

Figure 4.1

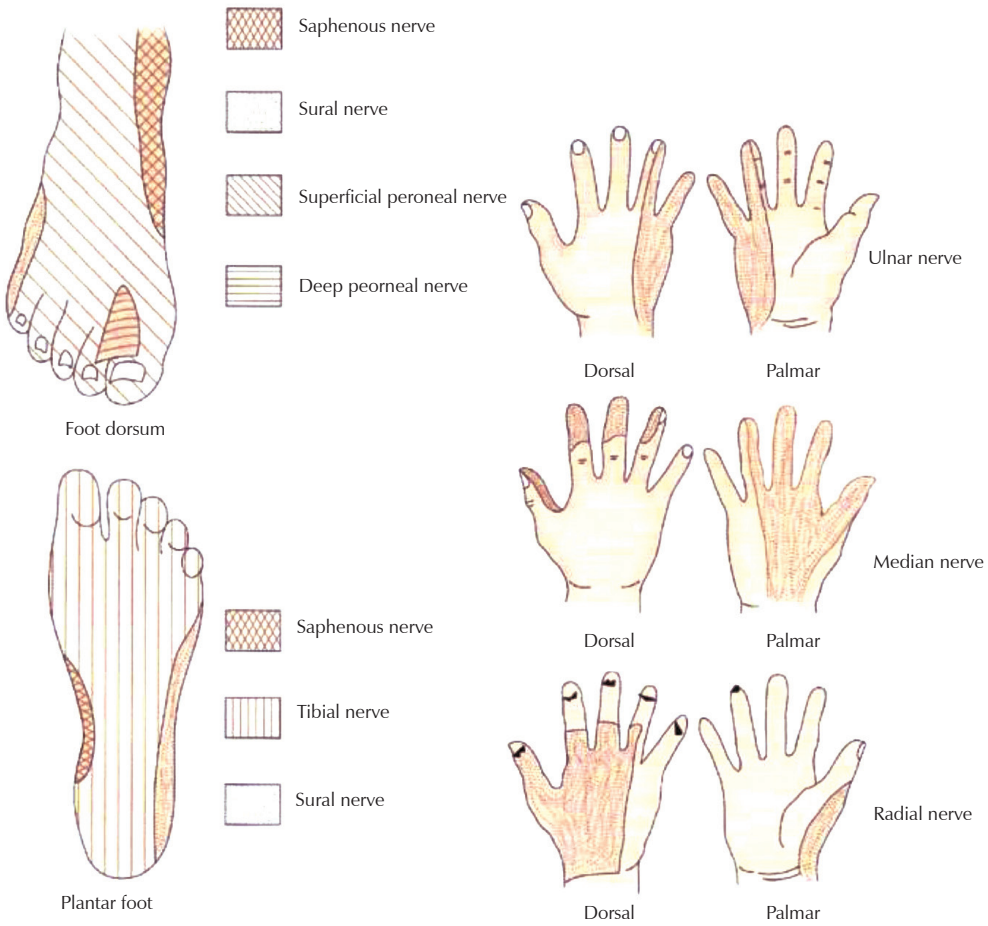


4.5.1 Assessment of Sensory Function of Nerve

Testing for sensory loss is done similar to the sensory testing of skin lesions, using the tip of a ball point pen.

Sensory testing of nerves

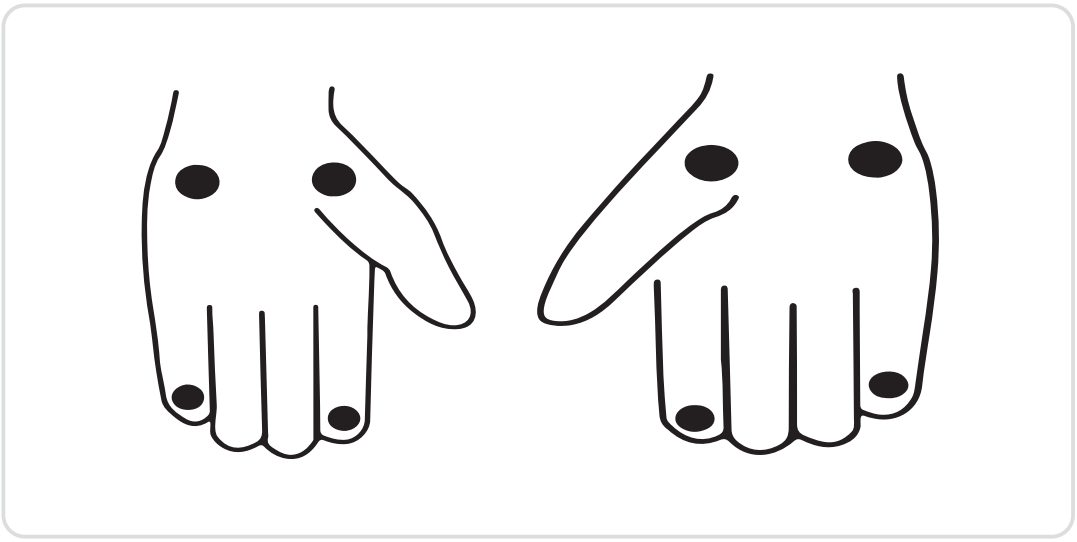
Figure 4.2



4.5.2 Sensory Test

One should test for sensation over the areas demarcated in the diagram. Given below are the suggested spots for testing sensation over the both palms and both soles

Figure 4.3



Interpretation of test for loss of sensation:

If no response	-	Loss of sensation (X)
If >3cm away	-	Reduced sensation
If within 3cm	-	Normal sensation (√)

Autonomic functions: Reduced sweating over the skin patches causes dryness over the lesions and dryness over the hands and feet.

4.6 Assessment of Motor Functions of Nerves

4.6.1 Facial Nerve (zygomatic and temporal branch)

Figure 4.4

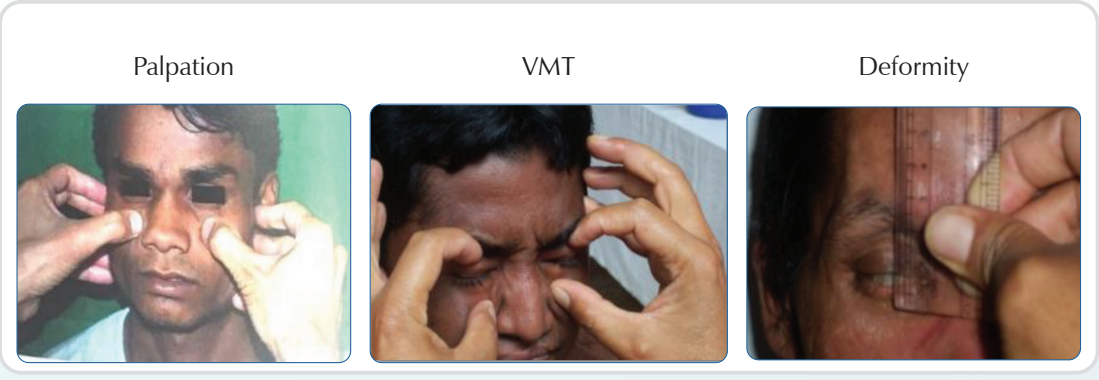


Table 4.2

Site	Zygomatic branch
Position	Sitting/standing with head kept straight
Method	Palpate with both thumbs on both sides of the nose and the index finger infront of the ear lobule and bring the fingers anteriorly across the zygoma Thread like structures in the middle of the arch and a twitching of corresponding eyelid confirms the nerve Facial nerve can be palpated just below and front of the ear lobule
VMT	Patient is asked to close the eyes tightly and examiner tries to open the eyelids
Deformity	Lagophthalmos

4.6.2 Radial Nerve

Figure 4.5

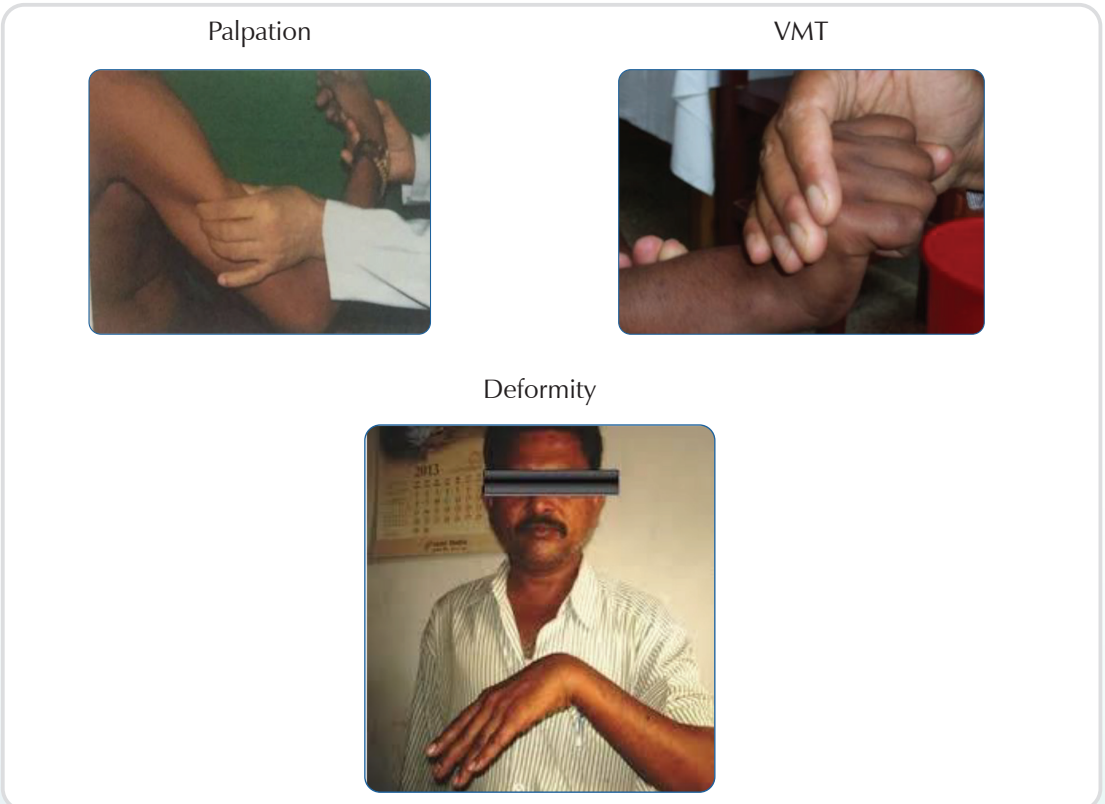


Table 4.3

Site	Spiral groove on Humerus
Position	Sitting/Standing with elbow kept at 90°. Examiner's right hand hold patient's left hand in shaking hand manner
Method	With elbows partially flexed and the arm held in position with shoulders internally rotated, radial groove at the insertion of deltoid muscle is identified. For the right radial nerve, fixing the flexor muscle mass with left thumb, the pulp of the fingers is pressed deep in the radial groove to palpate the nerve Left radial nerve is palpated with the right hand in the similar manner. Tingling down the course or local tenderness can be taken as a guide
VMT	Close the fist and dorsiflex the wrist against resistance
Deformity	Wrist drop

4.6.3 Ulnar Nerve

Figure 4.6

Table 4.4

Site	In the groove above and behind medial epicondyle of the elbow
Position	Both the patient and examiner facing each other.
Method	Use the Examiner's left fingers to locate the nerve in the groove ▪ To examine right ulnar nerve, ask the patient to flex the elbow joint slightly. ▪ Hold the right wrist with your right hand. ▪ With the left hand feel for the medial epicondyle. ▪ Pass behind the elbow and feel the ulnar nerve in the groove. ▪ Gently palpate with pulp of 2 fingers (index & middle) and feel across the nerve, constantly watching facial expression for signs of tenderness. Trace the nerve proximally as far as to ascertain the length of the swelling.
VMT	Abduction of little finger
Deformity	Claw hand deformity

4.6.4 Median Nerve

Figure 4.7

Table 4.5

Site	At the wrist, medial to the tendon of palmaris longus
Position	Sitting/Standing with elbow kept at 90° and wrist in supination Examiner's left hand stabilizes patient's left hand.
Method	Locate palmaris longus by asking the patient to flex the wrist against resistance. As this muscle is absent in 30% of the individuals, nerve can be located in line with the ring finger just above the crease of the wrist. Tingling or tenderness can be used to confirm palpation of the nerve
VMT	Abduction of thumb
Deformity	Ape thumb deformity

4.6.5 Lateral Popliteal Nerve (common peroneal nerve)

Figure 4.8

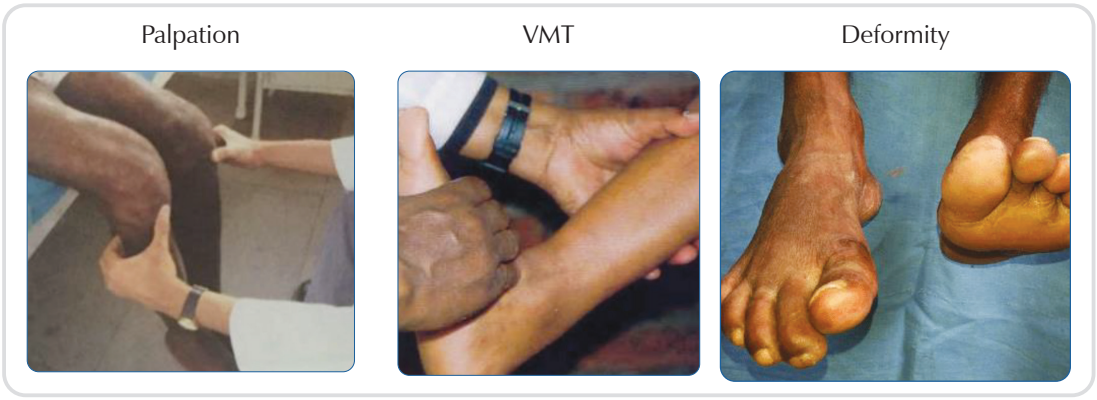


Table 4.6

Site	Just below lateral aspect of knee, at the neck of the fibula
Position	Sitting with legs dangling freely.
Method	Both sides can be palpated simultaneously. With the patient sitting on the stool or standing with knees slightly bent, the examiner sitting in front of the patient place the thumbs on tibial tuberosities and the fingers on the lateral aspect of the knees. Locate the fibula head and palpate the nerves just below it both posteriorly and winding round insertion of biceps femoris muscle on the neck of the bone
VMT	Dorsiflexion of foot
Deformity	Foot drop

4.6.6 Posterior Tibial Nerve

Figure 4.9

Table 4.7

Site	Below and behind the medial malleolus
Position	Sitting on bed with knee flexed/standing
Method	With the ankle in the neutral position the nerve can be palpated at the mid point between medial malleolus and the tuberosity of calcaneum
VMT	Retract toes by keeping feet firmly on the ground
Deformity	Claw toes

4.6.7 Ocular Examination

Figure 4.9

Corneal sensation: - (Trigeminal nerve)

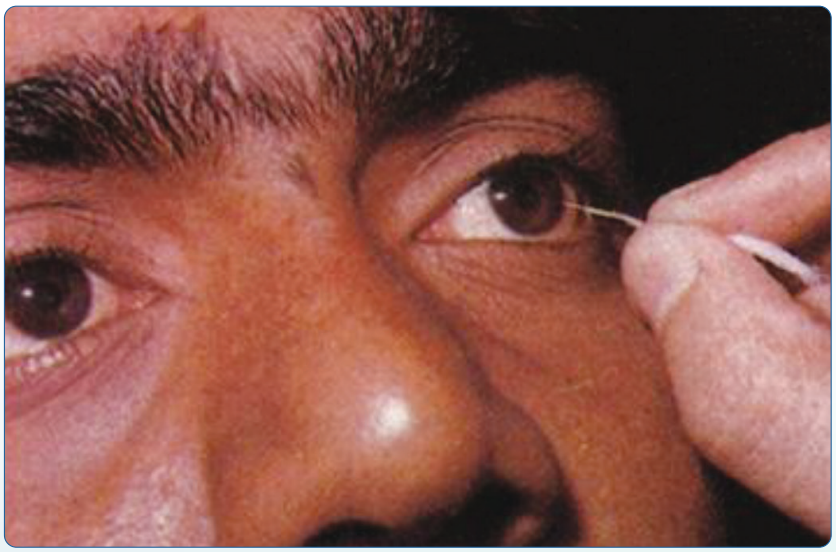


Table 4.8

Site	Cornea -2mm inside the limbus at the 6 O'clock position
Position	Sitting and looking straight
Method	Clean hands properly Take a wisp of cotton wool rolled into a point on one end Approach the patient from one side and touch the cornea gently 2mm inside the limbus at the 6 O'clock position while the patient looks straight.
Normal	brisk blink response
Abnormal	Unilateral loos of corneal reflex- involvement of ophthalmic nerve due to same sided periocular BT lesion Bilateral loss of corneal reflex- damage of corneal nerves due to advanced LL disease

Grading of VMT – Ulnar, Median, Radial, Lateral Popliteal nerves

S (Strong) – Able to perform the movement against full resistance

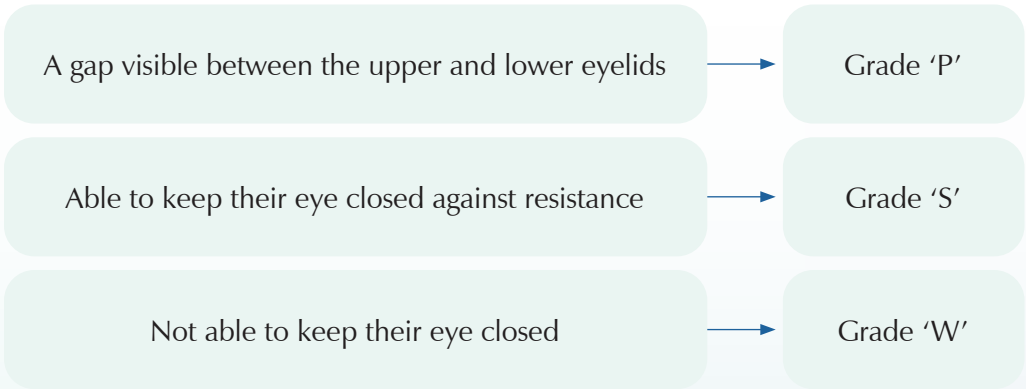
W (Weak – Able to perform the movement but not against full resistance

P (Paralysed) – Not able to perform the movement at all.

VMT for Facial Nerve

Ask the patient to close their eyes and keep them lightly closed as if in sleep. If there is no gap, ask them to close the eye tightly and try to pull the lower lid down and see whether the patient is able to keep their eyes closed against resistance.

Figure 4.10



5. Grading of Disability

Disability grading is important in preventing further impairment in patients affected with leprosy. It should be done at the beginning and end of treatment. The Eye Hand Foot (EHF) score is used to grade disability for **Hands and Feet, Eyes**

The EHF score is the sum of the individual disability grade for each eye, hand and feet. EHF score can range from 0 to 12.

Hands & Feet

Table 5.1

Grades	Deformities
Grade 0	No anaesthesia, no visible deformity or damage over palm/sole
Grade 1	Anaesthesia present, no visible deformity or damage over palm/sole
Grade 2	Visible deformity or damage present

Eyes

Table 5.1

Grades	Deformities
Grade 0	No eye problem due to leprosy; no evidence of visual loss
Grade 1	Eye problem due to leprosy present, but vision not severely affected as a result (vision 6/60 or better; can count fingers at six metres)
Grade 2	Severe visual impairment (vision worse than 6/60; inability to count fingers at six meters), lagophthalmos, iridocylitis and corneal opacity

5.1 Laboratory Investigations

There are two laboratory investigations utilized to grade disabilities; slit skin smears and skin biopsies. The latter can be performed in difficult to diagnose cases and in the relapse cases.

5.1.1 Slit Skin Smears

Slit skin smears are done to demonstrate AFB.

Smear is taken from at least four sites including the active skin lesions and bilateral ear lobes.

Method: Earlobe is cleaned with spirit and is then tightly pinched using the thumb and index finger for few minutes. An incision is then made with a Bard Parker No. 15 blade about 5mm in length and 2mm deep. The edge of the blade is reversed, and scrapping is taken to make the smear on a glass slide. The wound is dressed with tincture iodine. Slide is stained with Ziehl-Neelsen's technique. AFB are observed under the microscope as pink colored bacilli.

Examination of the smears:

Bacterial Index (BI)

BI indicates the density of lepra bacilli in smear and includes both living (solid-staining) and dead (fragmented or granular forms) bacilli.

BI is expressed in logarithmic scales:

1 + (1 bacillus in every 100 fields),

2 + (1 bacillus in every 10 fields),

3 + (1 bacillus in every field),

4 + (1–10 bacilli in every field),

5 + (10–100 bacilli in every field),

6 + (More than 100 bacilli and even globi in every field)

The Morphological Index (MI).

MI is the percentage of presumably living bacilli in relation to the total number of bacilli in the smear. These bacteria are viable bacteria which can potentially cause infection.

Criteria for solid staining AFB

- Entire organism must be uniformly stained.
- Longitudinal sides are parallel
- Both ends are rounded.
- Length is 5 times its width

6. Treatment of Leprosy

6.1 Basic Principles of Leprosy Treatment

- Provide adequate treatment to all new cases and cure them in a short period
- Render all infectious cases non-infectious in a short period
- Ensure early detection of complications and treat cases to prevent deformities
- Educate and counsel patients and public to eliminate social stigma
- Prevent spread of the disease and to eliminate leprosy

6.2 Multi-Drug Therapy (MDT)

The recent WHO guidelines (World Health Organisation, 2017) recommend a 3-drug regimen of Rifampicin, Dapsone and Clofazimine for all leprosy patients, with a duration of treatment of 6 months for PB leprosy and 12 months for MB leprosy. MDT is provided in blister packs, each containing 4 weeks treatment. Specific blister packs are available for MB and PB leprosy, with different doses for adults and children.

Assessment for the fitness of a patient for MDT

Before starting the treatment one must look for the following:

- Jaundice- if the patient is jaundiced, wait for the jaundice to settle
- Anaemia- treat anaemia simultaneously
- Tuberculosis - if the patient is taking Rifampicin ensure that they continue to take the dose required in Tuberculosis along with other drug regimen (except Rifampicin) required for the treatment of leprosy.

6.3 Steps to be taken Before Starting MDT

- Register the patient at the healthcare facility and fill the patient card
- Determine which type of MDT is required: PB or MB
- Counsel the patient (and the guardian) to indicate the need for regular treatment.
- Explain the possibility of side effects and complications which may need other treatment
- Give the first dose of treatment and explain how to continue the treatment at home.

The patient should take the first dose under direct observation of a health worker

The following are standard MDT regimens for both PB and MB leprosy in adults and children. The WHO recommends 3 drug regimens for both PB and MB with a shorter duration for the former.

6.4 MDT Regimens

The standard adult treatment regimen for MB leprosy is:

- Rifampicin: 600 mg once a month
- Clofazimine: 300 mg once a month, and 50 mg daily
- Dapsone: 100 mg daily
- Duration: 12 months (12 blister packs of 28 days each)

Figure 6.1

Front view of the MB Adult MDT blister pack

Monthly Supervised Treatment (Day 1)

- Top 2 lines break off: detachable):

Clofazimine 300mg (three capsules of 100 mg), Rifampicin 600mg (two capsules of 300mg) and Dapsone 100mg (1 tablet of 100 mg)

Unsupervised Daily Treatment (DAYS 2-28):

Clofazimine 50mg (one capsule of 50 mg) EVERY DAY and Dapsone 100mg (one tablet of 100mg) EVERYDAY

Duration of Treatment:

12 blisters packs to be taken within 12-18 months

Figure 6.2

Back view of the MB Adult MDT blister pack

R - Rifampicin: monthly supervised dose is 600mg (2 capsules, each of 300mg)

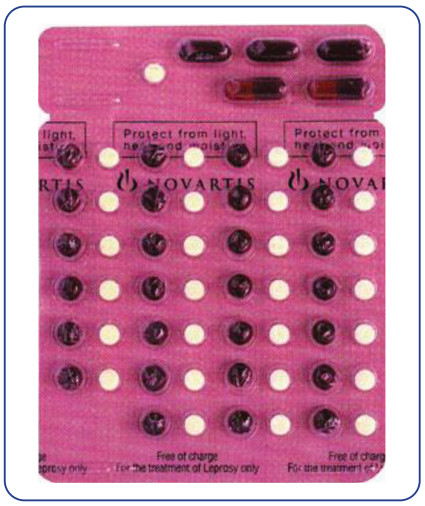
C - Clofazimine 100mg: monthly supervised dose is 300mg (3 capsules)

D - Dapsone: monthly supervised dose is 100mg (1tablet).

The figures 2-28 represent 4 weeks of unsupervised Clofazimine (50mg) **every day** and Dapsone (100mg) **daily**.

Actual size of blister pack:

106mm x 140 mm



Standard child (ages 10–14 years) treatment regimen for MB leprosy is:

- Rifampicin: 450 mg once a month
- Clofazimine: 150 mg once a month, and 50 mg every other day
- Dapsone: 50 mg daily
- Duration: 12 months (12 blister packs of 28 days each)

Figure 6.3

Front view of the MB Child MDT blister pack

Monthly Supervised Treatment (Day 1)

- Top 2 lines break off: detachable):

Clofazimine 150mg (three capsules each of 50mg), Rifampicin 450mg (two capsules, one of 300mg, theother of 150mg) and Dapsone 50mg (one tablet of 50mg)

Unsupervised Daily Treatment (DAYS 2-28):

Clofazimine 50mg (one capsule of 50mg), EVERY OTHER DAY and Dapsone 50mg (one tablet of 50mg) EVERY DAY

Duration of Treatment:

12 blisters packs to be taken within 12-18 months

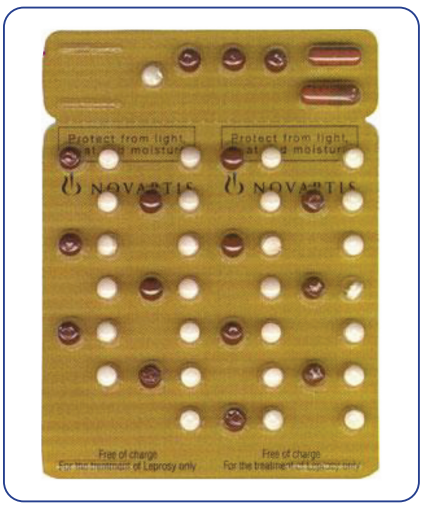


Figure 6.4

Back view of the MB Child MD1 blister pack

R - Rifampicin: monthly supervised dose is 450mg (2 capsules, one of 300mg, the other of 150mg)

C - Clofazimine 50mg: monthly supervised dose is 150mg (3 capsules)

D - Dapsone: monthly supervised dose is 50mg (1tablet).

The figures 2-28 represent 4 weeks of unsupervised Clofazimine (50mg) **every other day** and Dapsone (50mg) **daily**.

Actual size of blister pack:

106mm x 140 mm

For children below 10 years, the dose must be adjusted: for example Rifampicin 300mg, Dapsone 25mg, and Clofazimine 100mg for the monthly, supervised dose, followed by Dapsone 50mg and Clofazimine 50mg twice a week.

The standard adult treatment regimen for PB leprosy is:

- Rifampicin: 600 mg once a month
- Clofazimine: 300 mg once a month, and 50 mg daily
- Dapsone: 100 mg daily
- Duration: 6 months (6 blister packs of 28 days each)
- Duration: 6 months (6 blister packs of 28 days each)

Side effects and Adverse Drug Reactions to MDT:

Table 6.1

Minor	Drug	Management
Red urine	Rifampicin	Reassurance
Brown discoloration of the skin	Clofazimine	Counselling
Anaemia	Dapsone	Give iron and folic acid
Gastro-intestinal upset	All three drugs	Give drugs with food

Table 6.2

Major (serious)	Drug	Management
Itchy skin rash	Dapsone	Stop dapsone, refer
Allergy, urticarial rash	Dapsone or Rifampicin	Stop both, refer
Jaundice	Rifampicin	Stop rifampicin, refer
Shock, purpura, renal failure	Rifampicin	Stop rifampicin, refer

6.4.1 Chemoprophylaxis

The use of single dose of rifampicin (SDR) as preventive treatment for contacts of leprosy patients (adults and children 2 years of age and above), after excluding leprosy and tuberculosis disease, and in the absence of other contraindications is recommended.

Rifampicin for prophylaxis with a single dose (SDR)

Table 6.3

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

7. Management of Complications

Complications due to drugs used for the treatment

Complications of leprosy

Common Side Effects of MDT

Table 7.1

Drugs	Symptoms	Management
Rifampicin	Urine may stain slightly reddish Flu like symptoms	Explain to the patient that this is harmless, and no intervention is needed Flu like symptoms need treatment
Clofazimine	brownish hyperpigmentation & dryness of skin	Explain that hyperpigmentation will disappear within few months of completing the treatment. Advised to keep skin moisturized with sun-protection
Dapsone	Jaundice, anaemia Itching and skin rash; even blisters may appear and skin may start to peel off in case of Dapsone hypersensitivity Syndrome (DHS) with systemic symptoms	Stop Dapsone continue with only Rifampicin and Clofazimine in the usual dosage

7.1 Management of Leprosy Reactions

Leprosy reaction is the sudden appearance of acute inflammation in the lesions (skin patches, nerves, other organs) of a leprosy patient. This is due to an alteration in the immunological status of the patient. Reactions are the major cause of nerve damage and disability in leprosy. Therefore they should be detected as early as possible and treated promptly. Leprosy reactions are part of the natural course of the disease and can occur at any time. Reactions commonly occur during the early part of the disease. Sometimes patients report for the first time to a health facility because of a leprosy reaction. Some reactions are seen after completion of treatment.

Reactions may present as swelling and redness over the skin lesions which are warm and tender to touch.

There may be swelling, pain or tenderness of nerves, signalling neuritis, which is often accompanied by loss of nerve function.

The diagnosis and treatment of reaction is urgent because of the risk of permanent nerve damage and all health workers providing MDT should be aware of the signs and symptoms of leprosy reactions.

Predisposing factors to develop reactions:

- Multiple lesions
- Lesions close to the peripheral nerves (predisposes to neuritis)
- Lesions on the face
- People with nerve thickening with or without functional impairment
- Infections and infestations
- Vaccination
- Hormonal changes: Puberty, Pregnancy and Childbirth

MDT should always be continued during a reaction.

There are two types of reactions.

1. Reversal Reaction (RR) or type I reaction
2. Erythema Nodosum Leprosum (ENL) or type II reaction.

7.2 Type 1: Reversal Reaction

This is the most common type of reaction. This occurs in 10 - 20% of PB patients and in up to 40% of MB patients.

Only the severe reactions need treatment with corticosteroids (e.g. prednisolone)

A reversal reaction is considered severe if:

- Neuritis with or without loss of sensation and/or muscle weakness
- Recent loss of nerve function, that is, loss of sensation and muscle weakness with or without pain or tenderness;
- Pain or tenderness in one or more nerves

- A red, swollen skin patch on the face or overlying any major nerve trunk
- Ulcerating skin lesions
- Marked oedema of hands, feet or face

There can be silent neuritis without typical signs of neuritis, patient may develop deformity. It can only be found with voluntary muscle testing.

All other reactions without nerve involvement are classified as mild reactions and can be treated with analgesics.

7.2.1 Treatment of Type 1 Reactions

MDT should be continued and completed even during leprosy reactions.

Mild reactions:

These can be controlled by rest and the usual doses of analgesics (such as aspirin, paracetamol, ibuprofen) to reduce fever and the joint pain.

Severe reactions:

Treat severe reaction with prednisolone.

The standard schedule of the treatment of reversal reactions with prednisolone is as follows:

40 mg daily for weeks 1 and 2

30 mg daily for weeks 3 and 4

20 mg daily for weeks 5 and 6

15 mg daily for weeks 7 and 8

10 mg daily for weeks 9 and 10 and

5 mg daily for weeks 11 and 12.

Reversal reactions sometimes occur after completion of a full MDT course.

Explanations should be given to patients that reaction is not a relapse of the disease and the importance of treatment to prevent nerve damage.

7.3 Type 2: ENL

The signs of severe ENL reaction are:

- Appearance of painful and tender, erythematous evanescent nodules
- Fever and malaise
- Pain or tenderness in one or more nerves with or without loss of nerve function
- Ulceration of ENL nodules
- Pain and tenderness of the eye or redness of the eye
- Painful swelling of testes or the fingers
- Marked arthritis or lymphadenitis.

Mild ENL reactions can be treated with rest and analgesics. Patient should be examined for signs of new nerve damage at weekly intervals.If no improvements are observed after six weeks of analgesic administration, or if signs of a more severe ENL reaction occur, treatment should be replaced with prednisolone.

Treatment with MDT should always be continued until the standard MDT course is completed. Start prednisolone as given in Type I reaction.

Recurrent ENL Recurrent episodes of ENL are observed in some patients when the prednisolone doses are administered below 20mg or 15mg per day. This is called chronic or recurrent ENL.

Treatment of Severe and recurrent ENL

- Continue with the standard MDT course until it is complete.
- Administer Analgesics to control fever and pain.
- Prednisolone should be given in the standard course with the dosage not exceeding 1 mg per kg. body weight for a maximum duration of 12 weeks.

Clofazimine 100mg three times a day for a maximum of 12 weeks. Taper Clofazimine to 100mg twice a day.

7.4 Immuno-prophylaxis

Bacille Calmette-Guérin (BCG) vaccine at birth is given to all new-born babies to protect against Tuberculosis. Trials and studies have demonstrated BCG vaccine provides some protection against *M. leprae*, and this protection is greatest if given before 15 years of age.

7.5 Relapses in Leprosy

Relapse is defined as the re-occurrence of the disease at any time after the completion of a full course of treatment with MDT. Relapse is diagnosed by the appearance of definite new skin lesions and/ or an increase in the bacterial index (BI) of two or more units at any single site compared to BI taken from the same site at the previous examination. Care should be taken to exclude patients suffering from leprosy reactions.

- Suspected relapses should be referred for further investigation at a referral center.

7.6 Treatment of Special Cases

7.6.1 Leprosy in Pregnant and Lactating Women

MDT is safe during pregnancy and lactation. Patients should be counselled well about safety and possible complications before starting treatment.

Prophylactic perinatal Vitamin K is recommended for babies born to mothers taking Rifampicin during pregnancy.

Mothers should be informed of the possibility of skin discoloration in the baby.

7.6.2 Co-existent Leprosy with Active Tuberculosis (TB)

Screening for leprosy should be considered in all cases of active TB infection.

Patients diagnosed with both leprosy and TB should be treated with full course of TB and leprosy treatment. Currently only rifampicin is common to both regimens and should be given in the dose required to treat TB.

7.6.3 Alternate MDT Regimens

Substitutive/ alternative treatment regimens should be used only in cases with severe intolerance or contra-indication to one or more drugs of the standard MDT regimens or in the evidence of resistance.

Table 7.2

1. Rifampicin resistant	Ofloxacin 400mg + Minocycline 100mg OR Clarithromycin 500mg for 6 months and Ofloxacin400mg OR Minocycline 100mg for another 18 months This should be given along with other 2 drugs
2. Dapsone toxicity	Stop Dapsone Continue other 2 drugs
3. Clofazimine intolerance due to pigmentation	Substitute Clofazimine with Ofloxacin 400mg OR Minocycline 100 mg daily
4. MB cases treated with Dapsone monotherapy	All MB cases who were on Dapsone monotherapy previously and showing a negative SSS should be treated with an additional course of MDT -MB to prevent relapse
5. HIV patients with leprosy	Rifampicin is contraindicated with protease inhibitors Dose of Rifabutine should be reduced to half if Indinavir or Nelfinavir is to be given
6. Tuberculosis patients with leprosy	Standard anti tuberculous treatment should be given. Rifampicin is given in the dose of ATT. Other 2 drugs of MDT are continued as per regimen
7. Multidrug resistance in Leprosy	All relapsing leprosy patients must be treated with a minimum of 2 new antileprosy drugs in addition to Rifampicin

8. Rehabilitation

"Rehabilitation includes all measures aimed at reducing the impact of disability for an individual, enabling him/her to achieve independence, social integration, a better quality of life and self-actualisation." (United Nations). The strategies for rehabilitation involves multi-sectoral/ multidisciplinary approach, involving medical, social welfare and education sectors and good referral services by rehabilitation departments, reconstruction surgery units, and community-based rehabilitation (CBR) programs.

8.1 Rehabilitation Provision

Rehabilitation usually includes the following types of services.

- Early detection, diagnosis and intervention
- Medical care and treatment.
- Social, psychological and other types of concealing and assistance.
- Training in self-care activities, including mobility, communication and daily living skills.
- Provision of technical and mobility aids and other devices.
- Specialized education services
- Vocational rehabilitation services, vocational training, placement in open or sheltered employment.
- Follow up

8.2 Rehabilitation Interventions

Table 8.1

Issue	Rehabilitation interventions
Anatomical Deformity of the hand	Provision of protective footwear Provision of aids and appliances
Foot drop Amputation	Reconstructive surgery (RCS) and physiotherapy Ankle - foot orthosis
Psychological Depression	 Counselling
Functional Limitation to fine hand movements Mobility limitations	Occupational therapy Crutches or wheel chairs (Tricycles) Change in the life style
Social participation Stigma in the family Exclusion from community functions Children with disability	Counselling Education and advocacy Promoting inclusive education

8.3 Community Based Rehabilitation (CBR)

CBR is a strategy within general community development for the rehabilitation, equalization of opportunities and social inclusion of all people with disabilities (definition recognised by ILO, UNESCO and WHO)

The strategy of CBR intends to enhance the quality of life for people with disability through community initiatives. Local resources can be used to promote the rehabilitation of people with disabilities in their own communities. Involving family and community members and people affected by leprosy is a key strategy to empower people with disabilities. This will facilitate community action to ensure that they have same rights and opportunities similar to that of other community members in accessing health care, education, skill training, employment, social mobility and political empowerment.

9. Referral System

9.1 Management of New Cases and Referrals

At the island level & atoll level

- From the island health center and atoll hospital all suspected cases of leprosy should be referred to a dermatologist at the nearest Regional Hospital (RH) or central level hospital for diagnosis.
- All suspected cases should be reported to Health Protection Agency (HPA)
- Follow up of the cases for regular MDT treatment
- Ensure home based self-care for leprosy patients with disability

At the Regional Hospital level

- Dermatologist at RH should confirm diagnosis, classify into MB or PB, report to HPA and refer to central level hospital.
- If any case is difficult to diagnose clinically, for additional confirmation of the diagnosis, do a SSS and if necessary and if facilities are available, biopsy should be done or take biopsy and send for HPE to central level.
- All other necessary blood investigations including CBC, G6PD, LFT, renal function tests should be done if possible

At the Central level hospital

- Reconfirm all referred cases and register at the healthcare facility.
- If needed necessary investigations should be completed
- Provide the appropriate MDT pack for all confirmed cases. If possible, the initial dose should be administered as a supervised dose at the hospital.
- All the patients should be counseled regarding the disease, treatment and possible complications.

- All the patients should be assessed for any disability and given advice for self-care if any disability is present.
- After providing the first blister pack at central level, patient can be given the choice of collecting the MDT for the remaining period from the Health Center (HC)/ Atoll Hospital (AH)/RH
- Confirmation of relapses
- Investigation of patients with adverse drug reactions
- Patient Card with name and address, diagnosis, classification should be sent to the health facility of patient's island.
- Follow up should be done with a health care staff once a month and with a dermatologist at least once in every three months.
- Provision of reconstructive surgery
- Test for Anti-microbial resistance (AMR) in relapse cases

At the HC/ AH/ RH level

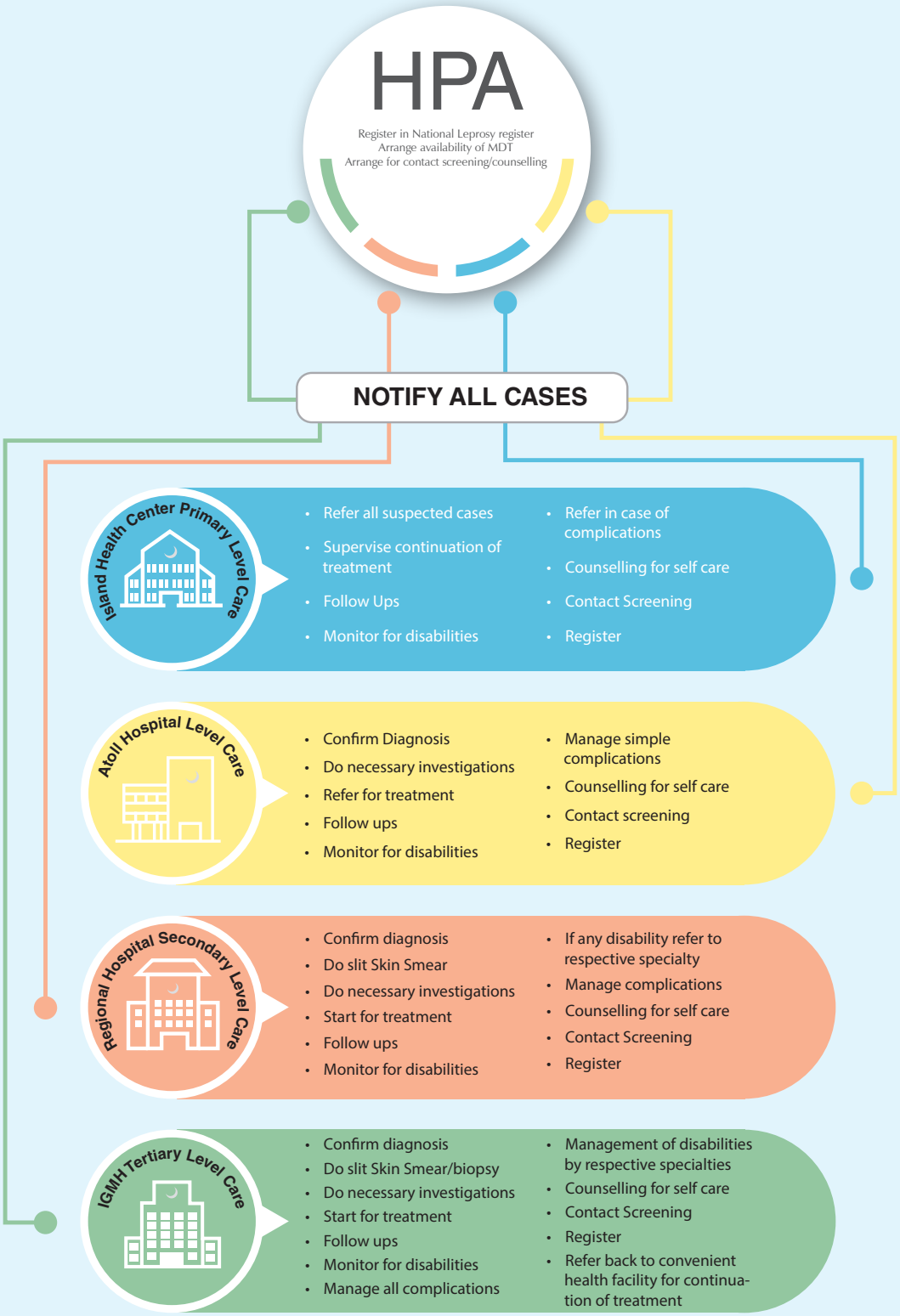
- Patient should be registered as a new case in the Leprosy register
- Patient card should be updated monthly.
- Healthcare facility must make arrangements to provide remaining MDT blister packs to the patient
- Patient should be monitored & counseled on every visit for treatment completion, complications and self-care.

At Central level

- Every patient on treatment should be consulted and examined by a dermatologist before releasing from treatment
- Patient should be provided with a written document mentioning the completion and release from treatment.

9.2 Surveillance and Public Health Response

- Any information on Suspected or positive Leprosy/case should be immediately notified with the communicable diseases form within 24 hours to the Health Protection Agency. The Communicable Disease Reporting Form is annexed (see annex 1)
- Referred cases should be investigated for diagnosis at respective levels
- All confirmed cases should be given treatment, registered in leprosy register at all levels and notified to HPA
- All suspected cases also should be informed to Surveillance division and atoll leprosy focal points and should be followed up until patients' conditions are confirmed.
- Contact screening for all the new cases should be carried out within 6 weeks and should be examined annually for 5 years for PB and 10 years for MB cases
- All the family members and close contacts of the patients should be informed about the signs of leprosy and to consult doctor if any signs or symptoms present
- Upon treatment completion, patients' release from treatment should be recorded in the patient card and registers at all levels.
- Contacts who are administered Single Dose Rifampicin (SDR) chemoprophylaxis should be examined once a year for five years.


HPA
Register in National Leprosy register
Arrange availability of MDT
Arrange for contact screening/counselling
NOTIFY ALL CASES
Island Health Center Primary Level Care
Refer all suspected cases
Supervise continuation of treatment
Follow Ups
Monitor for disabilities
Refer in case of complications
Counselling for self care
Contact Screening
Register
Atoll Hospital Level Care
Confirm Diagnosis
Do necessary investigations
Refer for treatment
Follow ups
Monitor for disabilities
Manage simple complications
Counselling for self care
Contact screening
Register
Regional Hospital Secondary Level Care
Confirm diagnosis
Do slit Skin Smear
Do necessary investigations
Start for treatment
Follow ups
Monitor for disabilities
If any disability refer to respective specialty
Manage complications
Counselling for self care
Contact Screening
Register
IGMH Tertiary Level Care
Confirm diagnosis
Do slit Skin Smear/biopsy
Do necessary investigations
Start for treatment
Follow ups
Monitor for disabilities
Manage all complications
Management of disabilities by respective specialties
Counselling for self care
Contact Screening
Register
Refer back to convenient health facility for continuation of treatment

10. Record Keeping

- Upon patient diagnosis, the patient card (see annex 13) should be completed and a copy must be provided to the patient. This copy must be brought to all subsequent follow-up appointments.
- Patient should be registered in leprosy registers at all levels and National leprosy register
- All the documents of screening including screen forms (see annexed) should be maintained at HPA
- Annual leprosy census should be taken and informed to focal points at all levels

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Total population survey to detect new leprosy cases – Rapid enquiry Survey

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11. Standard Operating Procedures for Total Population Survey to Detect New Leprosy Cases - Rapid Enquiry Survey

11.1 Background

Leprosy is a chronic disease caused by *Mycobacterium* leprae. Untreated leprosy affected Persons is the only known source of *M. leprae* in the Republic of Maldives. Leprosy can occur at any age and are reported across all genders. Skin is affected in most leprosy patients with hypo-pigmented or reddish colour skin patch with definite sensory impairment. Maldives continues to report new cases of leprosy. Hence it is vital to screen the population to detect leprosy early before they develop any deformities.

The total population survey in an island of Maldives will be carried out in the form of a rapid enquiry survey. The rapid enquiry survey will cover maximum population and also to increase community awareness towards leprosy.

11.2 Objective

The objective of rapid enquiry survey is to detect any hidden existing cases in a short period. This Rapid Enquiry Survey is to supplement the case detection work already carried out by the staff.

11.3 Purpose and Applicability

The purpose is to detect maximum number of new cases, register and treat with Multi Drug Treatment (MDT) to move towards zero leprosy status in an island. This will also ensure zero leprosy status leprosy elimination in the agenda of the health programmes.

11.4 Scope

This standard operating procedure applies to the workers who conduct the Rapid Enquiry Survey.

11.5 Definitions

- **Suspect of case of leprosy:** person with one or more of the following symptoms can be suspected having leprosy and should be referred to medical officer for confirmation of diagnosis
    - Hypo-pigmented skin or reddish patches 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
- Presence of visible deformities
- Nodules on skin
- Shiny skin thick and red in nature (infiltration) especially on the face

- **New case of leprosy:** a person diagnosed with leprosy who has never been treated for the disease;
- **Grade 2 disability:** Visible deformity of hands/ feet/ eyes due to leprosy

11.6 Prerequisites

- Availability of diagnostic picture-cards and pamphlets
- Capacity building of health staff in carrying out rapid enquiry survey
- Pocket sized atlas of leprosy
- Rapid enquiry survey register
- Reporting format
- A census house list (with age, gender) for the island (to be obtained from government census authorities)
- A spot map of each island should be prepared with easily distinguishable land marks for the identification.
- Establish a registry of non-local persons on each island

11.7 Procedural Steps (Method)

The exact procedure to be followed for rapid enquiry survey is indicated below:

- The national leprosy focal point of the island/ atoll/ city shall organize the rapid enquiry survey in consultation with respective public health unit by utilizing community health officer/ worker and or medical officer.
- A systematic house-to-house visit should be carried out covering entire island. Each household should be assigned a number.

- A visit to all the families in the area with the diagnostic picture-cards (Pocket sized atlas of leprosy), and pamphlets with a view to detecting new leprosy cases in the community. This can be done by community health officer/ worker of public health unit in the island
- A new rapid enquiry survey register will be introduced and the details of suspected persons will be recorded. This classifies the number of family members as adult male (AM), adult female (AF), child-male (CM), child female (CF). It is recommended to be completed by notations as AM-2, AF-2, CM-1, and CF-1. Should there be any individual showing suspected signs, their name, age, and sex should be recorded. Their suspected signs should be examined before details are recorded. The persons examined should be marked in appropriate columns of the rapid enquiry survey register (see annexe 1A)
- The total houses will be covered through a quick method of enquiry and selective examinations of survey. Examinations are done only on those persons with apparent signs or those who report suspicious signs or symptoms of leprosy. It is to be ensured that a female health worker examine women, or in the presence of another woman.
- At first, respondents of this survey should be informed on why it is being conducted; to eliminate leprosy from the Maldives and declare Zero Leprosy status. This should be followed by informing diagnosed and or suspected cases about the early signs and symptoms. Respondents should also be educated on facts about the disease to alter traditional beliefs to remove their fear and to develop a rational attitude towards leprosy. Use the diagnostic picture-cards, and pamphlets while explaining about disease.
- This rapid enquiry survey can be conducted upon reporting of suspected and/ or diagnosed cases. This survey should cover indigenous population and migrant population residing in the island.
- All suspected cases will be referred to the relevant referral centre on depending on severity of the case determined by the Medical Officer

11.8 Data and Records Management:

Rapid survey register is to be filled and maintained by the person who carries out the survey. A consolidated report should be prepared as per the reporting format (see Annex 1B) by the public health unit of the island and forwarded to Atoll level and HPA.

11.9 Responsibilities and Authorities:

HPA is the overall responsible body in preparing the calendar for rapid survey in the islands and ensure its implementation.

11.10 Monitoring:

Respective public health unit at regional hospital/ Atoll hospital will monitor the implementation of rapid survey and report to HPA.

Monitoring indicators:

1. Coverage: $\frac{\text{No. houses visited by health worker}}{\text{Total no. houses in the island}}$

2. No. persons with suspect leprosy symptoms/ signs:

3. Referrals:

$$\frac{\text{No. persons with suspects attended referral centre for confirmation of diagnosis} \times 100}{\text{Total no. persons with suspect leprosy symptoms/signs from the survey}}$$

4. No. persons diagnosed as suffering from leprosy (MB/ PB/ Age/ Gender-wise and indicate if they are local /non-citizen)

11.11 Quality Assurance and Quality Control:

Staff at HPA or dermatologists at IGMH should visit randomly selected islands where rapid survey was conducted to check the quality and coverage.

(Further reading: refer to e-module on "Suspect and referral" (module 1) developed by WHO. *http://labs.enablingdimensions.com/Leprosy/)*

Annex 1

Rapid Enquiry Surveys Register

(SOP for Total Population Survey to Detect New Leprosy Cases)

Annex 2

Rapid Enquiry Surveys Report

(SOP for Total Population Survey to Detect New Leprosy Cases)

12. Standard Operating Procedures for Contact Screening to Detect new Leprosy Cases

12.1 Background

An individual can contract leprosy irrespective of sex or age. Studies have shown that family contacts of the leprosy patients are at higher risk of developing leprosy when compared to general population. Of the various methods of active case detection, contact screening (contact examination/ contact surveillance) carries epidemiological significance.

12.2 Objective

To screen (examine) 95% of the household contacts of the index case annually to detect a case of leprosy among the contacts.

12.3 Purpose and Applicability

The main purpose of contact screening is to find the source of infection and transmission of disease to the contacts. The contact screening is generally accepted by the family as a family member has been diagnosed with leprosy.

12.4 Scope

It is probably more useful in areas of low endemicity, where there is greater clustering of leprosy cases. The contact examination is now a prerequisite to initiate chemoprophylaxis. This standard operating procedures apply to persons who conduct contact screening.

12.5 Definitions

Index case: Any confirmed case diagnosed with leprosy for the first time

Household Contacts: persons who have access to/ or share common spaces with the index case in a household for a duration not shorter than three months. This includes and is not limited to kitchens, dining rooms, living rooms, and toilets.

Contact screening: Examination of a contact having been in physical proximity to the index case to determine if they have signs or symptoms of leprosy.

12.6 Prerequisites

- Availability of diagnostic picture-cards.
- Capacity building of health staff in carrying out screening
- Contact screening register
- Reporting format

12.7 Procedural Steps (Method)

The exact procedure to be followed for contact screening is indicated below:

When the diagnosis of leprosy is confirmed at IGMH or regional hospitals, individual patient card with register number and other details should be completed. The contacts of the leprosy patient (index cases) should be enumerated in the individual patient card as per the Contacts of Index Cases (see annex 3).

Annex 3

Contacts of Index Cases

(SOP for Contact Screening to Detect new Leprosy Cases)

The referral centre where the diagnosis is made should forward the patients details and contact enumerated details to HPA, who in turn send to respective public health unit of island to carry out the contact screening.

MDT to be administered to index cases diagnosed with MB. Enumerated household contacts of said index case(s) must be examined within two months of index case registration.

Therefore, all the household contacts of all known leprosy patients should be examined once in a year for a period of 10 years (i.e. double the average incubation period of leprosy)

Contacts should also be educated to report any signs or symptoms that appear.

Contact examination can be carried out at their house or request the contacts to visit the nearest health centre.

Consent should be obtained from each individual before examination. In case of minor or those unable to consent, the guardian's consent should be obtained. Women and girls should be examined by a female health worker.

12.8 Data and Records Management

Contact screening register is to be filled and maintained by the authorised person who administers the survey. A consolidated report should be prepared as per suggested reporting format (see Annex 2B) by the said authorised person at the health facility. This report should be forwarded to public health unit at Atoll level and HPA.

12.9 Responsibilities and authorities

HPA is the overall responsible body in ensuring its implementation and preparation of a consolidated national report on contact screening.

12.10 Monitoring

Respective Public health unit at regional hospital / Atoll hospital will monitor the implementation of contact screening and report to HPA at Male'.

Monitoring indicators:

1. Coverage of contacts of new cases:

$$\frac{\text{No. household contacts examined by health worker}}{\text{Total no. household contacts of index cases (new cases) in the island}}$$

2. No. persons diagnosed as suffering from leprosy (MB/ PB/ Age/ Gender-wise) among the above.

3. Annual contact examination (secondary attack rate):

$$\frac{\text{No. household contacts examined during the reporting by health worker}}{\text{Total no. household contacts of in the contact register to be examined in the island}}$$

4. No. persons diagnosed as suffering from leprosy (MB/ PB/ Age/ Gender-wise) among the above.

12.11 Quality Assurance and Quality Control

Staff at HPA or staff of public health unit at regional/ Atoll hospital should visit randomly selected islands where contact screening was conducted to check the quality and coverage.

Annex 4

Contacts Suvey Register

(SOP for Contact Screening to Detect new Leprosy Cases)

Annex 5

Contact Survey Report

(SOP for Contact Screening to Detect new Leprosy Cases)

13. Standard Operating Procedures for School Screening to Detect New Leprosy Cases

13.1 Background

School students are well organised groups having proper records, addresses and can be followed up easily. A school survey is an effective intervention in itself and when done consistently in an area, will support to early diagnosis of leprosy and contribute considerably to reducing the transmission of *M. leprae* in the community. Occurrence of a child leprosy indicates that leprosy transmission is still going on in the community. One of the national targets/ milestones for leprosy is to attain 'Zero child cases' while moving towards attaining leprosy elimination in a country.

13.2 Objective:

The objective of school survey is to detect leprosy cases early among child population.

13.3 Purpose and Applicability:

The purpose is to detect leprosy early among the school going children to move towards zero child leprosy status in an island. If a child leprosy case is detected, it is an opportunity to examine other family members of children diagnosed as suffering from leprosy to find out the possible source of infection. It is also an opportunity to screen school teachers and other staff working in the school for detection of leprosy and other skin diseases.

13.4 Scope:

The screening of school children is easy due to existing data on them. The school students screening is recommended to be conducted as integrated skin disease screening. This standard operating procedures apply to persons who conduct school screening including school and healthcare facility staff.

13.5 Definitions

- **School:** An institution for educating children. A school is an educational institution designed to provide learning spaces and learning environments for the teaching of students (or "pupils") under the direction of teachers.
- **School students screening:** Examination of school students to determine if they have signs or symptoms of leprosy and other skin diseases.
- **School teacher;** a person who teaches in a school.

13.6 Prerequisites:

- Permission from school authorities, Ministry of Education and legal guardians of school children in advance
- Planning the visit of dermatologist from IGMH or Regional Hospitals to carry out integrated skin disease screening
- Availability of diagnostic picture-cards.
- School screening register
- Reporting format

13.7 Procedural Steps (Method):

The exact procedure to be followed for school screening is indicated below:

After getting permission from Ministry of Education, parents/ guardians and informing school authorities in advance, the dermatologist from IGMH or Regional Hospital in collaboration with Health Centre of the Island and Public health unit will to carry out integrated skin disease screening class by class.

Before actual screening of the student, health education session should be conducted regarding hygiene and sanitation and on common skin diseases.

In addition to students, school teachers and other staff working in the school should also be examined.

Women and girls should be examined by the female health worker.

The health worker / dermatologist should ensure that confidentiality of diagnosis of leprosy and other skin disease is maintained.

It is also necessary to examine the other family members and classmates of children diagnosed as suffering from leprosy.

Every school would be surveyed once in a year.

13.8 Data and Records Management:

School screening register is to be filled and maintained by the public health unit of the island

A consolidated report could be prepared as per the reporting format (see Annex 3A) by the public health unit of the island and forward to public health unit at Atoll level and HPA.

13.9 Monitoring:

Respective Public health unit at regional hospital/ Atoll hospital will monitor the implementation of school screening and report to HPA:

5. Coverage of schools:

$$\frac{\text{No. schools screened}}{\text{Total no. schools in the island}}$$

6. No. students screened (gender-wise)
7. No. leprosy cases detected among students: (Age, gender, MB/ PB)
8. No students with other skin disease
9. No. teachers and other staff screened: (Gender wise)
10. No. leprosy cases detected among teachers and other staff (Age, gender, MB/ PB)
11. No teachers and other staff with other skin disease

13.10 Quality Assurance and Quality Control:

Staff at HPA or staff of public health unit at regional/ Atoll hospital should visit randomly selected islands where school screening was conducted to check the quality and coverage.

(Further reading: refer to e-module on "Suspect and referral" (module 1) developed by WHO. *http://labs.enablingdimensions.com/Leprosy/)*

Annex 6

School Screening Register

(SOP School Screening to Detect New Leprosy Cases)

Annex 7

Details of the Students, Teachers and other Staff Detected

(SOP School Screening to Detect New Leprosy Cases)

14. Standard Operating Procedures for Diagnosis of Leprosy and MDT Treatment Including Retrieval of Lost for Follow-Up and Monitoring Adverse Drug Reactions

14.1 Background

In order to diagnose leprosy, a physical examination to establish the presence of one of the three cardinal signs is required. This can be followed by a slit skin smear test.

14.2 Objective:

The objective is to diagnose an individual with leprosy, classify and initiate appropriate treatment.

14.3 Purpose and Applicability:

Timely diagnosis of a new leprosy case may prevent development of disability and initiation of MDT treatment will interrupt the transmission chain. As there is no effective tool to prevent leprosy, the early diagnosis and regular schedule course of MDT is the most important strategy in the leprosy control/ leprosy elimination.

14.4 Scope:

It is mandatory that a set procedure is followed in respect of screening a person for the presence of leprosy, in order to ensure case is not missed out, nor wrongly diagnosed as leprosy. This standard operating procedures apply to healthcare professionals who are responsible for suspecting and diagnosing leprosy, as well as initiating MDT.

14.5 Definitions:

New case of leprosy: a person diagnosed with leprosy who has never been treated for the disease

Hypo- pigmented skin patch: Circumscribed area of altered coloration in skin, flat or elevated. In leprosy patients, the patch is pale in colour (hypo) which appears coppery on pigmented skin or red in colour.

Lost to follow-up: patients who have interrupted treatment for a total of 3 or more months (if PB) or a total of 6 or more months (if MB). This was previously defined as "default" but it has been changed to "lost to follow-up" to use a non-derogatory language towards persons affected by leprosy.

14.6 Prerequisites:

- Dermatologists who have capacity to diagnose leprosy and manage the case
- Individual leprosy patient record
- Availability of MDT blister packs
- Laboratory facilities for Slit Skin Smear (SSS) examination
- Assess Nerve Function
- Effective follow up mechanism – for lost to follow-up patient
- Effective Management Information System (MIS) to register the new case and inform HPA for further action.

14.7 Procedural Steps (Method):

The exact procedure can be divided into five sections:

a. History taking

b. Examination

c. Diagnosis

d. Classification

e. Counselling

14.7.1Patient history recording:

The following checklist will help the dermatologist to get a reasonably accurate history of the patient

- Present complaint and duration: patches, anaesthesia, nerve enlargement, deformity of hands, feet & eyes, nodules over the body, smooth & shiny skin, ulcers of hand & feet
- Symptoms of recent activity and its duration: fever, erythematous nodules, reddish swelling of existing skin patches, joint pains, pain & tenderness of peripheral nerves
- Family history: Contacts within family/ relatives with leprosy
- Previous treatment: details and progress

14.7.2Examination:

- Make a detailed note of the skin patches:
  - Colour: Hypo-pigmented or erythematous
  - Surface: macule, papule, nodule, plaque or smooth shiny skin.
  - Border: vague or well defined
  - Distribution on body: Number of patches; symmetry
- Infiltration of skin (especially ear lobes)
- Testing sensation on the patch
  - Test with the help of a wisp cotton or nylon fibre to elicit the sensation. If the patient does not feel light touch (cotton wool) on the patch, there is loss on sensation on the patch.
- Palpation of peripheral nerves
  - Palpate ulnar, median, radial lateral popliteal and posterior tibial nerves on both sides to note the enlargement (thickness) and tenderness. Any muscle weakness, paralysis of muscles supplied by these nerves. Any deformity of hands, feet, eyes (related deformities caused by leprosy)
- Laboratory Investigations:

  Conduct Slit Skin Smear (SSS) and record the bacteriological index.

  Perform biopsies in difficult to diagnose cases

14.7.3Diagnosis of leprosy:

At least one of the following cardinal signs must be present to diagnose leprosy:

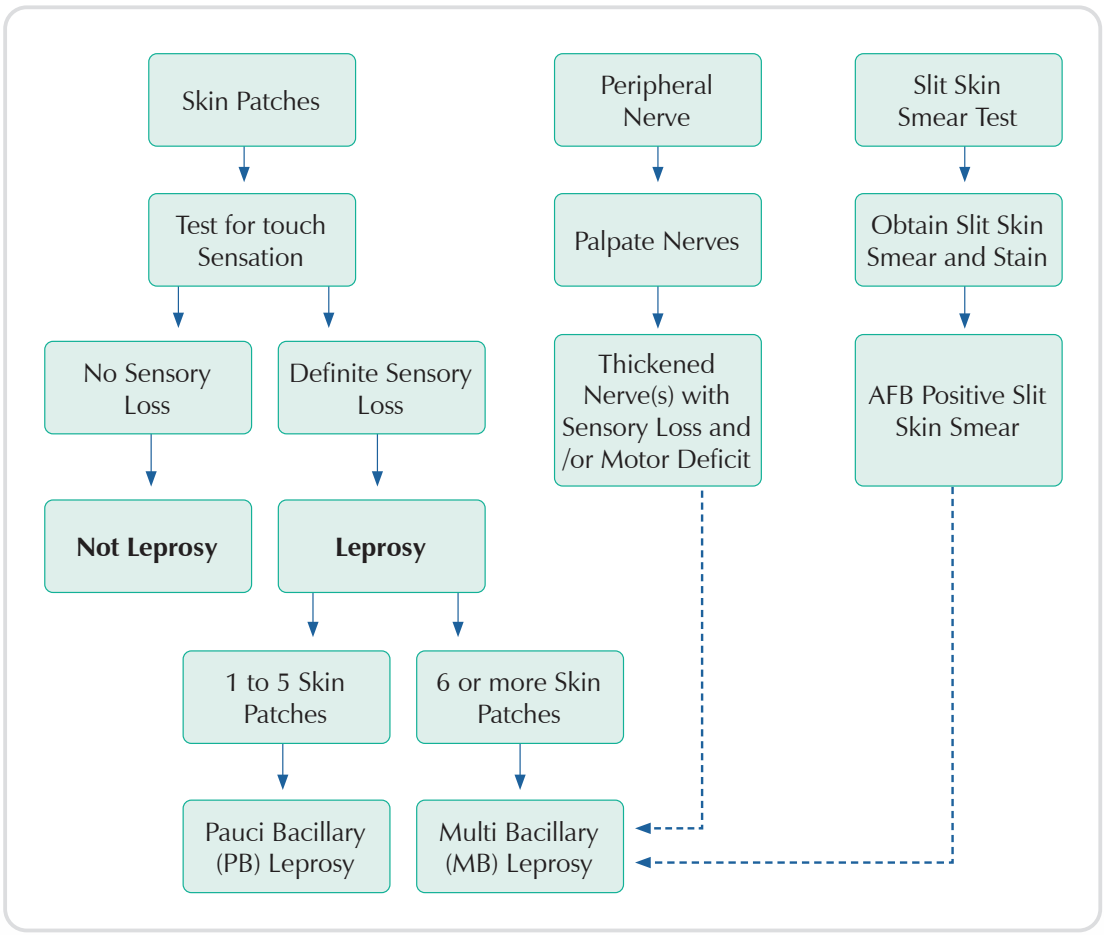
1. Hypo-pigmented or reddish skin lesion(s) with definite sensory deficit
2. Involvement of the peripheral nerves as demonstrated by definite thickening with loss of sensation and/ or weakness of muscles of the corresponding nerve
3. Demonstration of *mycobacterium* leprae in the lesions

14.7.4 Classification:

Paucibacillary Leprosy (PB): cases of leprosy with one to five skin lesions and without demonstrated presence of bacilli in a skin smear test

Multibacillary Leprosy (MB): cases of leprosy with six or more skin lesions, or with nerve involvement, or with demonstrated presence of bacilli in a slit skin smear test irrespective of the number of skin lesions

Figure 14.1



14.7.5 Treatment

Assess the fitness of a patient for MDT:

Before starting treatment, one must look for the following:

- Jaundice: If the patient is jaundiced, you will have to wait until jaundice subsides.
- Anaemia: If the patient is anaemic, treat the anaemia simultaneously
- Tuberculosis: If the patient is taking Rifampicin, ensure that they continue to take Rifampicin in the dose required for the treatment of tuberculosis along with other drug regimen required for the treatment of leprosy.
- Allergy to sulpha drugs: If the patient is known to be allergic to sulpha drugs, Dapsone should be avoided. Clofazimine may be used instead.
- Carry out G6PD, LFT, and Hb laboratory investigations

Treatment Regimen

Adult dose: MDT adult blister pack

- Monthly Supervised Treatment (DAY 1)
  - Rifampicin 600mg (two capsules of 300mg)
  - Clofazimine 300mg (three capsules of 100mg), and
  - Dapsone 100mg (one tablet of 100mg)
- Unsupervised Daily Treatment (DAYS 2–28)
  - Clofazimine 50mg (one capsule of 50mg) every day and
  - Dapsone 100mg (one tablet of 100mg) every day
- Duration of Treatment:
  - For MB - 12 monthly blister packs to be taken within 18 months
  - For PB - 6 monthly blister packs to be taken within 9 months.

Child dose: MDT child blister pack

- Monthly Supervised Treatment (DAY 1)
  - Rifampicin 450mg (two capsules, one of 300mg, the other of 150mg
  - Clofazimine 150mg (three capsules, each of 50mg),) and
  - Dapsone 50mg (one tablet of 50mg)

- Unsupervised Daily Treatment (DAYS 2–28):
    - Clofazimine 50mg (one capsule of 50mg) every other day
    - Dapsone 50mg (one tablet of 50mg) every day
- Duration of Treatment:
    - For MB - 12 monthly blister packs to be taken within 18 months
    - For PB - 6 monthly blister packs to be taken within 9 months

Children under 10 years of age should receive appropriately reduced doses of drugs as per the following guideline:

- Rifampicin: 10 mg/kg body weight once a month
- Dapsone: 2 mg/kg body weight per day
- Clofazimine: 1 mg/kg body weight to be given on alternate days,

14.7.6 Counselling

Upon confirmed diagnosis and initiation of MDT, patients should be informed that:

- MDT treatment is free of cost
- Leprosy is curable
- Regular treatment prevents deformities
- Patient can lead a normal life
- All the household contacts will be examined

14.8 Monitoring:

Once the diagnosis is made and MDT is initiated at referral centre, the health officer/ worker should ensure timely follow-ups and regular drug intake as per the prescribed does. The health worker/ officer should monitor patient for drug side effects and any further complications not limited to reactions and/ or neuritis.

14.9 Indicators:

- MDT treatment completion rates: new patients who have been treated for leprosy with a full course of MDT (6 pulses within 9 months for PB cases or 12 pulses within 18 months for MB cases);
- Defaulter rate: Number of leprosy patients on MDT irregular for treatment and lost for follow up

14.10 Data and Records Management:

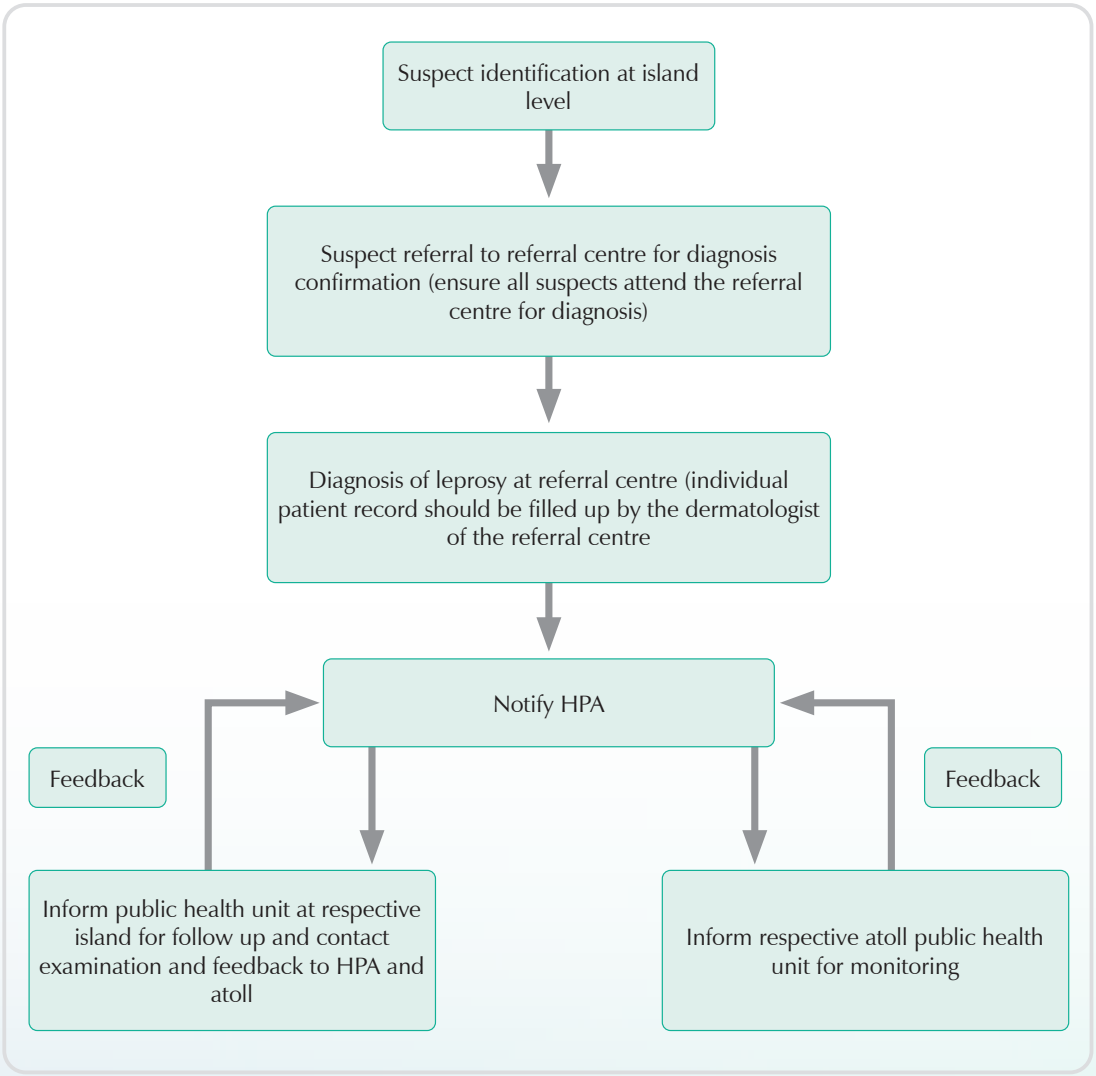
As soon as the diagnosis of leprosy is made, individual patient record should be filled up by the dermatologist of the referral centre where the diagnosis is made, including the details of household contacts and clinical and skin smear report

The patient's details should be forwarded to HPA, who in turn inform the Public health unit of respective island and atoll.

14.11 Responsibilities and Authorities:

HPA is the overall responsible body in ensuring the suspect referrals from islands, diagnosing leprosy at referral centre (IGMH) and follow up at the island level. A surveillance mechanism should be developed from suspect identification to diagnosis to follow up as follows:

Figure 14.2



14.11.1Monitoring Adverse Drug Reactions:

MDT is remarkably safe and serious adverse effects are very rare. However, few patients may develop mild or severe side effects to the MDT drugs and monitoring adverse Drug reactions is essential part of the leprosy programme to ensure prompt management.

Side effects to MDT drugs:

Table 14.1

Minor Side Effects	Drug	Management
Red urine	Rifampicin	Reassurance
Brown discoloration of the skin	Clofazimine	Counselling
Anaemia	Dapsone	Administer iron and folic acid
Gastro-intestinal upset	All three drugs	Administer drugs with food

Table 14.2

Major Side Effects	Drug	Management
Itchy skin rash	Dapsone	Stop dapsone, refer
Allergy, urticarial rash	Dapsone or Rifampicin	Stop both, refer
Jaundice	Rifampicin	Stop rifampicin, refer
Shock, purpura, renal failure	Rifampicin	Stop rifampicin, refer

15. Standard Operating Procedures for Slit Skin Smear (SSS) Examination

15.1 Background

Carrying out Slit Skin Smear examination is essential to diagnose leprosy in suspect cases in the absence of other two cardinal signs of leprosy. Slit skin smear tests are crucial in identifying the type of leprosy. Slit Skin Smear examination should be a mandatory test at the referral centre where the diagnosis of leprosy is made.

15.2 Objective:

The objective is to confirm the diagnosis of leprosy through slit skin smear examination and identify the type of leprosy.

15.3 Purpose and Applicability:

Timely diagnosis of a new leprosy case may prevent development of disability and initiation of MDT will interrupt the transmission chain. As there is no other effective tool to prevent leprosy, early diagnosis and regular course of MDT is the most important strategy in leprosy control and elimination. Therefore, it is important to:

a. Diagnose (decide what the disease is)

b. Classify (separate into groups MB/PB, on which treatment is based)

c. To know the prognosis of patient to the MDT treatment

d. Follow-up of patients after completion of MDT schedule course, in a case of suspected relapse

Early diagnosis via slit skin smear tests is important in the Maldives owing to a reasonable number of imported leprosy cases. In addition to using the three cardinal signs of leprosy for diagnosis, clinical approaches such as the slit skin smear test should be also considered for diagnosis.

15.4 Scope:

All the health facilities in Maldives (tertiary hospitals, Regional hospitals, Atoll hospitals, and Private Hospitals/ Clinics) have good laboratories. The SSS can be done in these health facilities with training of laboratory technicians. This standard operating procedures apply to laboratory staff conducting the slit skin smear examination.

15.5 Definitions:

- **Slit skin smear (SSS):** A skin smear is a test in which a sample of material is collected from a tiny cut in the skin and then stained for *M. leprae*, an acid-fast bacillus.
- **Bacteriological index (BI)** indicates the density of lepra bacilli in smear and includes both living (solid-staining) and dead (fragmented or granular forms) bacilli.
- **Morphological Index (MI)** is the percentage of presumably living bacilli in relation to the total number of bacilli in the smear.

15.6 Prerequisites:

- Dermatologists who have capacity to diagnose leprosy and manage
- Capacity of laboratory technician in taking, staining, reading and reporting SSS
- Laboratory facilities for Slit Skin Smear (SSS) examination including microscope, medical supplies/reagents as elaborated in section 15.7

15.7 Procedural Steps (Method):

Slit skin smears should be taken when:

a. At the time of diagnosing the leprosy

b. At the time of completion of scheduled course of MDT

c. At the time of suspecting relapse of leprosy

Skin smear is taken from minimum 4 sites:

a. Right or left ear lobe

b. Forehead (left side if smear is taken from right ear)

c. From two active patches, if there are many patches (selective sites)

d. If there are no patches:

- Left forearm dorsal side
- Left buttock in men / front of right thigh in women

Equipment required:

a. A binocular microscope

b. Glass slide

c. New scalpel blade No. 15

d. Diamond-tipped pencil

e. Spirit cotton

f. Benzoin cotton

g. A pair of disposable gloves

h. 1% Carbol fuchsin solution

i. 0.2% Methylene blue

j. 5% Sulphuric acid

Method:

1. Explain the procedure to the patient and obtain the consent
2. The laboratory technician should wear disposable gloves
3. Mark a new and clean slide with the patient identification number (National ID or passport number) and date near one end of the slide with a diamond-tipped pencil.
4. The selected skin site is cleaned thoroughly with spirit cotton and then the skin is pinched tightly between thumb and index finger to prevent blood flow.
5. A small cut about 4mm to 5mm long and 2mm to 3mm deep is made with scalpel blade.
6. The blade is then turned 90° degrees and the wound is scraped to get tissue and tissue fluid on the tip of the blade.
7. The material is spread evenly on the glass slide in a circular area of about 7-8mm in diameter. The cut is sealed with benzoin cotton.
8. The procedure is repeated to other 3 sites also.
9. The smear is air dried for 5-10 minutes and then fixed by warming the other side of the slide over a flame and then stained.

Staining procedure: (Ziehl-Neelsen's method of acid fast staining of M.leprae)

1. Place the slide with the fixed smear on a pair of glass rods over a sink
2. Flood the smear with carbol fuchsin for 5 minutes
3. Heat gently using a flame until steam raises. Do not allow the stain to boil
4. Wash gently with tap water
5. Flood the stain with decolourising agent (5% Sulphuric acid) for 10 minutes
6. Wash gently with tap water
7. Flood the stain with Methylene blue for 1 minute
8. Wash gently with tap water
9. Keep the slide on blotting paper in a stand to allow the water to drain off
10. Allow the slide to dry

Examination of Smear:

- *M. leprae* are pink rod shaped or slightly curved organisms.
- The stained slides are examined using the oil immersion objective (100x). The acid fast organisms are seen against a blue background lying singly, or as bundle of cigars or as globi.

Reporting the findings:

If no bacilli are found in all the 4 smears, the smear is called 'Negative' for M.leprae

Positive smears are graded (Bacteriological Index)

Bacteriological index (BI) indicates the density of lepra bacilli in smear and includes both living (solid-staining) and dead (fragmented or granular forms) bacilli. According to Ridley's logarithmic scale, it ranges from 1+ to 6+ and is based on the number of bacilli seen in an average microscopic field of the smear using an oil emersion objective.

Table 15.1

Bacteriological Index (BI)	
Negative	No bacilli in any of 100 average oil immersion fields
1+	1-10 bacilli in 100 average oil immersion fields
2+	1-10 bacilli in 10 average oil immersion fields
3+	1-10 bacilli in 1 average oil immersion fields
4+	10-100 bacilli in 1 average oil immersion fields
5+	100-1000 bacilli in 1 average oil immersion fields
6+	More than 1000 bacilli in 1 average oil immersion fields

Morphological Index (MI) is percentage of presumably living bacilli in relation to the total number of bacilli in the smear.

- MI is calculated after examining 200 pink-stained free-standing (i.e. not in clumps) bacilli. Out of 200 bacilli counted, note how many solid stained bacilli are present. (For example, if 20 solid stained bacilli are present out of 200 counted, the MI is 10%). This is first recorded for each smear.
- The percentages are then added up and divided by the number of smears to calculate the MI of the patient.
- Accurate recording of MI requires much skill and experience. This is a valuable indicator of patient's response to treatment with drugs, during the first few months and helps identify any drug resistance

Table 15.2

Preparation of reagents for staining:

1% Carbol fuchsin solution Basic fuschin – 10 gms 100% Ethyl alcohol – 100 ml Phenol crystals melted* – 50 gms Distilled water – 850 ml 1000 ml Do not heat phenol crystals directly. They should be taken in a conical glass flask and dipped in boiling water	Counter stain: (0.2% Methylene blue) Methylene blue – 2 gms Distilled water – 1000 ml
Decolourising agent: (5% Sulphuric acid) Concentrated Sulphuric acid - 50 ml Distilled water - 950 ml 1000 ml Note: add Sulphuric acid to the water slowly but do not add water to Sulphuric acid)	

Waste disposal:

- Used cotton swabs – yellow coloured plastic container with Yellow coloured bag
- Used stainless steel blade – in sharps disposal containers

15.8 Used gloves

Yellow coloured plastic container with Yellow coloured bag Stained glass slide – Stained glass slides should be kept in slide box for three months for any further reference and can be discarded after three months - yellow coloured plastic container with Yellow coloured bag Monitoring:

The dermatologist at IGMH and HPA will ensure SSS examination for all new cases diagnosed, suspect cases and suspected relapse

Monitoring indicators:

Coverage: $\frac{\text{No. cases for whom SSS taken among the new cases}}{\text{Total no. new cases registered in the reporting year}}$

15.9 Quality Assurance and Quality Control:

HPA staff or dermatologist/ microbiologist at IGMH would randomly select SSS slides and check the quality.

16. Standard Operating Procedures for Leprosy Referral System

16.1 Background

The present system in Maldives is that persons with suspected lesions of leprosy are referred from islands to the Department of Dermatology at Indira Gandhi Memorial Hospital (IGMH). There is no system (follow up) at the island to ensure that all the suspects referred have attended IGMH and the feedback to islands about the suspects attended at IGMH. If a case of leprosy is diagnosed at IGMH, the MDT is given at IGMH and the patients have to collect MDT at IGMH every month. There is no follow up of drug intake at island level.

It is important to strengthen the referral system to ensure all the suspected persons are screened at IGMH and follow up of the leprosy cases at island level for regular treatment with MDT.

16.2 Objectives:

1 Ensure that all the suspected persons are screened for diagnosis and that they complete treatment.

2 Persons affected leprosy with complications of any nature due to the disease should be identified early and managed promptly through a well-established functional referral system.

16.3 Purpose and Applicability:

Detect maximum number of new cases and register for multi drug treatment and complete scheduled course of MDT. It is beyond the capabilities of the health centres of islands to treat all the complications of leprosy. Therefore, a functional referral system should be established and strengthened that is on par with secondary and tertiary level facilities. Each level of referral facility should play a specific role.

16.4 Scope:

The health system in Maldives is well organized with island level health centres, atoll level hospitals, regional hospitals. IGMH is the main tertiary hospital in the country. The Health Protection Agency (HPA) and its public health units at Atoll and island level are competent to manage the data and MIS. The only requirement is to modify the MIS to collect the data on leprosy in order to ensure a functional referral system (i.e. referrals and feed-back). This standard operating procedures apply to persons at healthcare facilities who are responsible for conducting the referral process.

16.5 Definitions

- Suspected case of leprosy: person with following symptoms can be suspected having one or more of the following:
  - Hypo-pigmented skin or reddish patches 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
  - Presence of visible deformities
  - Skin nodules and infiltration
- New case of leprosy: a person diagnosed with leprosy who has never been treated for the disease
- Well established Referral system: ensure all the suspects are screened for diagnosis. Persons affected leprosy with complications of any nature due to the disease should be identified early and managed promptly. Ensure referrals and feedback (back referrals)

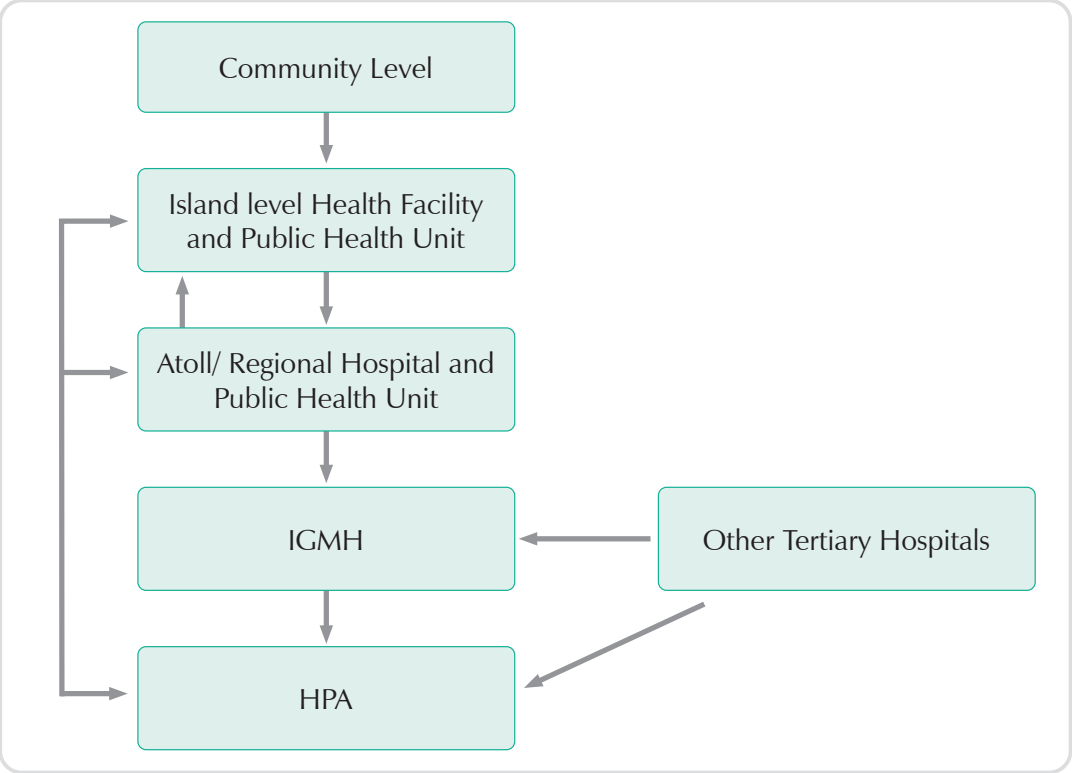
16.6 Prerequisites:

- Define role and responsibilities of each level of the referral system
- Inventory of facilities and distribution
- Dissemination of information about referral centres
- Preparation of Standard Operating Procedures (SOPs) including development of process, output and outcome indicators
- Capacity building (Training and Guidance)
- Develop management information system (MIS)
- Monitoring and Supervision
- Evaluation

16.7 Procedural Steps (Method):

Referral system is as follows:

Figure 16.1



Role of each level of referral system:

The following tables shows the activities to be implemented, referrals and inputs required to carry out the activities at each level of referral system:

16.7.1 Referral at community level:

Table 16.1

At Community Level	
Implementation of activities	• Suspect leprosy in a person • Monitor drug intake of patients on MDT • Suspect reaction/neuritis; drug reaction • Self-Care practice for persons with disability due to leprosy
Referral	• Refer to health centre at Island
Inputs required to carry out the activities	• Community awareness towards leprosy through health education to detect leprosy • Use persons affected by leprosy as champions by encouraging them • Education of family members of persons affected about importance of regular treatment; self-care practice

16.7.2 Referral level at Health Centre Island level and Public Health Unit:

Implementation of activities at Health centre	• Suspect leprosy in a person • Follow up of the patients on MDT for regularity of treatment • Self-care advice for those patients with disabilities due to leprosy • Suspect reaction/neuritis; drug reaction • Management of simple plantar • Single Dose Rifampicin (SDR) for contacts (Chemoprophylaxis)
Implementation of activities at Public health unit located in health centre	• Monitor drug intake of those patients on MDT • Maintenance of leprosy registry • Contact screening • School surveys • Population surveys • Assist in arranging skin camps • Ensure proper follow up of suspects referred • Disability care (self-care practices) • Data collection on new cases, patients on treatment, contact screening and other surveys/camps • Reporting on monthly/quarterly/annual basis and send to respective atoll
Referral	• Refer to respective Atoll hospital/ Regional hospital for confirmation of diagnosis; management of complications of leprosy • Forward leprosy data to Public health unit of Atoll

Inputs required to carry out the activities	• Build capacity of Medical officer of health centre to diagnose leprosy via: • Knowledge to suspect lepra reactions/ neuritis/ drug reactions • knowledge about Self-care practice • management of simple ulcers • Developing a software programme to enter the leprosy data • Build capacity of public health unit in MIS (leprosy)

16.7.3 Referral level at Atoll hospital/Regional Hospital level and Public Health Unit

Table 16.2

At Atoll hospital /Regional hospital level and Public health unit	
Implementation of activities at Atoll hospital/ Regional hospital	• Confirm diagnosis of leprosy (visit by dermatologist by IGMH) • Slit Skin Smears examination • Management of complications of leprosy (reactions / ulcers) • Follow up of contact screening and chemoprophylaxis at Island level
Implementation of activities at Public health unit located in health centre	• Maintenance of leprosy registry • Collection of information about each island and analyse
Referral	• Refer to IGMH for diagnosis of difficult to diagnose cases, confirmation of relapse, anti-microbial resistance studies • Forward leprosy data to HPA
Inputs required to carry out the activities	Build capacity of Medical officer/ Dermatologist at Atoll hospital/ Regional hospital to diagnose leprosy to: • Management of lepra reactions/neuritis/drug reactions; Management of simple and complicated ulcers; • Have knowledge about Self-care practice • Build capacity of laboratory technician to take, stain and read SSS. Provide required medical supplies • Build capacity of public health unit in MIS (leprosy)

Inputs required to carry out the activities	• Build capacity of Medical officer of health centre to diagnose leprosy via: • Knowledge to suspect lepra reactions/ neuritis/ drug reactions • knowledge about Self-care practice • management of simple ulcers • Developing a soft wear programme to enter the leprosy data • Build capacity of public health unit in MIS (leprosy)

16.7.4 Referral level at Indira Gandhi Memorial Hospital (IGMH)

Table 16.3

At IGMH	
Implementation of activities at IGMH	• Confirm diagnosis of leprosy • Slit Skin Smears examination • Biopsies and histopathology • Management of complications of leprosy (Reactions / Ulcers) • Anti-Microbial resistance (AMR) studies (PCR) • Research related to leprosy
Implementation of activities at IGMH	• Maintenance of leprosy registry • Collection of leprosy related information and forward to HPA
Referral	Leprosy data to HPA
Inputs required to carry out activities	• Build capacity of dermatologists at IGMH on recent guidelines of prevention, diagnosis and treatment of leprosy • Build capacity of laboratory technician to take, stain and read SSS. • Provision of required medical supplies. • Build capacity of Department of Immunology to carry out AMR • Build capacity of IGMH in MIS (leprosy)

16.7.5 Referral level at Private Hospitals/ Clinics

Table 16.4

At Tertiary hospitals	
Implementation of activities at Private Hospitals/ Clinics	• Confirm diagnosis of leprosy • Slit Skin Smears examination
Referral	• refer to IGMH for MDT
Inputs required to carry out the activities	Leprosy data to HPA
Inputs required to carry out activities	• Build capacity of dermatologists at Private Hospitals/ Clinics on recent guidelines of prevention, diagnosis and treatment of leprosy • Build capacity of laboratory technician to take, stain and read SSS. • Provision of required medical supplies.

16.7.6 Health Protection Agency (HPA)

Table 16.5

Health Protection Agency (HPA)	
Implementation of activities at HPA	• Report consolidation and data analysis • Follow up of contact screening and chemoprophylaxis at Island level • Feedback to respective Regional/ Atolls hospitals and Island health centres • Procurement of MDT blister packs for patients • Train atoll Medical officers and medical staff • Prepare and implement the activities to move towards zero leprosy status • Monitoring the leprosy control activities at Atolls/ Islands • Monitoring the achievements of milestones of zero leprosy • Establish inter sectorial collaboration • Strengthen collaboration with partners
Inputs required to carry out activities	• Provide adequate resources to implement, monitor and MIS of leprosy control activities.

16.8Data and Records Management:

A referral slip should be introduced at each level (Island, Atoll, Regional, IGMH and Private Hospitals/ Clinics) and should be sent to next referral facility. This slip should have a feedback form attached to it.

MIS should be modified to procure the data on the suspected cases referred and their follow up.

16.9Responsibilities and Authorities:

HPA is the overall body responsible in ensuring a functional referral system. IGMH could support HPA in ensuring a functional referral system.

16.10 Monitoring:

Table 16.6

Referral level	• Number of suspects attended IGMH out of total number of suspects referred • Number of cases on MDT taking regular MDT among those on MDT (defaulter rate) • Number of patients with complications due to leprosy who visited IGMH among the referred for treatment of complications • Number of contacts screened and administered SDR within the total contacts of new cases. • Number of persons with disabilities due to leprosy followed up among the persons with disabilities due to leprosy living in the Island • correct disabilities/deformities if required at referral hospitals with specialist care • Monthly reports sent to respective Public health unit of respective Atoll/ Regional level and HPA
At Referral at Atoll hospital/Regional Hospital level and Public Health Unit	• Number of new cases diagnosed among the suspected referrals from Islands • Number of new leprosy patients who underwent slit skin smear examination among newly diagnosed cases • Number of cases referred to IGMH for diagnosis of difficult to diagnose cases, confirmation of relapse • Anti-microbial resistance studies • Monthly reports sent to HPA
Report new case to HPA At IGMH	• Number of new cases diagnosed among the suspect referrals • Number of new leprosy patients had slit skin smear examination among the new cases diagnosed • Number of leprosy cases treated for complications • Number of cases confirmed as relapse (leprosy) • correct disabilities/deformities if required?

Report new case to HPA At private hospitals/ Clinics.	• Number of new cases diagnosed among the suspected persons. • Number of new leprosy cases referred to IGMH
At Health Protection Agency (HPA)	• Feedback to respective Regional/ Atolls hospitals and Island health centres • Number of Medical officers of Atoll and island health facilities trained in leprosy among the total medical officers • Prepare and implement the activities to move towards zero leprosy status and its status of implementation • Monitoring the achievements of milestones of zero leprosy and prepare a status report.

16.11 Quality Assurance and Quality Control:

HPA/ MOH staff or dermatologist from IGMH would visit randomly selected islands and Atolls to ensure the functional referral system is in place. Follow instructions of quality assurance division in ministry.

17. Standard Operating Procedures for the Management of Leprosy Reactions

17.1 Background

Leprosy reaction is the sudden appearance of acute inflammation in the lesions (skin patches, nerves, other organs) of a patient with leprosy. This is due to an alteration in the immunological status of the patient. Leprosy reactions are part of the natural course of the disease and can occur at any time. Reactions commonly occur during the early part of the disease. Sometimes patients report for the first time to a health facility because of a leprosy reaction. Reactions may also be observed after completion of treatment.

17.2 Objective:

To diagnose lepra reactions early to avoid disabilities

17.3 Purpose and Applicability:

Reactions should be diagnosed early and managed promptly as it is the leading cause of nerve damage and consequent disability among leprosy patients.

17.4 Scope:

The leprosy patients during the MDT treatment period and after treatment are under the surveillance of health care system in order to detect the lepra reactions early. Providing information about the signs/ symptoms of reactions to the patient and relatives/ caretakers in cases of minors during counselling sessions during diagnosis, follow-ups and completion of treatment may help the patient to report to the health facility early. This standard operating procedures apply to persons at healthcare facilities who are tasked with the management of leprosy reactions.

17.5 Definitions:

Lepra reaction: Reactions in leprosy may be defined as "the clinical manifestations of alterations in the immunological balance between host and infective organism."

17.6 Prerequisites for Diagnosis and Management of Lepra Reactions:

- Health worker at field level should have knowledge and capacity to suspect lepra reaction
- A well established and functional referral system to refer the patient with lepra reaction to regional hospital/ IGMH
- Physiotherapy facilities at referral centres
- Availability of prednisolone tablets and other supportive medicines at regional hospital/ IGMH

17.7 Diagnosis and Management of Lepra Reactions:

There are two types of lepra reactions, Type 1 reaction (Reversal Reaction) and Type 2 reaction (Erythema Nodosum leprosum - ENL).

Type 1 lepra reaction (Reversal Reaction):

Mechanism:

Type 1 reaction is a delayed hypersensitivity reaction and is an example of "Coombs and Gell Type IV". The antigen of *M. leprae* stimulates T lymphocytes causing a change in Cell Mediated Immunity (CMI) by enhancing their response.

The signs and symptoms are:

Table 17.1

Symptoms and signs	Type 1 reaction
Skin manifestations	Inflammation (swelling, redness and warmth) of existing skin patches) or crops of fresh lesions (patches) in previously uninvolved skin
Nerve manifestations	Swelling with pain and tenderness along the course of the involved peripheral nerve Impairment of nerve function along the nerve distribution (motor and sensory loss)
Eye manifestations	Related to nerve damage; for instance corneal anaesthesia and lagophthalmos
Other manifestations	Oedema of extremities (hand and feet)

Management of type 1 reaction

Type 1 reactions are usually managed with a course of oral corticosteroids over a course of six months; oral corticosteroids are administered in tapering doses as per the following table. Patients on anti-leprosy treatment (MDT) must continue their treatment while on steroids. However, those who have completed their course of MDT do not need anti-leprosy treatment while on steroids.

Table 17.2

Daily dose of prednisolone	Weeks of course
40mg	2 weeks followed by
30mg	2 weeks
20mg	2 weeks
15mg	2 weeks
10mg	2 weeks
5mg	2 weeks

Note: Recent nerve damage, duration being less than six months, can be reversed by steroids (Prednisolone) but nerve damage lasting more than six may be irreversible.

While the patient is on prednisolone treatment period, nerve function assessments should be carried out once every two weeks to note the progress.

All instances of nerve function impairment, dosage and any changes to administered

doses and changes to nerve function should be recorded. Steroids should be tapered at regular intervals as mentioned above. In the event of nerve function deterioration, steroid doses may be increased by 10mg. The steroid dose should be titrated against the response as ascertained by the Nerve Function Impairment record and not tapered as in a predetermined regime.

Note: Do not stop MDT if the patient is on scheduled course of MDT for leprosy

Type 2 lepra reaction (ENL)

ENL stands for 'erythema nodosum leprosum' and is a frequent complication of MB leprosy.

Mechanism:

ENL is an immune complex syndrome – antigen antibody reaction involving complement. This reaction may be considered as a clinical manifestation of Arthus Phenomenon (Coombs and Gell Type III reaction). The immune complexes are deposited in the tissue where *M. leprae* are present

Precipitating Factors:

Stress, inter-current infection, surgery, chemotherapy, underlying tuberculosis and pregnancy may act as precipitating factors.

Signs and symptoms.

Table 17.3

Symptoms and signs	Type 2 reaction (ENL)
Skin manifestations	• Painful tender nodules on the skin all over the body (Erythema Nodosum Leprosum (ENLs). These nodules appear in crops and disappear after two weeks and fresh crop of nodules appear (evanescent) • Mostly these nodules are cutaneous but sometimes subcutaneous • In severe cases , ENL nodules may become vesicular, pustular, bullous or gangrenous and break down with considerable tissue damage (ulceration)
Nerve manifestations	• Swelling with pain and tenderness along the course of the involved peripheral nerve • Impairment of nerve function along the nerve distribution (motor and sensory loss)
Eye manifestations	Iridocyclitits, scleritis
Systemic symptoms	• Fever and joint pains • Enlargement of Lymph nodes; liver and spleen may be enlarged and tender, arthritis, dactylitis and epididymo-orchitis may also be present.

Management of type 2 reaction

ENL reaction is managed with oral corticosteroids, which is given for period of six weeks' duration. To avoid steroid dependence; the drug is tapered in the following way:

Table 17.4

Daily dose of prednisolone	Weeks of course
40mg	1st week
30mg	2nd week
20mg	3rd week
15mg	4th week
10mg	5th week
5mg	6th week

Type 2 reactions can often last for months or even years, and so there is a risk of patients becoming dependent on steroids. Type 2 reactions can be treated with a combination of prednisolone and clofazimine.

Patients with recurrent episodes of ENLs can be managed with high doses of Clofazimine which is given in decreasing doses as follows, along with steroids as dosage mentioned above.

Table 17.5

Daily dose of clofazimine	Duration
300mg daily	1 month
200mg daily	3-6months
100mg daily	as long as symptoms continue

Note: Do not stop MDT if the patient is on scheduled course of MDT for leprosy

17.7.1 Eye Involvement in Lepra Reaction

Signs and symptoms of eye involvement:

- Pain, redness, diminution of vision in the affected eye with photophobia (corneal ulcer/iritis);
- new weakness in eye closure with watering (lagophthalmos).

Patients at high risk for complications of the eye (should be targeted for education of signs and symptoms of eye problems)

1. Any decrease in Visual Acuity on regular checks
2. Impaired corneal sensation
3. Lagophthalmos
4. Periorbital/ facial patch
5. Repeated red eye (Iridocyclitis, scleritis)
6. History of reaction/ neuritis/ eye involvement within last 12 months
7. Patient with vision in one eye only

Criteria for referral to an ophthalmologist

1. Any patient with Visual Acuity < 6/60 (for more expert examination, spectacles or cataract surgery)
2. Any patient with decrease in Visual Acuity on routine follow up, patients on steroids included.
3. Any lagophthalmos. If the duration of lid gap is less than six months, the patient would be referred for minimum 5-6 months of Prednisolone along with eyelid strengthening exercises ±TMT. If the duration is more than 6 months, would be referred for surgery. In both cases self-care training is indicated.
4. Any facial patch in Type 1 reaction for steroid therapy to prevent lagophthalmos
5. Any red eye (corneal ulcer, iritis, iridocyclitis, scleritis or conjunctivitis)

Further reading: refer ILEP Learning Guide two: How to recognise and manage leprosy reactions.
http://www.ilepfederation.org/wp-content/uploads/2016/11/How-to-Recognise-and-Manage-Leprosy-Reactions-NEW-LOGO.pdf

17.7.2 Guidelines for the Use of Steroids

BEFORE STARTING STEROIDS - Check for symptoms and history of

- Diabetes
- Hypertension
- Coronary Vascular Disease
- Dyslipidaemia
- Peptic Ulcer
- Affective Disorder
- Fractures
- Ongoing Infections
- Acne
- Fungal Infections
- TB
- Concomitant Medications
- Symptoms of Peptic Ulcer
- History of Abdominal Surgery
- Physical Exam:
    - Weight
    - Height
    - Body Mass Index (BMI)
    - Blood pressure
    - Chest for signs of TB
    - Signs of sepsis
    - Any ulcers or infections (if patient has ulcer or infection and needs steroids, admit, treat and give under supervision. But consider deferring steroids till the crisis is over)
- Laboratory Investigations
    - Urine analysis
    - Hb, Complete Blood Count, ESR
    - Chest X Ray if clinical suspicion of TB
    - Blood Sugar

WHILE ON STEROIDS - Check for

- Blood Pressure (every visit for Out Patient and Weekly for Inpatient)
- Blood Sugar after 1 month and thereafter once in 3 months
- Monitor blood sugar levels of in-patients once a week
- Visual acuity as required (for steroid induced cataract)
- Where possible intraocular pressure every month (for steroid induced glaucoma)
- Symptoms and signs of pulmonary tuberculosis
- Other side effects

SIDE EFFECTS OF STEROIDS

- Increased susceptibility to infections
- Acid Peptic Disease, Peptic Ulcer
- Diabetes Mellitus
- Hypertension
- Osteoporosis and pathological fractures (prolonged treatment > 6 months)
- Suppression of pituitary adrenal axis on prolonged therapy (> 6 months) and
- Withdrawal syndrome - fever, myalgia, arthralgia, malaise, anorexia, nausea,
- Vomiting, weight loss, hypotension Hypocalcaemia
- Posterior sub capsular cataracts (prolonged treatment); steroid induced glaucoma
- Cushingoid Features – central Obesity, Moon face, Striaie, Buffalo Hump
- Steroid induced Acne
- Steroid induced Psychosis (rare)
- Striae, easy bruisability and skin atrophy

ADVICE FOR PATIENTS

- Do not stop steroids suddenly
- Report to the nearest health facility in the event of fever, infection of ulcers
- Do not adjust the dose on your own

Annex 8

Steroid Card

(SOP for Chemoprophylaxis Treatment of Contacts of a Leprosy Patient)

- Regular activity/ exercise is a must
- Do not lift heavy weights
- Should the patient have other health issues and require consultations with other healthcare professionals, the patient must inform them of the current steroid dosage and produce the steroid card
- Seek medical assistance if the patient vomits or has diarrhoea
- Always carry the steroid card with you
- Seek medical assistance if the patient has severe abdominal pain or black stool

18. Standard Operating Procedures for Counselling of Persons Affected with Leprosy

18.1Background

Leprosy is a chronic disease caused by *Mycobacterium* leprae and there is stigma associated with leprosy. The present disease control measure is by secondary prevention i.e. early diagnosis and regular treatment with MDT. To ensure regularity of the treatment and timely reporting of leprosy related complications, counselling places an important role.

18.2Objective:

Person affected with leprosy should recognize and understand the importance treatment for their well-being and to ensure better compliance with the treatment regimen

18.3 Purpose and Applicability:

The purpose of counselling is for the patient to understand the illness better and is vital to build patient's confidence to cope with leprosy and lead a normal life. Counselling is a helping process where a doctor or health worker decisively gives their time, attention and skills to assist a leprosy patient to explore their situation, identify and act upon the solutions within the boundaries of their environment.

18.4 Scope:

Patient counselling is one of the major duties of the doctor and other health workers and helping process aimed at – problem solving. Counselling provides confidential support. This standard operating procedures apply to persons at healthcare facilities who are responsible for providing persons affected by leprosy with counselling.

18.5 Definitions:

Counselling: process of advising individuals and families affected by leprosy to help them understand and adapt to the medical, psychological and familial implications contributions to disease and to develop a cope-up mechanism.

18.6 Prerequisites:

- The doctors and health workers should have thorough knowledge about leprosy and basic counselling skills

18.7 Procedural Steps (Method):

General principles:

- The provision of professional assistance and guidance in resolving patient's personal or psychological problems. Counselling is face to face communication by which health worker helps persons affected
- Counselling is a process of talking about and working through patients' personal problems with a counsellor. The counsellor helps the patient and their family to address their problems in a positive way by helping to clarify the issues, explore options, develop strategies and increase self-awareness.
- The counselling process is a planned, structured dialogue between a counsellor and a client.
- It is a cooperative process in which a counsellor helps a person affected by leprosy to identify sources of difficulties or concerns that they are experiencing.

- The fundamental values of counselling and psychotherapy include a commitment to:
    - Respecting human rights and dignity.
    - Protecting the safety of clients.
    - Ensuring the integrity of counsellor-client relationships.
    - Enhancing the quality of professional knowledge and its application.
    - Alleviating personal distress and suffering.

18.8 Counselling – Outline

Counselling at the time of diagnosis and initiation of MDT:

1. The following points should be covered:
    - Leprosy is a bacterial infection
    - Leprosy is curable
    - MDT treatment is free of cost
    - Regular treatment prevents deformities
    - Patient can lead a normal life
    - Not to worry if urine is red in colour (it is due to capsule Rifampicin)
    - All the household contacts will be examined
2. During MDT, the following points should be covered under counselling:
    - Appreciate regularity of treatment (if patient is irregular encourage patient to be regular)
    - Keep MDT blister packs in safe place and out of reach of the children
    - If there are any changes on skin patches or develop new patches, patient should report to the health facility immediately
    - If the patient notices any weakness in their hands, feet, eye lids, or redness of eye, they should report to the health facility for examination and further treatment

3. Upon completion of MDT, the following points should be covered under counselling

- Leprosy is cured. Multi-drug therapy is no longer required
- Do not worry about the patches on the body, they will slowly disappear and they are harmless
- If they notice any changes on the skin patches or develop new patches, report to the health facility immediately
- If you notice any weakness hands or feet or eye lids, redness of eye should report at the health facility for examination and further treatment
- If the patient has any deformity advise them to continue to practise self-care for insensitive hands and feet and eyes in order to prevent further deformity
- Deformities can be corrected with reconstructive surgery

4. Counselling if the patient develops lepra reaction:

- If the patient is on MDT, treatment should continue
- If the patient is on steroids, ask them to present their steroid card
- Regular treatment with prednisone (steroids) is important
- Explain the side effects of steroids and ask to report to health facility
- Explain some patients develop lepra reactions and not to worry. It is treatable

(Further reading e module 3 – *Counselling for leprosy developed by WHO.* *http://labs.enablingdimensions.com/Leprosy/*

19. Standard Operating Procedures for Nerve Function Assessment - Leprosy.

19.1 Background:

Leprosy is a chronic mycobacterial disease and is caused by *Mycobacterium* leprae primarily affecting peripheral nervous system and secondarily involving skin and certain other tissues. Nerve involvement is a significant feature of leprosy that eventually leads to deformities. Regular nerve function assessments are essential to diagnose neuritis early and manage promptly to prevent developing deformities (Brandsma,1981).

19.2 Objective:

To prevent developing deformities by carrying out regular nerve function assessments

19.3 Purpose and Applicability:

The purpose is to detect early nerve damage as to prevent any disability during and post MDT. Prevention of deformities is a major activity of the leprosy control programme.

19.4 Scope:

It is an opportunity to carry out nerve function assessment every month during treatment period as the patient attends the health facility for monthly follow ups. This standard operating procedures apply to persons at healthcare facilities conducting nerve function assessments on leprosy patient or suspect cases.

19.5 Definitions:

Nerve function assessment: Evaluating the various functions (autonomic, sensory, motor) of the nerves especially peripheral nerves

19.6 Prerequisites:

- The doctors and health workers who treat leprosy should have thorough knowledge and skills in carrying out sensory testing and voluntary muscle testing of the peripheral nerves
- Individual leprosy patient record should have section on documenting nerve function assessments

19.7Procedural Steps (Method):

Cutaneous nerves affected in leprosy are:

Table 19.1

Site	Duration
Leprosy skin lesions	Nerve twig to the lessons
Face	Supra orbital
Neck	Great auricular
Upper limb	Radial cutaneous nerve at wrist
Lower limb	Musculo cutaneous nerve on the dorsum of foot Sural nerve (posterior aspect of lower third of leg

Peripheral nerve trunks affected in leprosy are:

Table 19.2

Site	Name of Peripheral nerve trunk
Face	Facial nerve Trigeminal nerve
Upper limb	Radial nerve Ulnar nerve Median nerve
Lower limb	Lateral Popliteal Posterior Tibial nerve

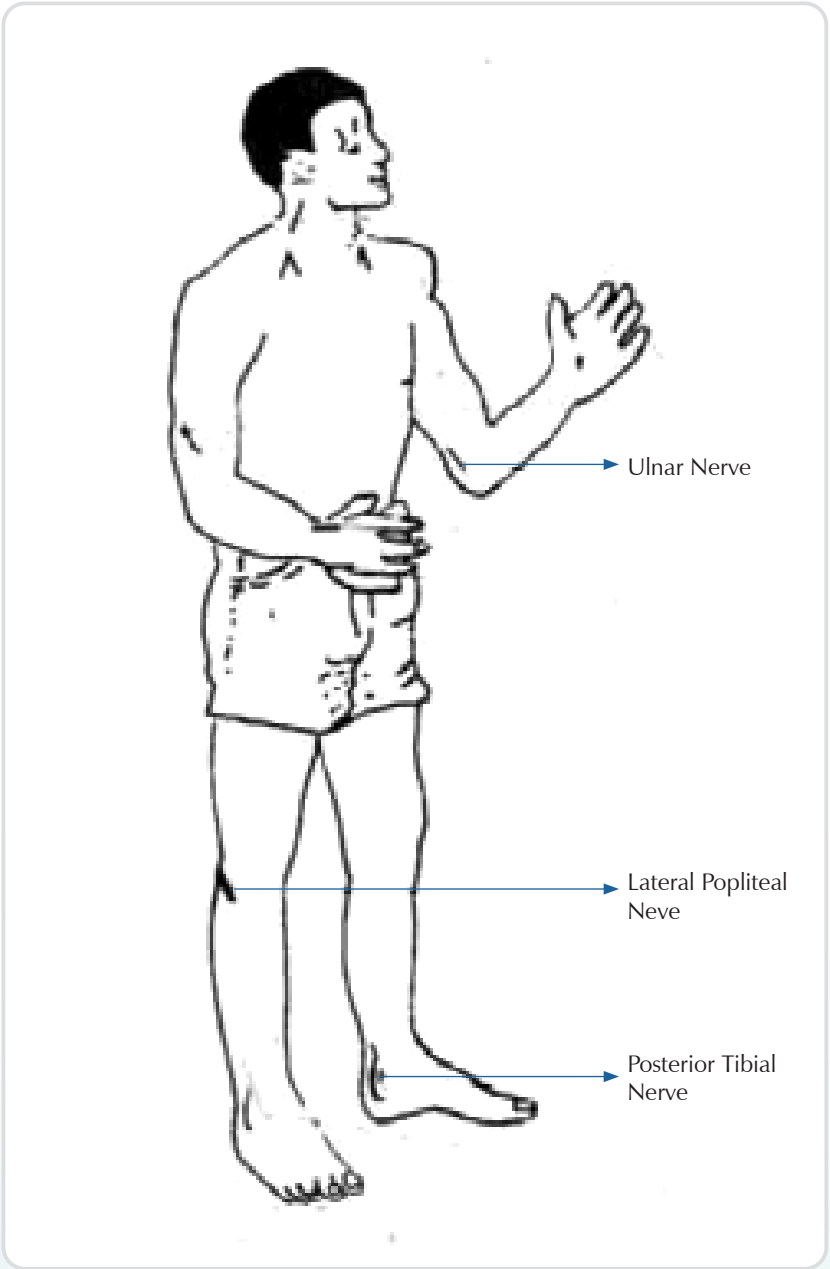
19.7.1 Details of Nerve Function Assessment of Peripheral Nerves Affected in Leprosy

The examination of nerves to assess peripheral nerve function affected in leprosy includes nerve palpation, sensory testing (ST) and Voluntary Muscle Testing (VMT)

Nerve examination involves palpation of the nerves for thickening, tenderness and consistency

- Both patient and examiner should be positioned correctly.
- Locate the correct nerve
- Observe the patient's face while palpating the nerve to elicit tenderness.
- Palpate gently with the pulp of the two fingers, not the tips of fingers,
- Always palpate across the course of the nerve.
- Feel along the nerve as far as possible in both directions.

Figure 19.1



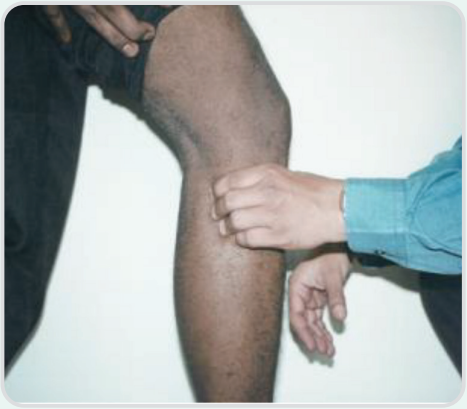
Ulnar Nerve

Table 19.2

- Site: In the groove above and behind medial epicondyle of the elbow.
- Position of patient: Both the patient and examiner facing each other.
- To examine right ulnar nerve, ask the patient to flex the elbow joint slightly.
- Hold the right wrist with your right hand.
- With the left hand feel for the medial epicondyle.
- Pass behind the elbow and feel the ulnar nerve in the groove.
- Gently palpate with pulp of 2 fingers (index & middle) and feel across the nerve, constantly watching facial expression for signs of tenderness.
- Trace the nerve proximally as far as to ascertain the length of the swelling.

Lateral Popliteal Nerve

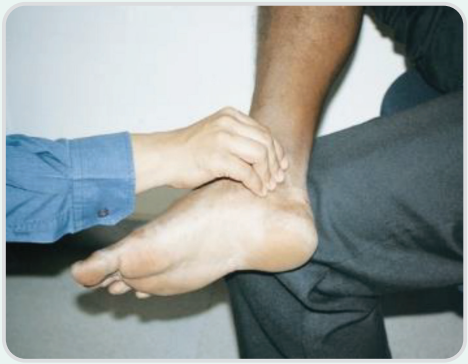
Table 19.3



- Site: back of the knee, behind the head of fibula.
- Position of patient: Patient standing with knees slightly flexed (not total) and examiner squatting.
- Identify the head of fibula on the lateral aspect of knee in line with lower end of patella.
- Pass backwards and feel the nerve just behind the fibular head.
- Gently palpate with pulp of 2 fingers (index & middle) and feel across the nerve, constantly watching facial expression for signs of tenderness.
- The palpable course of the nerve is very short.

Posterior Tibial nerve

Table 19.4



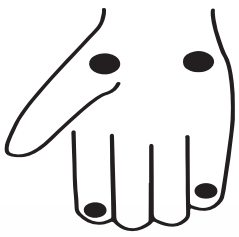
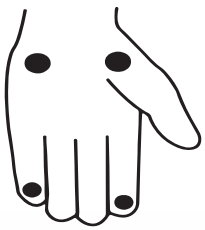
- Site: Below and behind the medial malleolus
- Position of Patient: to rest the ankle on thigh
- Identify the medial malleolus. Locate the nerve just below and behind medial malleolus (approximately at the midpoint between medial malleolus and heel)
- Palpate with the pulp of finger and feel across the nerve constantly watching facial expression for signs of tenderness.
- The palpable course of the nerve is very short

Nerve function assessment includes testing for power of muscles supplied by the nerve referred to as Voluntary Muscle Test (VMT) and for sensory loss in the area supplied by the nerve called as Sensory Test (ST).

Sensory Test (ST)

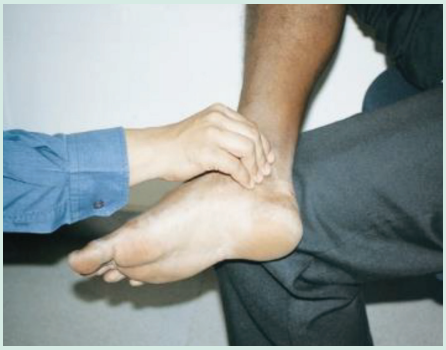
One should test for sensation over the areas demarcated in the diagram. Given below are the suggested spots for testing sensation over the palms and soles.

Table 19.5

Right	Left
	
	

Sensory Test on Palms & Soles

Figure 19.6



Interpretation of test for loss of sensation:

If no response – loss of sensation

If >3cm away – reduced sensation

If within 3cm – normal sensation

Voluntary Muscle Test (VMT)

Table 19.3

Facial nerve	Eye closure
Trigeminal nerve (sensory nerve)	Blinking of eye
Ulnar nerve	Little finger out
Median nerve	Thumb up
Radial nerve	Wrist up
Lateral popliteal nerve	Foot up
Posterior Tibial nerve	Spreading of toes

Voluntary muscle testing is performed by checking the range of movement to see whether movement is normal, reduced or absent due to paralysis. If movement is normal, a test for resistance is then done. Press gently in the opposite direction while asking the patient to maintain position, resisting pressure as strongly as possible. Then gradually press more firmly and judge whether resistance is normal, reduced or absent. The grading of the result can be done as follows:

S (Strong) - Able to perform the movement against full resistance

W (Weak) - Able to perform the movement but not against full resistance

P (Paralysed) - Not able to perform the movement at all.

VMT for Facial Nerve

Ask the patient to close their eyes and keep them lightly closed as if in sleep. If there is no gap, ask them to close the eye tightly and try to pull the lower lid down and see whether the patient is able to keep his eyes closed against resistance.

Table 19.4

A gap visible between the upper and lower eyelids	Grade 'P'
Able to keep his eye closed against resistance	Grade 'S'
Not able to keep his eye closed	Grade 'W'

VMT for Median Nerve:

Ask the patient to hold their thumb in a right angle to the palm. To test for weakness, push the thumb towards index finger while the patient tries to hold it in the test position. The pressure should be applied at the base of thumb. Grade the muscle power as 'S', 'W', or 'P'.

VMT for Radial Nerve:

Ask the patient to make a fist and then dorsiflex the wrist. To test for weakness, press the hand downwards as shown in the diagram while the patient tries to hold it in the test position. Grade the muscle power as 'S', 'W', or 'P'.

VMT for Lateral Popliteal Nerve:

Lift the foot off the ground and support at calf region. Then ask the patient to dorsiflex their foot fully. To test for weakness, push the foot downwards while the patient tries to hold it in the test position. Grade the muscle power as S', 'W', or 'P'.

19.8 Grading of Disability for Leprosy

The three-grade WHO disability grading system (0, 1, 2) has been in use for several years and has proved to be a good basis for measuring the magnitude of the problem and organizing physical rehabilitation activities at both individual and community levels.

Grading of disability

Table 19.5

	Grade 0	Grade 1	Grade 2
Hand	No anaesthesia, no visible deformity or damage	Anaesthesia, but no visible deformity or damage	Visible deformity or damage present
Feet	No anaesthesia, no visible deformity or damage	Anaesthesia, but no visible deformity or damage	Visible deformity or damage present
Eyes	No eye problems due to leprosy; no evidence of visual loss	Eye problem due to leprosy present, but vision not severely affected as a result (vision 6/60 or better; can count fingers at six metres)	Severe visual impairment (vision worse than 6/60; inability to count fingers at 6 metres), lagophthalmos, iridocyclitits, corneal opacities

19.9 Disabilities in Relation to Peripheral Nerve Damage

Disabilities in leprosy patients can occur as a result of nerve damage. Damage to the nerves results in impairment of sensory, motor and autonomic functions, leading to anaesthesia, paralysis of muscles in eyes and extremities (Hand and Foot), loss of sweating and fissures/ cracks/ulcers over extremities.

Table 19.6

Site	Nerve	Features
Hand	Ulnar	Clawing of 4th and 5th fingers Loss of sensation and sweat over the little finger and the inner half of ring finger
	Median	Inability to move the thumb away (abduction) and touch the tips of other fingers(opposition) Loss of sensation over the thumb, index, middle and outer half of ring finger
	Ulnar & Median	Clawing of all five fingers Loss of sensation and sweat over the whole palm
	Radial	Wrist drop Loss of sensation and sweat over the back of the hand
Foot	Lateral Popliteal	Foot drop Loss of sensation over the lower leg and dorsum of the foot
	Posterior Tibial	Claw toes, loss of sensation and sweat over the sole of the foot.
Face	Facial	Inability to close the eye (Lagophthalmos)
	Trigeminal	Loss of sensation over cornea

20. Standard Operating Procedures for Chemoprophylaxis Treatment of Contacts of a Leprosy Patient

20.1 Background:

Leprosy is associated with important clinical and social consequences. Prevention of leprosy would be preferable to treating patients after clinical presentation and would provide additional public health benefits in terms of reducing the spread of the disease. The main risk of exposure to *M. leprae* is in close contacts of new, untreated leprosy cases.

20.2 Objective:

To bring a significant reduction in the incidence of leprosy among the contacts of the leprosy patients

20.3 Purpose and Applicability:

Epidemiological studies have shown that the chance of finding a new leprosy patient is ten times higher in household contacts of leprosy patients than in the general population, and the chance of finding leprosy among different categories of neighbors and social contacts is between three and five-fold. Therefore, contacts are the main focus to ensure prevention of leprosy so this is an effective public health intervention.

20.4 Scope:

A major benefit of administering SDR is that household contacts of leprosy patients are examined, thus facilitating early case detection. This standard operating procedures apply to persons at healthcare facilities that will administer SDR to contacts of leprosy patients

20.5 Definitions:

Index case: Any confirmed case diagnosed for the first time as leprosy case

Household Contacts: persons who have access to/ or share common spaces in a household with an index case for a duration not shorter than three months. This includes and is not limited to kitchens, dining rooms, living rooms, and toilets.

Chemoprophylaxis: Post-exposure prophylaxis with one or more antibiotics given to contacts of an infectious disease case. A single dose of rifampicin is used to reduce the risk of developing leprosy in contacts of leprosy patients (index cases).

Single-dose rifampicin prophylaxis: Post-exposure prophylaxis in which a single dose of rifampicin, with dosage based on the body weight, is given to contacts of an index case. In this document single dose rifampicin prophylaxis is referred as Post-Exposure-Prophylaxis (PEP).

- Body weight > 35 kg – 600 mg
- Body weight 20 – 35 kg – 450 mg
- Body weight < 20 kg – 10-15 mg/kg

20.6 Prerequisites:

- Approved as a national policy (by Health Protection Agency – HPA) as one of the leprosy elimination components
- Availability of adequate quantity of Capsule Rifampicin in different doses
- Knowledge about PEP and its implementation among the health workers by conducting sensitization/ orientation meetings
- Systematic contact screening (Refer to SOP for contact screening)
- Records and registers for details of PEP
- Reporting system to collect data on the PEP related information

20.7 Procedural Steps (Method):

The exact procedure to be followed for contact screening is indicated below:

When the diagnosis of leprosy is confirmed at IGMH or Regional hospitals, individual patient card with register number and other details should be filled up. The contacts of the leprosy patient (index cases) should be written (enumerated) in the individual patient card as per Table 20.1

Table 20.1

Name of the index case:					
Date of detection of index cases:					
Classification: (MB / PB)					
Address:					
No.	Name of the household contact	National ID/ Passport	Age	Gender	Relationship with index cases

The referral centre at which the patient is diagnosed should forward patient details and enumerated contact details to HPA. This should then be forwarded to the respective public health unit in the island to carry out contact screening. In the event of an index case diagnosis, patient details must be enumerated by HPA and forwarded to focal points.

The enumerated household contacts (registered) for an index cases (newly diagnosed leprosy case) should be examined within two months of registration of index case for MDT.

Therefore, all the house hold contacts of all known leprosy patients should be examined once in a year for a period of 10 years (i.e. double the average incubation period of leprosy)

Eligibility criteria for PEP

Inclusion criteria

- A household contact of index case who found to be not suffering from leprosy
- Age ≥ 2 years.

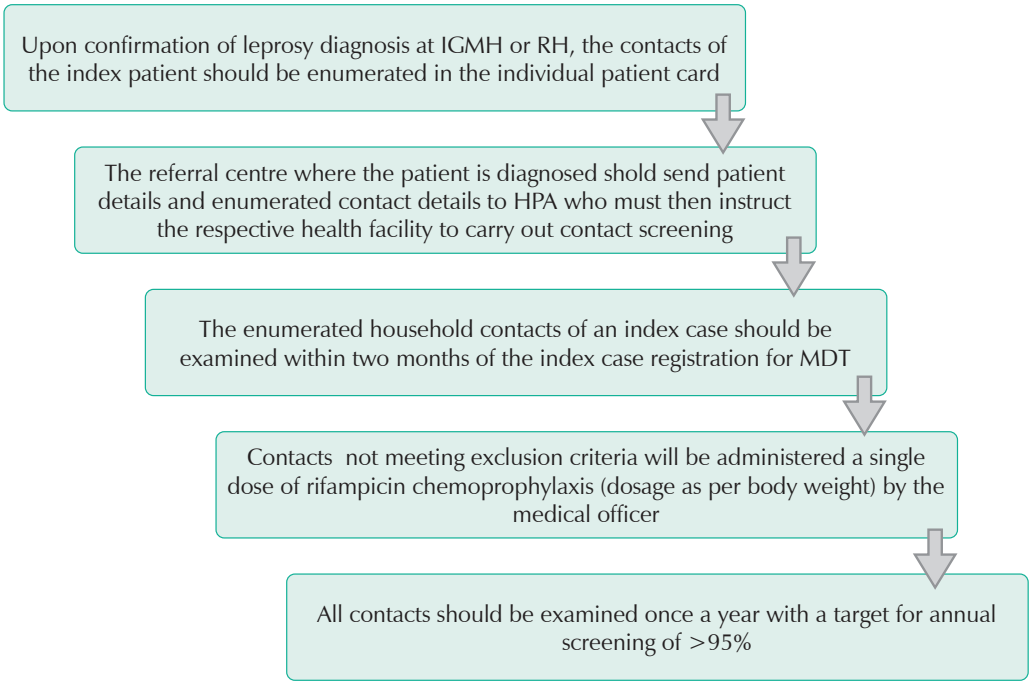
Exclusion criteria for PEP

- Pregnant women (PEP can be given after delivery).
- People receiving rifampicin therapy for any reason in the last two years (e.g. for tuberculosis [TB] or leprosy treatment, or as a contact from another index case).

- People with a history of liver disorders (ask for H/o jaundice, right sided abdominal pain and swelling, swelling in legs and ankles, pale coloured stool) or renal disorders (ask for H/o decreased urine output, swelling in legs and ankles/o high BP).
- People who have likely signs and/or symptoms of leprosy.
- People who have possible signs and/or symptoms of TB (patients having any of the following symptoms should be screened for TB: cough for more than two weeks, night sweats, unexplained fever, and weight loss).
- Person with acute febrile illness.
- Persons with history of allergies to Rifampicin

Post Exposure Prophylaxis with Rifampicin

Figure 20.1



Adverse event management:

The adverse events following administration of single dose of rifampicin is rare. If any side effect occurs record and report to the Health Protection Agency (HPA)

Side effects to Rifampicin:

Table 20.2

	Symptoms / signs	Management
Minor	Red urine	Reassurance / Counselling
Major (serious)	Allergy, urticarial rash	Treat allergy Not to give rifampicin for any other disease
	Jaundice	Investigate and treat Not to give rifampicin for any other disease
	Shock, purpura, renal failure	Investigate and treat Not to give rifampicin for any other disease

20.8 Monitoring and supervision:

The assigned Zero Leprosy Programme focal point of the Island health facility is responsible for ensuring screening of all the contacts of each and every leprosy patient. The Medical Officer has also to ensure that the guidelines specified for inclusion and exclusion criteria is being followed while screening of contacts. The Medical Officer of the Island health facility will also be responsible for adverse event management.

Annex 9

Reporting for Monitoring Purposes

(SOP for Chemoprophylaxis Treatment of Contacts of a Leprosy Patient)

Annex 10

Follow-up of Contacts who received Single Dose Rifampicin as PEP

(SOP for Chemoprophylaxis Treatment of Contacts of a Leprosy Patient)

Annex 11

Details for Whom PEP Administered as SDR

(SOP for Chemoprophylaxis Treatment of Contacts of a Leprosy Patient)

Annex 12

Communicable Disease Notifying Form

Annex 13

Leprosy Treatment Card

Annex 14

Leprosy Contract Tracing and Screening Form.

21. Standard Operating Procedures for Surveillance of Antimicrobial Resistance (AMR) in Leprosy

21.1 Background:

The emergence of drug resistance is a concern and a threat for many infectious disease intervention programmes, especially those that have secondary prevention (chemotherapy) as the main component of their control strategy. As the multidrug therapy for leprosy is primarily based on rifampicin, it is important to monitor the emergence of rifampicin-resistant strains. Recent reports and publications have indicated the existence of rifampicin resistance in several endemic areas. More drug resistant mutations were significantly detectedin leprosy relapse (Matsuoka et al., 2007)

21.2 Objectives:

The objective of the surveillance system is to determine resistance to rifampicin among leprosy cases, either alone or combined with resistance to dapsone and/ or ofloxacin among new cases (a proxy for primary resistance) and among retreatment cases (a proxy for secondary resistance), and to monitor resistance rates over time.

21.3 Purpose and Applicability:

Relapse of the disease in leprosy after the scheduled course of MDT treatment has profound implications for case management, compliance, disease transmission and elimination. To meet the challenge of containing the disease and being able to respond to an increase in circulation of drug-resistant strains, it is essential to assess drug-sensitivity patterns nationally, as well as to monitor resistance among both new and retreatment leprosy cases.

21.4 Scope:

The Health Protection Agency (HPA) should take a long-term view of surveillance and design a system to that best fits its needs in order to review the drug resistance surveillance data and to review trends in relapses reported by the national programme. Maldives may combine components from the different surveillance mechanisms (survey, continuous, sentinel) in order to meet their specific needs and capacities.

21.5 Definitions:

- **Anti-microbial resistance in leprosy:** Antimicrobial resistance to leprosy drugs occurs when *Mycobacterium leprae* change in ways that render the medications used to cure the infections they cause ineffective. The bacteria survive and continue to multiply causing more harm.
- **New case (of leprosy):** a patient diagnosed with leprosy who has never been treated for the disease;
- **Retreatment case (of leprosy):** a patient diagnosed with leprosy who has already received treatment for the disease in the past. Retreatment cases shall be further classified into the following groups:
    - **Retreatment after loss to follow-up:** a patient diagnosed with leprosy who have abandoned treatment before its completion and return to the health facility to complete treatment beyond 3 months for Pauci-bacillary (PB) cases and beyond 6 months for Multibacillary (MB) cases;
    - **Relapse:** a patient who has completed a full treatment course for leprosy in the past and who returns with signs and symptoms of leprosy that are not deemed due to a reaction according to the clinician; and/ or an increase in the bacteriological index (BI) of two or more units at any single site compared to BI taken from the same site at previous examination.
    - **Transferred in:** a patient who has started treatment in one facility and reports to another facility to continue treatment;
    - **Other retreatments:** any leprosy case that does not fall in any of the above categories and requires treatment.

21.6 Prerequisites:

- Laboratories to carry out slit skin smear investigation at regional hospitals and IGMH.
- Facility to carry out skin biopsies at regional hospitals and IGMH and availability of expertise to examine and report histopathology findings
- Collaboration with an identified sentinel laboratory for PCR and DNA sequencing. Setting up a transportation system for sending samples to the testing sentinel laboratory
- Laboratory chemicals and equipment to transport specimen to sentinel laboratory

21.7 Procedural Steps (Method):

Surveillance of drug resistance in leprosy will be carried out based on a sentinel surveillance model with the aim to monitor the trends over a period of time.

For the purpose of this surveillance (taking into consideration the present limitations in extracting DNA from tissue specimens) new leprosy cases, retreatment case and relapse cases with a bacteriological index (BI) of +2 and above will be recruited.

21.8 Outline of the Surveillance System

Component 1:

- Systematic collection of samples in the field
  - Identify referral centres at country level where the diagnosis of leprosy including relapsed will be done
  - Collection of data and appropriate tissue samples from new leprosy cases and retreatment leprosy cases (includes relapse cases)

Component 2:

- Testing bases on DNA sequencing for Rifampicin and Dapsone resistance
  - Reference laboratory (sentinel laboratory) will receive, test and provide feedback to the National Leprosy Programme (HPA)

Component 3:

- Dissemination of data
  - WHO country office, Maldives will collate data from HPA and forward the information WHO Global Leprosy Programme for annual publication in the WHO Weekly Epidemiological Record

21.8.1 Protocol for Specimen Collection & Transport

Health facilities are identified for collecting samples where slit-skin smears/biopsies are routinely done to assess and classify patients. At each sample collection health facility, the appropriate forms should be filled.

21.8.2 Systematic Collection of Samples

For all cases that meet the inclusion criteria, skin smear sampling would be done with the patient's consent according to the clinical practice and laboratory processing:

- either two slit skin smear samples of the lesion with a BI ≥2+ should be taken, with the earlobe being the preferred sampling site together with the most prominent skin lesion; or
- one skin biopsy (e.g. 4 mm punch biopsy) should be taken from a prominent lesion with a BI ≥2+.

Written patient consent must be obtained. For patients below 18 years of age, legal guardians' written consent should be sought.

Slit skin smear samples

Slit skin smear samples are collected in the same manner as skin smears for BI examination, using a disposable stainless steel blade. Caution should be taken to prevent cross contamination.

The stainless steel blade containing the tissue scrapings should be rinsed into a 1.8 mL micro centrifuge tube (with screw cap) pre-filled with 1 mL of 70% ethanol (molecular biology grade absolute ethanol at 70% v/v + sterile deionized water from MilliQ), making sure that the tissue scrapings are washed from the surface of the blade and are suspended in the solution.

In doing so, two slit skin smear samples would be collected and labelled according to assigned case number and National ID number (citizens) and passport number (non-citizens)

Slit skin samples are also kept on a Whatman® FTA® card. Make as small a smear of the sample as possible on the card. Both materials can be stored at room temperature.

Figure 21.1

No. 15 stainless steel blade as a standard surgical tool for slit skin smear

Figure 21.2

Micro Centrifuge Tube (MCT) Screw type

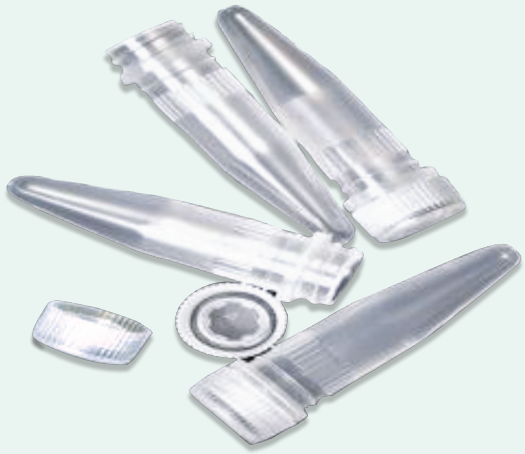


Figure 21.3

Preservation

- Immediately after collection, put surgical blade with smear into a micro centrifuge tube (MCT-2 ML 'O' ring) containing 1ml 70% ethanol and rinse the tissue content.
- Take out the blade.
- Close the lid tightly.

One blade (one sample) in one micro centrifuge tube (MCT)

Figure 21.4

Storage

- Keep MCT in the MCT rack in upright position.
- Store in the refrigerator.
- Transport to the sentinel laboratory as early as possible before ethanol evaporates.

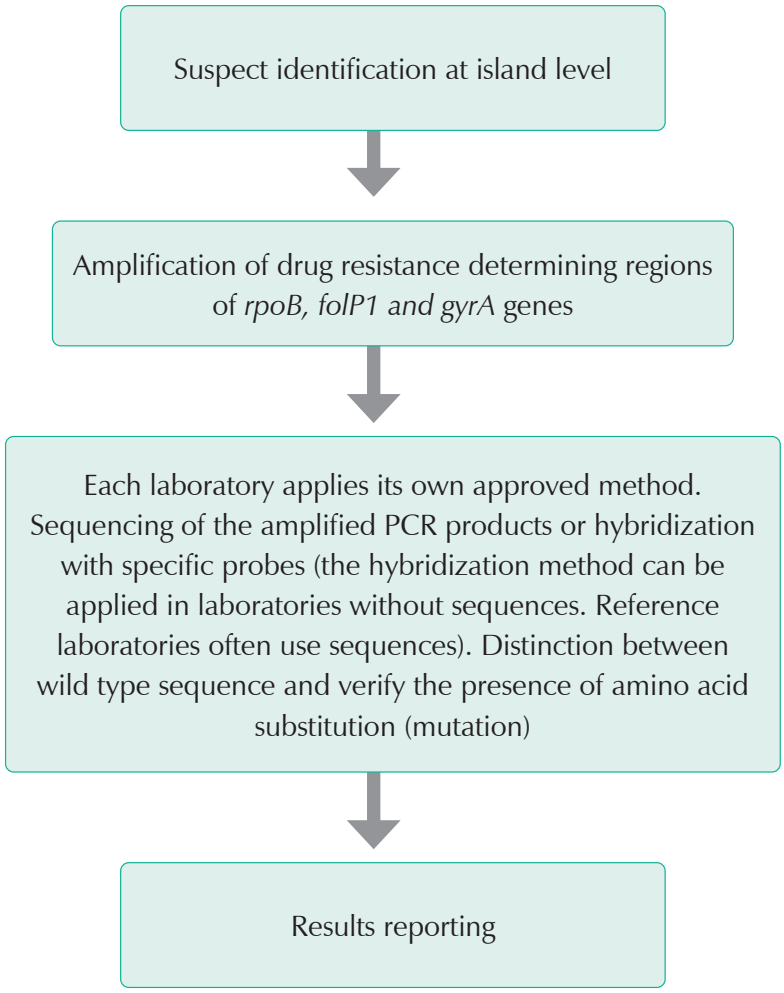
21.8.3 Projected issues

- Delayed transfer of specimens
- Inverted position of tubes during transport
- Samples can be kept in the refrigerator until they are sent to the sentinel laboratory, possibly in batches, depending on the cost of transportation and on the number of samples per month. Bacilli are rapidly inactivated, which means that samples can be sent by routine transport without the need to control the temperature during transportation, or take additional precautions for biohazard control.

Laboratory tests

Once the testing laboratory, whether national or international, receives the samples, the following steps would have to be undertaken:

Figure 21.5

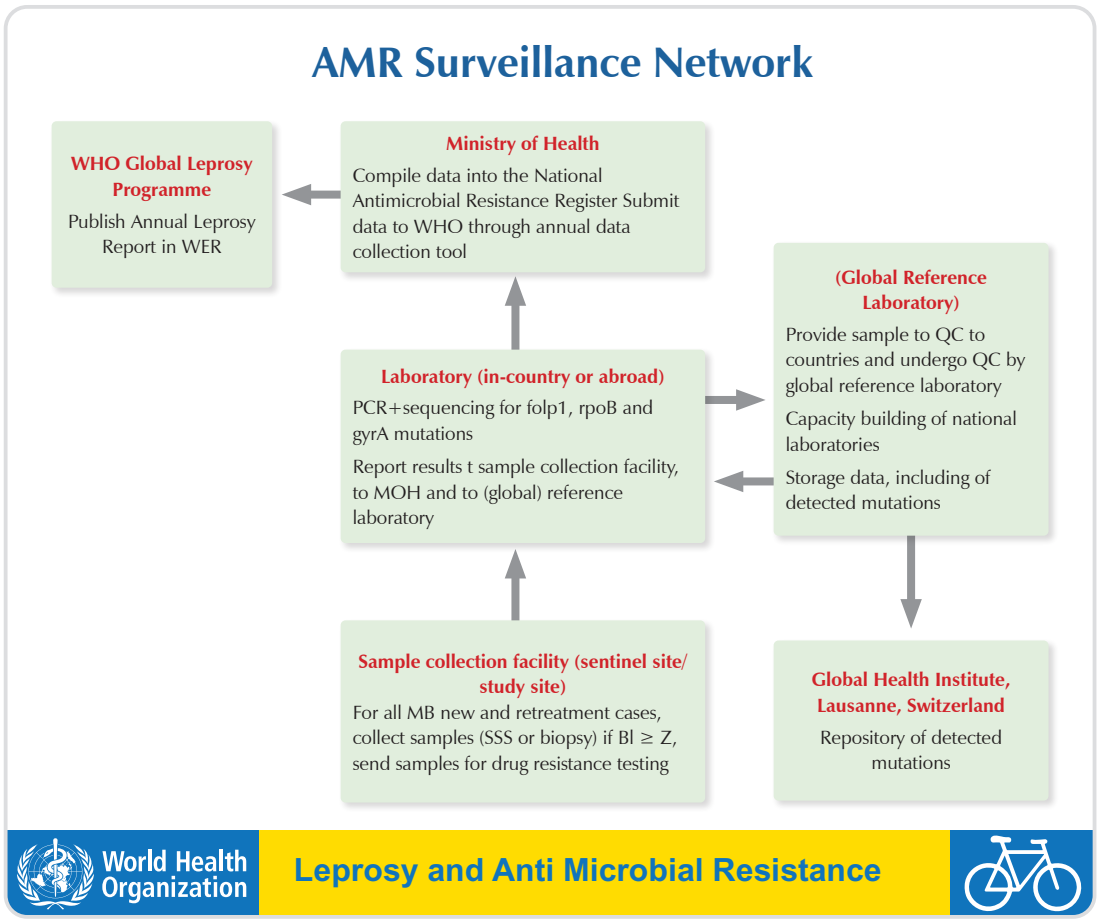


21.8.4 Monitoring antimicrobial resistance

The National Leprosy Programme will monitor the trends over time of resistance among new and retreatment cases, along with monitoring the proportion of patients tested.

Scheme for surveillance of AMR in leprosy:

Figure 21.6



Further reading:

A guide for surveillance of antimicrobial resistance in leprosy – 2017 update; World Health Organization.

https://www.who.int/lep/resources/9789290226192/en/

Global Leprosy Strategy 2016-2020, Monitoring and Evaluation Guide, WHO, 2016.

https://www.who.int/lep/resources/9789290225492/en/

Zero Leprosy Programme

Rapid Enquiry Surveys Register

Island:

Date of visit	House No	Local (L) or Migrant (M)	Household Focal Point	No. persons enumerated					No. persons examined					If any person with suspected symptoms of leprosy give details (Name/age/gender/reason for suspicion of leprosy
				AM	AF	CM	CF	Total	AM	AF	CM	CF	Total	

AM – Adult Male **CM** – Child Male

AF – Adult Female **CF** – Child Female

Please attach additional copies if required

Annex 2

Zero Leprosy Programme

Rapid Enquiry Surveys Report

Island											
Date/dates of rapid enquiry survey											
	Local					Migrants					Grand total
No. Households (as per the census record)											
No. Households visited by the health worker											
% of Households visited by the health worker (Target – 100%)											
	AM	AF	CM	CF	Total	AM	AF	CM	CF	Total	Grand total
No. persons enumerated											
No. persons examined											
No. persons with suspected symptoms of leprosy											

Details of persons with suspected symptoms of leprosy

Name	National ID/ Passport	Age	Gender	Address (Indicate whether local/migrant)	Reason for suspicion of leprosy	Status of confirmation of diagnosis

AM – Adult Male **CM** – Child Male

AF – Adult Female **CF** – Child Female

Please attach additional copies if required

Annex 3

Zero Leprosy Programme

Contacts of Index Cases

Name of the index case:					
Date of detection of index cases:					
Classification: (MB / PB)					
Address:					
No.	Name of the household contact	National ID /Passport	Age	Gender	Relationship with index cases

Please attach additional copies if required

Health Protection Agency

Zero Leprosy Programme

Contacts Survey Register

Name of the index case:	
Date of detection of index cases:	
Classification: (MB / PB)	
Address:	

No.	Name of the household contact	National ID/ Passport	Age	Gender	Relationship with index cases	Date of 1st examination	Date of 2nd examination	Date of 3rd examination	Date of 4th examination	Date of 5th examination	Remarks (If found suffering from leprosy during examination

Please attach additional copies if required

Annex 5

Zero Leprosy Programme

Contact Survey Report

This contact survey report should be submitted by each island annually

Name of the Island:	
Reporting year:	
1	No. New cases detected during the year
2	No. Contacts of the above new cases enumerated
3	No. Contacts among the above (Row 2) examined
4	No. contacts found suffering from leprosy among examined (Row 3)
5	No. health contacts of the due for examination in the reporting year) i.e. repeat annual examination
6	No. Contacts among the above (Row 5) examined
7	No. contacts found suffering from leprosy among examined (Row 6)

Health Protection Agency

Zero Leprosy Programme

School Screening Register

Island					
Name of the school					
Date of screening					
Screening conducted by (name/designation/address):					
	M	F	Total		
No. School students					
No students found to be suffering from leprosy (new cases)					
No students found to be suffering from other skin diseases					
No. teachers & other staff					
No teachers & other staff found to be suffering from leprosy (new cases)					
No teachers & other staff found to be suffering from other skin diseases					

AM – Adult Male **CM** – Child Male

AF – Adult Female **CF** – Child Female

Please attach additional copies if required

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Health Protection Agency

Zero Leprosy Programme

Details of the students and teachers and other staff detected

No.	Indicate student/teacher/other staff	Name	National ID/ Passport	Age	Gender	Details of leprosy (PB/MB) (any deformity)	Action taken

AM – Adult Male **CM** – Child Male

AF – Adult Female **CF** – Child Female

Please attach additional copies if required

Annex 8

Health Protection Agency

Zero Leprosy Programme

Steroid Card

Name: ..... National ID/ Passport:..... Age:..... Sex:..... Type 1.....Type 2..... THIS PERSON IS ON LONG TERM STEROID TREATMENT FOR LEPRA REACTION Steroid:..... Address:..... .... Emergency Contact No:	Date of steroid commencement: Hosp. No/ register no.: .... Hospital address: .... Signature of Doctor: Date: .....

Health Protection Agency

Zero Leprosy Programme

Reporting for Monitoring Purposes

The Public health unit at Island level is responsible for this reporting (monthly/quarterly/annually)

Island:			Reporting period: From: _____ To: _____		
No. New leprosy cases registered during the reporting period	No. contacts enumerated	No. Contacts examined	Total no. of contacts found eligible for PEP	Total no. contacts for whom of PEP administered as single dose rifampicin	Remarks if any

Please attach additional copies if required

Health Protection Agency

Zero Leprosy Programme

Follow-up of Contacts who Received Single Dose Rifampicin as PEP

The Public health unit at Island level is responsible for this reporting (monthly/quarterly/annually)

Island:			Reporting period: From: _____ To: _____	
No. contacts for whom of PEP administered as single dose rifampicin (Cumulative) (Colum 1)	Out of column No. 1 Contacts examined (Colum 2)	Percentage of contacts examined (Colum 3)	No. contacts developed leprosy (Colum 2)	If any contact developed leprosy, give details

Please attach additional copies if required

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Annex 11

20.9 Details for whom PEP administered as Single dose Rifampicin:

Health Protection Agency

Zero Leprosy Programme

Details for Whom PEP Administered as SDR

1	Name of the contact for whom Single dose Rifampicin administered	
2	Date of birth /Age	
3	Gender	
	Body weight of the person	
4	Name of the index cases	
5	Registration number of index case	
6	Type of contact (relationship with index case)	
7	Date of contact screening	
8	Inclusion criteria (Yes /No) specify	
9	Exclusion criteria	
9 a	Pregnancy Y/N	
9 b	Rifampicin therapy for any reason in the last two years (e.g. for tuberculosis [TB] or leprosy treatment, or as a contact from another index case) Y/N	
9 c	History of liver disorders (ask for H/o jaundice, right sided abdominal pain and swelling, swelling in legs and ankles, pale coloured stool) Y/N	
9 d	History of renal disorders (ask for H/o decreased urine output, swelling in legs and ankles, H/o high BP) Y/N	
9 e	Possible signs and/or symptoms of leprosy. Y/N	
9 f	Presence of acute febrile illness. Y/N	
10	Whether eligible for chemoprophylaxis: Y/N	
11	Date of Rifampicin administered	
12	Dosage of Rifampicin administered	
13	Name and designation of Medical officer who administered SDR	
14	Signature of Medical officer who administered SDR	
15	Name and designation of person responsible in the Public health unit at Island level who is responsible for the follow up	

*Consent should be obtained from the person for whom SDR will be administered (In case of a child, consent should be obtained from the guardian)

Annex 12: Communicable Disease Notifying Form

Communicable Disease Notifying form

Health Protection Agency
Male', Republic of Maldives

V8 - Oct - 2019

Reporting Facility	☐ *Re-notification (required for changes in diagnosis (e.g. Dengue Fever to DHF), case confirmation or outcome (e.g. death)

Notifiable Diseases (Place ✓ appropriately)

Immediately notifiable via form and Telephone (✆+960 3014496/contact HPA surveillance focal point)	Notifiable within 24 hrs. to HPA via email (surveillancereportshpa@gmail.com) or fax (+9603014484)
☐ AEFI ☐ Acute Flaccid Paralysis (use Polio investigation form) ☐ Cholera ☐ Diphtheria ☐ Encephalitis (specify organism if known) ☐ Food Poisoning (use investigation form) ☐ Measles (complete measles investigation form) ☐ Meningitis (specify organism of known) ☐ Mumps ☐ MERS (Middle East Respiratory Syndrome) ☐ Pertussis/whooping cough (use investigation form) ☐ Rabies ☐ Rubella/Congenital Rubella Syndrome (Use investigation form ☐ Shigella ☐ Tetanus / f Neonatal tetanus ☐ Tuberculosis (use TB investigation form) ☐ Yellow Fever	☐ Chikungunya f Zika (complete investigation form) ☐ DF/fDHF/fDSS ☐ GBS (Guillain-Barré syndrome) ☐ Hepatitis A / B / C / D / E (circle as appropriate) ☐ Hepatitis A / B / C / D / E (circle as appropriate) ☐ Leprosy ☐ Leptospirosis ☐ Malaria ☐ Plague ☐ Pyrexia of unknown origin (PUO) Pneumonia with cause ☐ Rota virus (complete Rota virus lab surveillance form) ☐ Scrub Typhus ☐ SARI (Severe Acute Respiratory Infection = ARI requiring hospital admission) ☐ Scabies ☐ STIs – Gonorrhea/Chlamydia/Genital warts/Genital Herpes (Circle as appropriate) ☐ Suphillis / ☐ Congenital Syphilis ☐ Typhoid / ☐ Paratyphoid (complete case investigation form) ☐ Toxoplasmosis / ☐ Congenital toxoplasmosis ☐ Others (specify) _____

Case Details (Mandatory fields are marked with (*) and underlined. Please make sure to complete them.

1-*Case classification: Suspect ☐ Probable ☐ Confirmed ☐ (as per surveillance case definition)

2-*Patient National ID No: A _____ For foreigners include passport number	3- *Patient Name:	4- *Age:	5- *Sex: ☐ M ☐ F if pregnant ☐
6-*Patient's residential Address with Atoll/Island (Usual address of residence)	**7-*Patient's permanent Address with Atoll/Island**	**8-Contact Number**	**9-Nationality** country of origin

10-*Date of onset of illness: DD / MM / YYYY	**11-Date of consultation:** DD / MM / YYYY
12-*Patient category ☐ **Out-patient** ☐ **in-patient:** ☐ Ward _____ Bed _____ ☐ ICU _____ Bed _____	**13-*Case outcome:** ☐ Death ☐ On treatment ☐ Referred to higher center ☐ Recovered with disability ☐ Recovered fully
14-Recent travel history (include countries/islands visited) **14-Dates of travel** DD / MM / YYYY	***if on treatment, specify what is being given**
16-Clinical details (include risk factors, mode of transmission, etc.)	**17-Laboratory Confirmation:** ☐ Confirmed: Test specifics _____ ☐ If Requested, Date: DD / MM / YYYY
18-Condition of patient: ☐ Stable ☐ Sick ☐ Critically ill	☐ Not Requested
Notifiers details (e.g.: Dr, Nurse, HW or another designated person) Name: _____ Designation: _____ Contact number: _____ Signature: _____ Date: DD / MM / YYYY	**Data entry use** (use by PHUs and entry users) Date received: DD / MM / YYYY Date of entry: DD / MM / YYYY Checked and entered by: _____

Annex 13: Leprosy Treatment Card

LEPROSY TREATMENT CARD

Health Protection Agency / Ministry of Health
Respiratory Medicine Clinic (RMC)
Male' Republic of Maldives
National leprosy Control Programme

Leprosy No.:	Registration Date:	Positive (+vc)			MB		
		Negative (-vc)			PB		

Name:.....

Age: ( ) Sex: Male ( ) Female ( )

Permanent Address: .....

.....

Treatment Supervisor:

Contact Address:

Any Treatment Before? Yes: ( ) No: ( ) Last regimen ( ) Was full treatment completed? Yes: ( ) No: ( )

When? ( ) Where? ( )

Contact History:

Method of case finding

Voluntary	Hose Hold Survey	Date of Cure		
School Survey	Contact Survey	Cured		
Referred	Others	Without Disabilities Grade 2		
		With Disabilities Grade 2		

Back Side

Front Side

TREATMENT								Treatment Start Date																							
Month	Dapsone							Rifampicine								Clofazimine								Lamprene							
	mg			No. Tab				mg				No. Tab				mg				No. Tab				mg				No. Tab			
	1	2	3	4	5	6	7	0	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31

REMARKS

Case closed ☐ Date of closure

Treatment Stopped date

Treatment Outcome

Signature:

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Clinical Examination

A. Assesment of Skin Lesion:

Type	:	Mascules / Papules / Plaque / Nodules
Number	:	Single / Few / Many / Numerous
Distribution	:	Symmetrical / Asymmetrical
Size	:	Large / Medium / Small
Colour	:	Erythmatous / Hypopigmented / hyperpigmented
Margins	:	Well defined / Ill defined
Surface	:	Dry / Smooth / Shiny / Scaly
Infiltration	:	Yes / No specify the areas
Sensation	:	Normal / Impared / Absent
Warmth	:	Yes / No

A. Nerves Assessment:

G. Auricular	Normal		Enlayed -		Tende
Radial	R	L	R	L	R
Median					
Ulnar					
R. Cutaneous					
L. Popliteal					
Post Tibial					

C. Others:

Extremeties	R	L	Lower Limb	R
Upper Limb			Normal	
Normal			Claw toes	
Claw Finger			Foot Drop	
Contracture			Contracture	
Fissure			Fissure	
Blister/Ulcer			Blister/Ulcer	
Absortion of Digits			Absortion of Toes	

D. Complications:

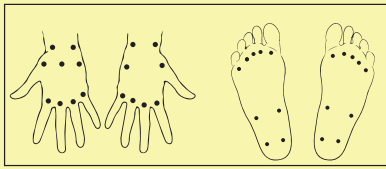
Type - I Reaction
Type - II Reaction
Neuritis :
Eye Complication :
Ulcers :

E. Other Medical Problems:

SENSATION TEST

Key : Test here | Wound | Clawing
Feels | Open Crack | Shortening Level
Does not feel | Sometimes feels. Sometimes does not feel

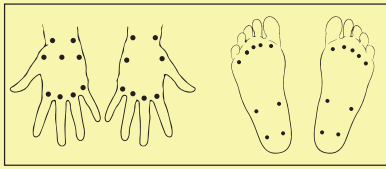
1. **RIGHT Palm LEFT** **RIGHT Palm LEFT**



Comments :

Examiner : **Date :**

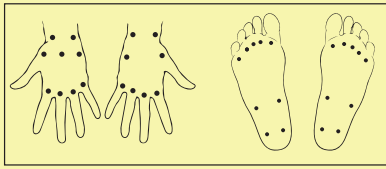
2. **RIGHT Palm LEFT** **RIGHT Palm LEFT**



Comments :

Examiner : **Date :**

3. **RIGHT Palm LEFT** **RIGHT Palm LEFT**



Comments :

Examiner : **Date :**

Contact Tracing Sheet

No	Name	Permanent Adress:	Age	Sex	Others

LEPROSY CONTACT TRACING AND SCREENING FORM

Reporting Facility:	**Form No:**

Case Details (Mandatory fields are marked with (*) and underlined. Please make sure to complete them.

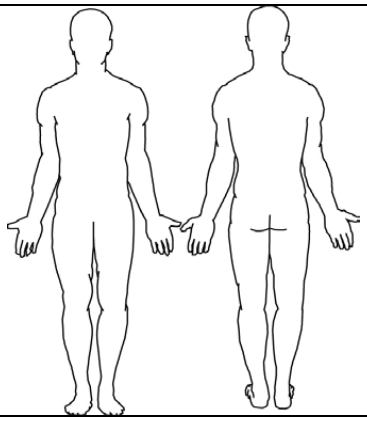
1-*Case classification: Suspect ☐ Probable ☐ Confirmed ☐ Screening ☐

2-* ID No: For foreigners include passport number	**3-* Name:**	**4-*Age:** YY / MM	**5-*Sex:** ☐M ☐F If pregnant ☐
6- *Permanent Address:	**7-*Atoll/Island:**	**8-*Contact number):**	**9-Foreigner** ☐ Yes ☐ No
10-*Residential Address:	**11. Country of Origin (Nationality):**		

12- History

Complaints:	
Symptoms:	
Duration:	
Contact history:	
Associated diseases:	
Treatment:	

13-Examination:

Skin lesions:	
Nerves:	
Other systems:	

14- Recommendations:		**15- Investigator Details**
Follow up within:		Name:_____
Investigations:		Designation: _____
Refer:		Signature: _____
Treatment:		Date: DD/ MM/ YYYY

For further information or inquiries, please contact:
Health Protection Agency, Ministry of Health,
Roshanee Building, Sosun Magu, Male'.
Tel:+960-3014 496, Hotline: +960-3014 333, Fax: +960-3014 484
Forms and case definition booklet are available on http://www.hpa.gov.mv , http://www.health.gov.mv

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- *https://www.leprosy-information.org/resource/ilep-learning-guide-one-how-diagnose-and-treat-leprosy*
- *(Further reading: refer to e-module on "Diagnosis of leprosy" and "Treatment for leprosy" (module 2 & 3) developed by WHO. http://labs.enablingdimensions.com/Leprosy/)*