وزارة الصحة
Ministry of Health

Saudi Arabia
Leprosy Guideline

First Edition 2021

Deputyship for Public Health

General Directorate for Control of Infectious Diseases

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Preface

The Deputyship for Public Health (DPH), Ministry of Health (MOH), Kingdom of Saudi Arabia strives for continuously keeping healthcare workers (HCWs), throughout the Kingdom, abreast of recent advances in public health surveillance of communicable diseases. The MOH realizes the critical importance of such activity in successful development and implementation of plans for control of communicable diseases and promotion of other related public health activities.

This book entitled: "Leprosy Guideline" is produced by the Directorate General for Control and Prevention of Communicable Diseases as part of its activities to further develop the capacities of a wide variety of health professionals, including academicians, practitioners, HCWs and students; especially in the field of surveillance. The scope of this book incorporates recent advances and updates in the information on the chain of infection of leprosy, summarizes recent accurate, reliable information on the epidemiology of the disease in the Kingdom. The book describes the role of different levels of HCWs in the MOH and the private sector in implementing prevention and control measures, delivering medical care and health education.

Leprosy

Introduction

Leprosy (Hansen's disease) is a disease that predominantly affects the skin, peripheral nerves, eyes, and lining of the nose (nasal mucosa). This infection results in neuropathy and associated with long term consequences, including deformities and disabilities. The social stigma is usually associated with leprosy disease particularly when deformities are present. The leprosy cases continue to occur, regardless of the elimination of leprosy as a public health problem (defined as achieving a point prevalence of below 1 per 10000 population) globally in 2000 and at a national level in most countries by 2005. In 2016, more than 200000 new leprosy cases were reported. Thus, the preventive measures including early detection and proper treatment of leprosy cases is crucial for reducing the burden of this disease.

The Leprosy is classified as paucibacillary (PB) or multibacillary (MB) according to the following criteria:

- The number of skin lesions.

- Presence of nerve involvement.

- Identification of bacilli on slit skin smear.

The description of standard treatment depend on the type of leprosy (PB or MB) and age of the patient (adult or child). The multi drug therapy (MDT) two or three drugs. In addition to, the duration of treatment, dose and number of antibiotics. World health organization (WHO)reported the strategies to prevent leprosy include vaccination or use of prophylactic antibiotics among persons with exposure.

Leprosy control programme in Saudi Arabia coincide with the WHO strategies for diagnosis and treatment of leprosy cases by MDT for more than three decades. This was culminated by achieving the elimination of leprosy in Saudi Arabia (achieving a point prevalence of below 1 per 10 000 population) (1,2).

The kingdom of Saudi Arabia adopted The Global Leprosy Strategy 2016–2020 launched by WHO "Accelerating towards a leprosy-free world" aims at early detection of leprosy disease and prompt treatment to prevent disability and reduce transmission of infection in the community. The proportion of G2D cases among newly diagnosed patients and the G2D rate in a population indicate the efficiency of early detection of leprosy. They also indicate indirectly the

awareness levels of early signs of leprosy, access to leprosy services and skills of health-care staff in diagnosing leprosy. The strategy is designed to achieve a long-term goal of a 'leprosy-free world", which refers to a situation wherein the community is free of morbidity, disabilities and social consequences due to leprosy.

Vision

The vision of the Programme strategy is a leprosy-free Kingdom.

Goal

The goal of the strategy is to further reduce the local leprosy burden (To eliminate leprosy in Saudi Arabia (achieving a point prevalence of below 1 per 10 000 population).

Objective of the leprosy programme:

The envisioned targets by the Strategy by 2020 include the following:

- Zero G2D among paediatric leprosy patients.
- To reduce G2D among new leprosy cases to less than one case per million population.
- Zero legislation allowing discrimination on basis of leprosy.

Guiding principles:

- Governmental commitment and responsibility to increase collaboration and strengthening partnerships at national and subnational level.
- Sustaining expertise in leprosy
- Emphasize provision of sustainable leprosy services with high quality which meets the patients need including children and women as well as satisfaction of health care providers.
- Consider the participation of leprosy patients and their community in planning for leprosy services.
- Ensure equity and protection of human rights
- Encourage research to study different elements of leprosy control program.

Elimination: means bringing the disease burden down to a very low level.

Strategic pillars

- Strengthen government ownership, coordination and partnership.
- Stop leprosy and its complications
- Stop discrimination and promote inclusion

Case definition:

A case of leprosy is a patient present with at least one of three cardinal signs:

(i) Definite loss of sensation in a pale (hypo pigmented) or reddish skin patch;

(ii) Thickened or enlarged peripheral nerve with loss of sensation and/or weakness of the muscles supplied by that nerve; or

(iii) Presence of acid - fast bacilli in a slit skin smear.

Other diagnostic tests are:

- ELISA
- PCR

Paucibacillary (PB) case:

A case of leprosy with 1 to 5 skin lesions and without demonstrated presence of bacilli at a skin smear;

Multibacillary (MB) case:

A case of leprosy with >5 skin lesions; or with nerve involvement (pure neuritis or any number of skin lesions and neuritis); or with demonstrated presence of bacilli in a slit skin smear irrespectively from the number of skin lesions.

New case:

A patient diagnosed with leprosy that 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 multi-bacillary (MB) cases;

Relapse:

A patient who has completed a full treatment course for leprosy in the past and returns with signs and symptoms of the disease which are not deemed due to a reaction according to the clinician.

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.

Treatment outcome:

Treatment completed within standard duration; 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);

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.

Transferred out:

Patients diagnosed with leprosy who started treatment in one health facility that recorded them and then have been transferred to another health facility (as much as possible such patients shall be assigned a treatment outcome enquiring with the referral health facility).

Died:

Patients who have been diagnosed with leprosy and died due to any cause during the course of treatment.

Insufficient/unsatisfactory clinical response to treatment:

Patients who despite adequate treatment do no respond clinically.

Symptoms and Signs of Leprosy

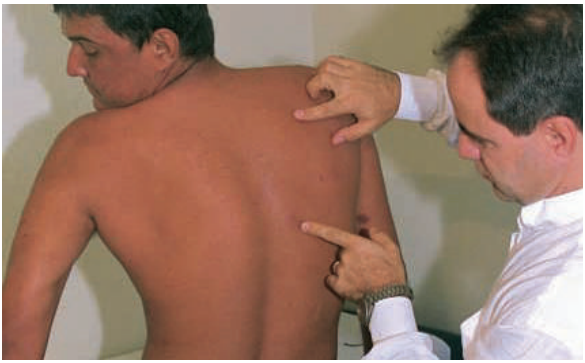
- Skin patch or patches with a definite loss of sensation;

Leprosy patches:

- Can be pale or reddish or copper-colored
- Can be flat or raised;
- Do not itch; Usually do not hurt;
- Lack sensation to heat, touch or pain;
- Can appear anywhere.
- Other signs of leprosy include:
- Reddish or skin-colored nodules or smooth, shiny diffuse thickening of the skin without a loss of sensation.

Leprosy patches... can be pale or reddish or copper- colored

How to examine a Patient for leprosy



In case you suspect leprosy disease without sensory loss or have any doubts, please refer the patient to infectious disease consultant or dermatologist.

- Examine the skin in daylight or in a well-lit room.
- Examine the whole body, taking care to respect the patient's privacy.
- Ask the patient if the patch itches. If so, it cannot be leprosy.
- Test only one or two skin patches for sensory loss. If there is a definite loss of sensation, it is leprosy.
- Ask about treatment received in the past.
- A person who has completed a full course of MDT very rarely needs further treatment. Look for any visible disability of eyes, face, hands and feet.
- When in doubt about the diagnosis, always send the patient to the nearest referral center.

Definitions of disability:

1- Hands and feet:

- Grade 0 = No anaesthesia, no visible deformity or damage
- Grade 1 = Anaesthesia, but no visible deformity or damage
- Grade 2 = Visible deformity or damage present

2 - Eyes:

- Grade 0 = No eye problems 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 meters)
- Grade 2 = Severe visual impairment (vision worse than 6/60; inability to count fingers at 6 meters), lagophthalmos, iridocyclitits, corneal opacities.

Mode of transmission

- The exact mode of transmission of leprosy is not well known and poorly understood.
- Transmission may be through inhalation of droplets containing the causative agent, (M. leprae). However, transmission via skin contact or other means cannot be entirely excluded.
- The leprosy cannot be transmitted by a casual contact with a persons who has leprosy disease like:
  - Hands shaking or hugging
  - Sitting next to each other on the bus
  - Sitting together at a meal

Incubation period:

It progresses slowly and it is variable, ranging from 2 to 20 years with an average incubation period of 3 years.

Susceptibility:

Leprosy can affect all ages and both sexes.

Laboratory diagnosis of leprosy:

Hansen's disease is diagnosed based on clinical presentation and the diagnosis is confirmed by skin or nerve biopsy and acid fast staining.

Some serological tests have been developed and promoted by some investigators, but they lack sufficient sensitivity and specificity to be used as diagnostic tests. For this reason they are not used to diagnose Hansen's disease. (1)

Specimens and Tests

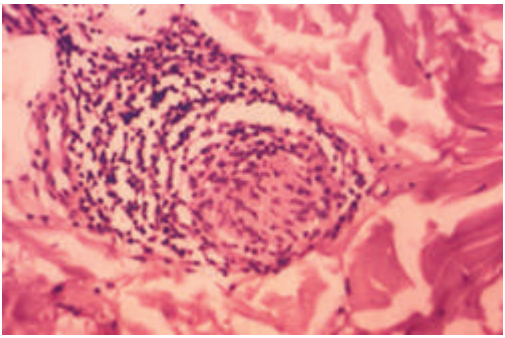
Depending on the form of leprosy suspected by the treating physician, the following specimens may be collected(1):

1. Skin smears from the earlobes, elbows, and knees
2. Skin biopsy from edges of active patches
3. Nerve biopsy from thickened nerves

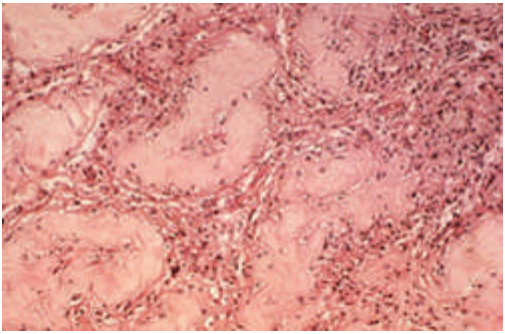
Skin and nerve biopsy:

Biopsies are needed to definitively confirm a diagnosis of Hansen's disease and to classify the disease, and slit skin smear may also be helpful in diagnosing those with multibacillary disease. (1)

In the Multibacillary form of Hansen's disease, tissue biopsy of various affected sites may reveal typical histopathologic changes that show large numbers of foam cells. Foam cells are macrophages that have ingested, or phagocytized, M. leprae bacteria, but are unable to digest the organisms, who in turn multiply and use the macrophage as a method of transport throughout the body. This is how the bacteria cause the multiple lesions that may appear in all parts of the body in MB leprosy patients. Photomicrograph reveals some of the classic histopathologic changes found in a skin section from an individual with a case of the leprosy(1)



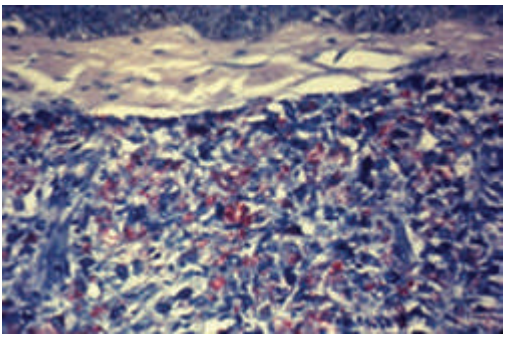
This photomicrograph reveals some of the classic histopathologic changes found in a skin section from an individual with a case of the leprosy, which may have been the Paucibacillary form of the disease, though this has not been confirmed. Shown here is a nerve surrounded by a dense infiltrate consisting of undifferentiated histiocytes and large numbers of lymphocytes. The nerve sheath and endoneural region of the nerve were also infiltrated. This neural involvement was found to be independent of any pathology of the upper corium.



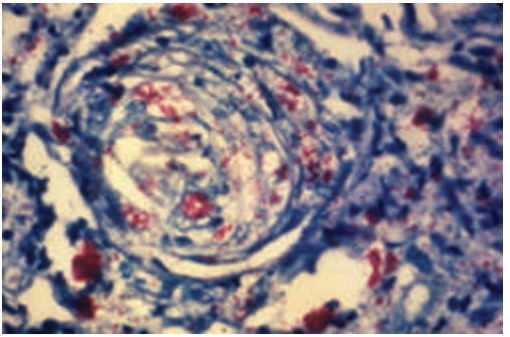
Photomicrograph reveals some of the histopathologic changes in a specimen of human testicular tissue. This photomicrograph reveals some of the histopathologic changes in a specimen of human testicular tissue, which included a large number of “foam cells”. These changes were attributed to a case of Multibacillary (MB) leprosy.

Acid fast staining

The Ziehl-Neelson method using 5% sulphuric acid as decolorizing agent is used. The presence of acid-fast bacilli confirms the diagnosis of Hansen's disease.



Acid-fast-stained photomicrograph of a tissue sample extracted from a patient. This acid-fast-stained photomicrograph of a tissue sample extracted from a patient with leprosy shows a chronic inflammatory lesion known as a granuloma, within which numerous red-colored M. leprae bacteria are visible.



Photomicrograph of a skin tissue sample from a patient with leprosy shows a cutaneous nerve. This photomicrograph of a skin tissue sample from a patient with leprosy shows a cutaneous nerve, which had been invaded by numerous M. leprae bacteria (shown in red).

Bacillary index is expressed in logarithmic scales (2):

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 sensitivity and specificity of the WHO classification has been reported to be around 90% (3)

Leprosy treatment:

Early detection is important for management and prevention of disability. The WHO new guidelines recommend a 3 drug regimen of rifampicin, dapsone and clofazimine for all leprosy patients. The duration of treatment depend on leprosy type, which will be treatment duration of 6 months for PB leprosy and 12 months for MB leprosy. This new regimens is differ from the current standard treatment for PB leprosy, which is rifampicin and dapsone for 6 months, due to some evidence indicating better clinical outcomes with a 3 drug, 6 month regimen over a 2 drug, 6 month regimen.

The potential advantages of using the same three drugs for PB and MB leprosy are:

- Simplification of treatment regimen (i.e. the same blister pack could be used for treating both types of leprosy).
- Reduced impact of misclassification of MB leprosy as PB leprosy, since all patients will receive a 3drug regimen. For MB leprosy, the current standard treatment is a 3drug regimen for 12 months.
- Simplified logistics since only two types of blister packs of drugs (adult and child) would be required.
- Potential benefits of clinical outcome of three drug regimen over

two drug regimen for treating the PB leprosy.

For rifampicin resistant leprosy, the WHO guidelines recommend treatment as following:

- at least two-second line drugs (clarithromycin, minocycline or a quinolone) plus clofazimine daily for 6 months,
- this to be followed by clofazimine plus one of these drugs for an additional 18 months.
- When ofloxacin resistance is also present, a fluoroquinolone should not be used as part of second line treatment. The regimen of choice in such cases shall consist of 6 months of clarithromycin, minocycline and clofazimine followed by clarithromycin or minocycline plus clofazimine for an additional 18 months.

Leprosy can be cured. MDT kills the bacteria and stops the spread of the disease. Leprosy patients can lead completely normal lives.

If detected early and treated with MDT, leprosy will not lead to disabilities.

Prevention of leprosy through chemoprophylaxis:

Single dose rifampicin (SDR) may be used as leprosy preventive treatment for contacts of leprosy patients (adults and children aged 2 years and above), after excluding leprosy and tuberculosis (TB) disease, and in the absence of other contraindications. This intervention shall be implemented only by programs that can ensure: (a) adequate management of contacts ,and (b) consent of the index case to disclose his/her disease.

The best way to prevent the spread of leprosy is early detection and to treat all patients with MDT.

MDT Regimens

- MB adult treatment for 12 months
- PB adult treatment for 6 months

Once a month: Day 1

– 2 capsules of rifampicin (300 mg X 2)

– 3 capsules of clofazimine (100mg X 3)

– 1 tablet of dapsone (100 mg)

Once a day: Days 2–28

– 1 capsule of clofazimine (50 mg)

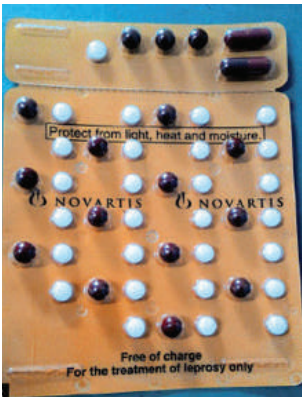
– 1 tablet of dapsone (100 mg)

· MB child (10-14 years) treatment for 12 months

· PB child (10-14 years) treatment for 6 months

· MB child (<10 years or < 40kg body weight) treatment for 12 months

· PB child (<10 years or < 40kg body weight) treatment for 6 months



Once a month: Day 1

2 capsules of rifampicin (300 mg+150 mg)

– 3 capsules of clofazimine (50 mg X 3)

– 1 tablet of dapsone (50 mg)

Once a day: Days 2–28

– 1 capsule of clofazimine (every other day) (50 mg)

– 1 tablet of dapsone (50 mg)

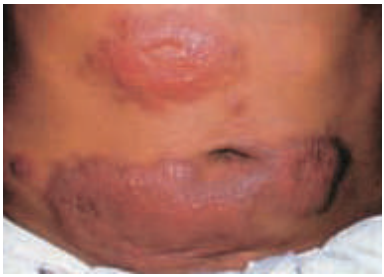
For children younger than 10 years old or less than 40 KG, the dose must be adjusted according to body weight. Rifampicin (10mg/kg once month), clofazimine (6mg/kg once a month and 1mg/kg daily), and Dapsone 2mg/kg daily.

Leprosy Reactions

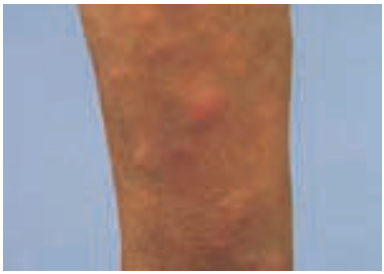
Patients can develop reactions, which are part of the natural course of the disease. Reactions are not a side effect of MDT. They are the body's response to leprosy and do not mean that the disease is becoming worse or that the treatment is not working.

Signs of reactions include:

- Existing skin lesions become reddish and swollen
- Painful reddish nodules appear
- Peripheral nerves become painful, tender and swollen
- Signs of nerve damage such as loss of sensation and muscle weakness
- Fever and malaise
- Hands and feet may be swollen.



Patients must continue to take MDT during a reaction



Reactions are not a side effect of MDT

Managing Leprosy Reactions:

- Reactions require urgent treatment with special medicines as they can lead to irreversible deformities.
- Give aspirin or paracetamol to reduce pain and fever.
- Advise the patients to rest as that is essential.
- Corticosteroids Maximum dose of prednisolone is 1 mg per kg of body weight.

· If you have a course of corticosteroids (e.g. prednisolone), please administer:

  - o 40 mg daily for weeks 1 and 2,
  - o 30 mg daily for weeks 3 and 4,
  - o 20 mg daily for weeks 5 and 6,
  - o 15 mg daily for weeks 7 and 8,
  - o 10 mg daily for weeks 9 and 10,
  - o 5 mg daily for weeks 11 and 12.

Important Points about MDT:

Safety:

- MDT is very safe and effective in curing leprosy.
- MDT is safe during pregnancy.
- MDT is safe for patients being treated for tuberculosis (TB) as well as those who are HIV-positive.
- Rifampicin is common to the treatment of leprosy and TB and must be given in the doses required for TB.

Common Side Effects of MDT:

Red colored urine;

This is due to the colour of rifampicin, which is taken once every month. This lasts for only a few hours after taking the drug. Please assure patient that it is harmless.

Darkening of skin;

This is due to clofazimine used daily for treating MB patients. This is harmless and will disappear within a few months after completing the treatment. Please encourage patient to take the medicines regularly.

Allergy

As with any medicine, some patients may be allergic to one of the drugs in MDT. Most commonly there will be severe itching and red /dark spots on the skin. In such cases, ask the patient to stop taking the medicines and refer him or her to the nearest hospital.

When Treatment is completed:

Congratulate the patient for the successful completion of treatment.

Thank family and friends who accompanied the patient for their support.

Reassure patients that they are completely cured of leprosy.

If patches are still visible, reassure the patient that these will gradually disappear.

If disabilities exist, tell patients how to protect themselves from injuries (see the table below).

Tell them to return to the health center if they have any questions or problems.

In the rare cases where patients may see a new skin patch, they must come back for check-up.

Health education messages:

- All leprosy patients will be cured of leprosy if they take the drugs in the blister packs as advised.
- Tell the patients, they must complete their treatment.
- The drugs stop the disease from spreading, and patients can lead normal lives.
- skin patches without sensation, which do not itch, can be leprosy,

- They can live at home, go to school, work, play, get married, have children, participate in social events, patients can lead perfectly normal lives.
- The MDT blister packs are free of charge.
- They should keep the blister packs in a dry, safe, and shady place and out of the reach of children.
- If the drugs are spoiled (changed color, broken), the health worker will replace them.
- The medicines will turn their urine red and their skin darker. Patients should not worry: both will return to normal once the treatment is completed.
- They must go immediately to a health center if they have any problems(pain, fever, malaise, new lesions, muscle weakness)
- Patients should return for a check-up after they complete their treatment.
- Patients with insensitive hands or feet injure themselves without noticing it.These wounds can get infected and over time, lead to irreversible deformities. The wounds should be managed just as you would any other cuts or wounds, dry skin, or eye problems.
- If they already have disabilities, tell them how to protect themselves from injuries.
- Whenever you refer a patient, write down details of the complaint, when this first occurred and medicines taken. Send this note with the patient to show to the doctor.
- patients who have completed their treatment are cured even if they have deformities,

Table 1: Simple measures to prevent disabilities

Affected body part	Recommendation
Feet	
Feet with dry cracks and fissures	Advise to soak feet for 20 minutes every day in water and apply cooking oil /Vaseline regularly. Advise to use shoes or slippers to protect their feet from injury.
Blister on the sole or between toes	Dress blister with clean cloth. Apply cotton wool and bandage.
Feet with ulcers without any discharge	Clean the ulcer with soap and water. Cover with clean dressing. Advise rest.
Feet with ulcers with discharge	Clean the ulcer. Apply antiseptic dressing. Advise rest. If no improvement in 4 weeks, refer to hospital.
Care of hands	
Injury on hand while working/cooking	Clean wound and apply clean dressing. Advise rest. Advise to use a cloth to protect the hands when touching hot or sharp objects.
Hands with dry cracks and fissures	Advise to soak hands for 20 minutes every day in water and to apply Vaseline or cooking oil regularly.
Care of eyes	
Patient presents with red eye, pain, blurring of vision and discharge	Give aspirin or paracetamol. If available, apply 1% atropine drops and steroid ointment. Keep eye covered with a pad. Whenever possible, advise to go to the hospital.
Patient with injury on cornea (corneal ulcer)	Apply antibiotic ointment. Keep eye covered with a pad. Wherever possible, advise to go to the hospital.

Reporting system:

The responsibilities of treating doctors:

- Notification and reporting: As stated in paragraph of reporting mentioned below:
- Confirm the diagnosis of the case: as mentioned in the standard case definition and laboratory investigations.
- Specific treatment for cases of leprosy: According to the type of leprosy mentioned above with consideration of the following:
    - Make sure the patient's comply to treatment, the duration of treatment and the use multi drugs therapy as described.
    - Educate the patients about leprosy and follow up until the patient cure.
    - Treat the disability if any and referred the patients to specialist.
    - Medical examination of the contacts.

Health care provider:

- Health centers and hospitals (governmental and nongovernmental) to fill the infectious disease reporting form for any suspected case, and send the patients for consultation either to infectious disease or dermatology clinics. Notify this suspected case to director of health institution or public health officer, who will notify the coordinator of TB and leprosy program at directorate of health affairs.
- Public or private hospitals (infectious disease or dermatology clinics) to fill the leprosy notification form and the leprosy epidemiological form for confirmed cases. Prepare weekly report to public health officer in the institution, who will send this report to the coordinator of TB and leprosy program at directorate of health affairs.
- Laboratory: to notify confirmed cases to coordinator of TB and leprosy program or TB field teams within a week
- The TB and leprosy program coordinator at the Public health department: Collection of notifiable disease forms sent from the health institutions and notify these cases monthly to the National TB and leprosy at ministry of health. Also to coordinate for preventive measure including contacts investigation.

NB: In the health facilities without equipped labs to perform confirmatory test for suspected leprosy cases as stated in the definition of a standard case, or there is no possibility of providing the required health care, to refer the case or send the sample to the nearest health institution or to the highest level of health care, where the required tests and health care are available (depending on the system used).

Leprosy Patient card

Identification Data

Name _____

Sex (M / F) Age _____ Nationality _____ Occupation _____

Address _____

Mobile _____ Telephone _____

<table>
<tr><td>Number of skin lesions</td><td colspan="2"></td><td colspan="4" rowspan="5">Remarks (Any complaints, referrals, other events like default and death)</td></tr>
<tr><td>Classification</td><td>PB (1–5 patches)</td><td>MB (more than 5)</td></tr>
<tr><td>Date of detection</td><td colspan="2"></td></tr>
<tr><td>Visible disability on detection</td><td>Yes</td><td>No</td></tr>
<tr><td>Date of first dose of MDT</td><td colspan="2"></td></tr>
<tr><td rowspan="2">Number of doses given</td><td>2</td><td>3</td><td>4</td><td>5</td><td colspan="2">6 large dose for PB</td></tr>
<tr><td>7</td><td>8</td><td>9</td><td>10</td><td>11</td><td>12 last dose for MB</td></tr>
<tr><td>Accompanied MDT given</td><td>Yes</td><td>No</td><td colspan="3"></td></tr>
<tr><td>Date of cure</td><td colspan="2"></td><td colspan="4"></td></tr>
</table>

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WORLD LEPROSY DAY