Chapter: 7

Classification & Management of Leprosy

Structure

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Learning Objectives: At the end of the session trainees will be able to

- Describe principle of using MDT and assign appropriate fixed duration regimen to LAP
- Enumerate side effects of MDT and describe the management of side effects
- Enumerate Instructions to be given during counseling to ensure regularity and completion of treatment

Teaching methods – Lecture discussion, demonstration of MDT BCPs, case studies, exercises
7.1 Introduction

Very effective treatment is available for cure of leprosy. Person affected with leprosy is treated with combination of drugs called Multi-Drug Therapy (MDT). MDT is available free of cost at all the health care facilities. Drug is taken orally and is available in blister packs containing drugs for 28 days (four weeks taken as one month of regimen).

7.2 Grouping of leprosy

To assign the correct regimen for treatment of a leprosy patient, they are grouped into either Paucibacillary or Multibacillary types of leprosy, based on the number of skin and nerve lesion and bacteriological status. This is important because it helps in selecting the correct combination of drugs (regimen) for a given person.

7.2.1 Criteria for grouping

<table>
<thead>
<tr>
<th>S. No.</th>
<th>Characteristic</th>
<th>PB (Pauci bacillary)</th>
<th>MB (Multi bacillary)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Skin lesions</td>
<td>1 – 5 lesions</td>
<td>6 and above</td>
</tr>
<tr>
<td>2</td>
<td>Peripheral nerve involvement</td>
<td>No nerve / only one nerve with or with out 1 to 5 lesions</td>
<td>More than one nerve irrespective of number of skin lesions</td>
</tr>
<tr>
<td>3</td>
<td>Skin smear</td>
<td>Negative at all sites</td>
<td>Positive at any site</td>
</tr>
</tbody>
</table>

Note: If skin smear is positive irrespective of number of skin and nerve lesions, the disease is classified as MB leprosy but if skin smear is negative it is classified on the basis of the number of skin and nerve lesions.

7.2.2 Treatment of leprosy

7.3.1 Drugs used in MDT

The treatment of leprosy is in the form of Multi Drug Therapy (MDT), which is the combination of two or three of the following drugs:

- Cap. Rifampicin
- Tab. Dapsone
- Cap. Clofazimine
7.3.2 Standard regimen of MDT

Four types of standard regimens are available in blister packs for treatment of leprosy

MDT is provided in convenient-to-use blister calendar packs (BCPs) with medicine for four weeks or 28 days, which is loosely referred to as one month. BCPs for PB leprosy contain two medicines and that for MB leprosy contain three medicines. BCPs for children contain the same medicines as the BCPs for adults but in smaller doses.

PB Adult: For people with PB leprosy and 15 years of age or more
MB Adult: For people with MB leprosy and 15 years of age or more
PB child: For people with PB leprosy and 10-14 years of age
MB child: For people with MB leprosy and 10-14 years of age

Blister packs are not available for children under 10 years of age. Treatment of children belonging to this age group is given after calculating the dose according to their body weight. Recommended daily doses as per kilogram of body weight (Kg bw) are:

- Rifampicin: 10 mg/ kg body weight, monthly once
- Clofazimine: 1 mg /kg body weight daily and 6 mg/kg body weight, monthly once
- Dapsone: 2 mg /kg body weight daily

7.3.3 Duration of treatment

Leprosy persons with PB leprosy need 6 months treatment that must be completed in maximum of 9 consecutive months. This means PB leprosy person cannot miss a total of more than 3 pulses during treatment. MB leprosy person needs 12 months treatment that must be completed in 18 consecutive months. All the efforts must be made to complete 6 pulses in 6 months for PB cases and 12 pulses in 12 months for MB cases.

Note: Rarely, specialists may consider treating a person with high bacterial index for more than 12 months; decision is based on clinical and bacteriological evidence.
Table showing recommended dose of MDT for person affected by leprosy

<table>
<thead>
<tr>
<th>Type of leprosy</th>
<th>Drugs used</th>
<th>Frequency of Administration Adults (children in bracket)</th>
<th>Dosage (adult) 15 years &amp; above</th>
<th>Dosage (Children 10-14 years)#</th>
<th>Dosage Children Below 10 years*</th>
<th>Criteria for RFT</th>
</tr>
</thead>
<tbody>
<tr>
<td>MB leprosy</td>
<td>Rifampicin</td>
<td>Once monthly</td>
<td>600 mg</td>
<td>450 mg</td>
<td>300 mg</td>
<td>Completion of 12 monthly pulses in 18 Consecutive months</td>
</tr>
<tr>
<td></td>
<td>Clofazimine</td>
<td>monthly</td>
<td>300 mg</td>
<td>150 mg</td>
<td>100 mg</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Dapsone</td>
<td>Daily</td>
<td>100 mg</td>
<td>50 mg</td>
<td>25 mg</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Clofazimine</td>
<td>Daily for adults (every other day for children)</td>
<td>50 mg (alternate day, not daily)</td>
<td>50mg (weekly twice)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PB leprosy</td>
<td>Rifampicin</td>
<td>Once monthly</td>
<td>600 mg</td>
<td>450 mg</td>
<td>300mg</td>
<td>Completion of 6 monthly pulses 9 consecutive months</td>
</tr>
<tr>
<td></td>
<td>Dapsone</td>
<td>Daily</td>
<td>100 mg</td>
<td>50 mg</td>
<td>25 mg daily or 50 mg alternate day</td>
<td></td>
</tr>
</tbody>
</table>

* For children below 10 years, doses (as per kg body wt) should be provided loose (capsules/tablets) after opening appropriate BCP.

# For children between 10-14 yrs whose body weight is greater than 35 kgs, adult BCP should be given.

### 7.3.4 Advantages of Multi Drug Therapy (MDT)

- MDT kills bacilli (M. leprae) in the body. It stops the progress of the disease, prevents further complications and reduces chances of relapse.
- As the M. leprae are killed, the patient becomes non-infectious and thus the spread of infection in the body is reduced. Moreover, chances for transmission of infection to other persons are also reduced to a considerable extent.
- Using a combination of two or three drugs instead of one drug ensures effective cure and reduces chances of development of resistance to the drugs.
- Treatment with multi-drug therapy reduces duration of the treatment.
- Duration of treatment is short and fixed.
- MDT is safe, has minimal side effects and has increased patient compliance.
- Available in blister pack; easy to dispense, store and take.

Indications for prescribing MDT

- **New case of leprosy:** Person with signs of leprosy who have never received treatment before.
- **Other cases:** Under NLEP all previously treated cases, who need further treatment are recorded as “other cases”. It has been decided that all migrant cases from another state reporting at any state Health Institution will also be grouped under this category. Other cases include both PB & MB cases (Please refer Annexure XI)

Categorization of other cases (recorded for PB and MB)

(a) **Relapse Cases of PB/MB:** – Persons who have developed new lesion at any time after the completion of a full course of treatment. Diagnosis must be evidence based and must be made after adequate screening. Cases receive the same treatment as a new case of PB/MB leprosy depending on the current classification.

(b) **Reentered for treatment (include defaulters)** - These are previously treated cases, where clinical assessment shows requirement of further treatment and patient admits that treatment was not completed. Defaulters are included in this category. Defaulter is a person who fails to complete the treatment within maximally allowed time framework i.e. 6 pulses in nine consecutive months for PB leprosy and 12 pulses in 18 consecutive months for MB leprosy. On retrieval of defaulter, reassess the person for classification and disability status and start the treatment as a fresh case but register the case as reentered patient (Other cases) and not a new case.

(c) **Referred cases** – Patient referred for completion of treatment (remaining doses) by tertiary or second level institutions after diagnosis and issue of first dose, or from another Health centre on patients request or migratory patient from another District/State. All referred cases should have a referral slip showing diagnosis and remaining doses to be given.
(d) **Change in classification** – Persons with PB leprosy; reclassified as MB leprosy due to appearance of more lesions (skin lesions or nerve involvement/ become smear positive) during the treatment and need full course of MB treatment.

(e) **Cases from outside the state & Temporary migration or cross border cases.**

Before deciding a case to be recorded as from other state, the residential status at the place of diagnosis is carefully examined. A person who has migrated and is residing for **more than six months**, is likely to stay till completion of treatment, and recorded as indigenous case and will not be categorized under “other cases”.

Information regarding other cases is shown separately in the monthly progress reports. Once it has been decided that a person needs treatment, register the person in Leprosy Treatment register and make the Leprosy Record Card. Take care to indicate type of patient (new/others) correctly. Decide the regimen and counsel the person (Refer section 11.6. and chapter on counselling).

### 7.3.6 Assessing fitness of a leprosy patient for MDT

Before starting treatment, you must look for the following:

- **Jaundice**: If the patient is jaundiced, wait till jaundice subsides.
- **Anaemia**: If the patient is anaemic, start treatment for anaemia simultaneously along with MDT.
- **Tuberculosis**: If the patient is taking Rifampicin, ensure that he continues to take Rifampicin in the dose required for the treatment of tuberculosis along with other drugs in the regimen required for the treatment of leprosy.
- **Allergy to sulpha drugs**: If the patient is known to be allergic to sulpha drugs, avoid Dapsone. Refer person for prescription of alternate drug regimen.

### 7.3.7 Assigning appropriate MDT regimen

Based on the grouping, the patients may be given any one of the standard MDT regimen mentioned below.

In children, the dose must be adjusted suitably. When the patient has completed the required number of doses the treatment is stopped and RFT (Released from Treatment) is written against the name of the person in the leprosy treatment register

**MDT regimen**

First dose containing rifampicin, Clofazimine and Dapsone for MB leprosy and rifampicin and dapsone for PB leprosy as indicated in the figure is given once in a month on first day of every month (Day 1 of every BCP) in front of the health worker (under direct observation). Following this daily dose of Dapsone and Clofazimine for MB and only Dapsone for PB leprosy is taken by the affected person at home for next 27 days. Six such pulses for PB must be completed within 9 months or less where as 12 pulses of MB must be completed in 18 months or less.
7.3.8 Treatment of leprosy during pregnancy

MDT is safe and can be continued during pregnancy.

7.3.9 Treatment of leprosy & tuberculosis

MDT is continued but rifampicin is omitted from MDT for leprosy and is given in the doses recommended as per guidelines of RNTCP (Revised National Tuberculosis Control Programme)

7.3.10 Treatment of leprosy in HIV positive patients

MDT for leprosy can be safely given to HIV affected persons and to those on antiretroviral therapy.
### 7.3.11 Side effects of anti-leprosy drugs and its management

**DAPSONE**

<table>
<thead>
<tr>
<th>Side effects</th>
<th>Signs and symptoms</th>
<th>What to do if side effects occur</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Minor</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anaemia</td>
<td>Paleness inside the lower eyelids, tongue and fingernails, Tiredness, oedema of feet and breathlessness</td>
<td>Give anti-worm treatment and iron and folic acid tablets. Continue dapsone.</td>
</tr>
<tr>
<td>Abdominal symptoms</td>
<td>Abdominal pain, nausea, and vomiting with high doses</td>
<td>Symptomatic treatment. Reassure the patient Give drug with food</td>
</tr>
<tr>
<td><strong>Serious</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Severe skin complication (Exfoliate dermatitis)</td>
<td>Extensive scaling, itching, ulcers in the month and eyes, jaundice and reduced urine output Itchy skin rash</td>
<td>Stop Dapsone. Refer to hospital immediately. Never restart.</td>
</tr>
<tr>
<td>Sulphone hypersensitivity</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Haemolytic anaemia</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Liver damage</strong></td>
<td>Jaundice (yellow Colour of skin, eyeballs and urine) Loss of appetite and vomiting</td>
<td>Stop Dapsone. Refer to hospital Restart after the jaundice subsides</td>
</tr>
<tr>
<td>(Hepatitis)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Kidney damage</strong></td>
<td>Oedema of face and feet. Reduced urine output</td>
<td>Stop Dapsone. Refer to hospital</td>
</tr>
<tr>
<td>(Nephritis)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Dapsone may cause haemolysis of red blood cells. People with glucose-6-phosphatase dehydrogenase deficiency are more susceptible to haemolysis. It is usually mild and symptom less. Methaemoglobinemia may also occur due to dapsone therapy. Lips and nails may develop blue hue that may disappear spontaneously or on reducing the dose and is not an indication to interrupt therapy. Both are rare in therapeutic doses used for leprosy.
### RIFAMPICIN

<table>
<thead>
<tr>
<th>Side effects</th>
<th>Signs and symptoms</th>
<th>What to do if side effects occur</th>
</tr>
</thead>
<tbody>
<tr>
<td>Minor adverse effects</td>
<td>Red discoloration of body fluids</td>
<td>Reddish coloration of urine, saliva and sweat</td>
</tr>
<tr>
<td>Flu like illness</td>
<td>Fever, malaise and body ache</td>
<td>Symptomatic treatment</td>
</tr>
<tr>
<td>Abdominal symptoms</td>
<td>Abdominal pain, nausea, and vomiting</td>
<td>Symptomatic treatment. Reassure the patient. Give drug with food</td>
</tr>
<tr>
<td>Serious adverse effects</td>
<td>Hepatitis (liver damage)</td>
<td>Jaundice (yellow colour of skin, eyeballs and urine). Loss of appetite and vomiting</td>
</tr>
<tr>
<td>Allergy</td>
<td>Skin rash or Shock, purpura, renal failure</td>
<td>Stop Rifampicin</td>
</tr>
</tbody>
</table>

### CLOFAZIMINE

<table>
<thead>
<tr>
<th>Side effects</th>
<th>Signs and symptoms</th>
<th>What to do if side effects occur</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skin pigmentation (Not Significant)</td>
<td>Brownish-red discoloration of skin, urine, and body fluids</td>
<td>Reassure the patient, it disappears after completion of treatment</td>
</tr>
<tr>
<td>Acute Abdominal symptoms</td>
<td>Abdominal pain, nausea and vomiting on high doses</td>
<td>Symptomatic treatment. Reassure the patient. Give drug with food If intractable stop clofazimine</td>
</tr>
<tr>
<td>Ichthyosis (diminished sweating)</td>
<td>Dryness and scaling of the skin, itching</td>
<td>Apply oil to the skin. Reassure the patient.</td>
</tr>
<tr>
<td>Eye</td>
<td>Conjunctival dryness</td>
<td>Moistening eye drops/ frequent washing of eyes</td>
</tr>
</tbody>
</table>

**NOTE:**

1. In case of urticaria or drug rash stop both Dapsone and Rifampicin and refer to hospital.
2. Stop both dapsone and rifampicin in case of hepatic/renal symptoms and clofazimine in severe gastritis.
7.3.12 Ensuring regularity of treatment

Counsel the person adequately regarding the disease, its curability, duration of treatment and importance of regular & complete treatment. Encourage the person constantly to complete the treatment.

- Tell the basic facts about the disease e.g. disease is curable, skin patches may not disappear or take some time to disappear after the completion of the treatment
- Explain the method of taking drug. Ask person to swallow first dose in front of the health worker / doctor (Assign a person to observe intake of first dose)
- Tell them that medicine is to be collected every 28 days (better to collect 1-2 days in advance).
- Tell the person about possible side effects and when to report.
- Encourage person to ask questions
- Ask person to bring the previous blister pack
- Every time patient comes to collect medicine, examine and assess for any complication or worsening of disability
- Contact the person who has not reported to collect the monthly blister pack with the help of your team members or members of the community. Find out the reason and try to find a solution to the patient’s problem. Reasons for interruption of treatment may be many like:
  - Poor accessibility of the clinic (Distance/ connectivity / timings)
  - Difficulty in taking time off work
  - Lack of understanding about disease and importance of regular treatment
  - Stigma often fed by negative attitude and fear in the community
  - A poor relationship with health care providers
- Adopt, accompanied MDT, whenever it is essential
- Ensure timely release from treatment of MDT

If a Patient has discontinued treatment, they can still continue with the course – as long as they have not missed

- More than three consecutive months of treatment for PB regimen, 
  or
- More than six months of treatment for MB regimen 
  or
- Has missed more than the above mentioned period but not consecutively

Such Patients should be reassessed clinically to ascertain the group and Start the whole course of treatment again or as per expert’s recommendation
7.3.13 Accompanied MDT

Some people may find it difficult to come to the clinic every month especially people from remote areas or areas that are cut off during rainy season, or from areas with law and order problem. These patients are given more than one blister pack at a time. In this case, make sure that patient understands how to take the medicine. If possible, take help of another person (a family member, a reliable neighbour or a health worker) who can help the patient in taking the treatment regularly.

**Encourage regular and complete treatment**

- Patients who are not collecting drug on time should be contacted immediately to identify the reasons and take corrective actions.
- Flexibility in MDT delivery (more than one pulse at a time) may be adapted whenever it is essential.

7.3.14 Follow up of patient on MDT

When ever a patient comes to the PHC, reassure the patient, ensure regularity of treatment, and look for side effects of MDT or sign /symptoms of reaction/ Neuritis.

7.3.15 Completion of treatment with MDT

Skin lesions due to leprosy may not disappear immediately on completion of fixed duration treatment with MDT. In some people, light-colored patches remain on the skin permanently. Persons with residual patches at the time of completion of treatment must be told this, otherwise, they may not understand why their treatment has been stopped and may try to take treatment from somewhere else.

Loss of sensation, muscle weakness and other nerve damage may also remain. Educate the patient about the difference between persistence of light-coloured patches or loss of sensation despite successful therapy as an expected outcome, appearance of new lesions or new sensory loss, nerve involvement, ocular involvement or other signs and symptoms of reaction as danger signs for which the person should report immediately.

Ensure that person with disability knows about “self care” for prevention of disability or it’s worsening. (For self care refer POD)

Ask persons with low risk for development of reaction/ disability to report immediately on appearance of any of the signs/ symptoms and people with high risk to come for follow up after three months for first year after completion of treatment and every six months for next two years. Those taking steroid therapy are asked to come after two weeks.
After completion of treatment, a very small number of patients may get new skin patches because of relapse. Refer such PAL to referral center for confirmation of relapse and treatment.

7.3.16 Criteria to restart course of MDT

On relapse of disease, MDT is restarted. Relapse must be differentiated from Leprosy Reaction.

Drop out cases that discontinued MDT for more than three months in PB and more than six months in MB leprosy regimen, restart treatment as other cases.

Any new lesion reappears after completion of full course of MDT. Refer the case to identified referral center for confirmation of relapse.

After the completion of the course of MDT, new nerve damage / Reaction may appear

- Do not start MDT for such patients.
- Treat such persons for reaction (Refer leprosy Reaction)