ILEP

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OPERATIONAL GUIDELINES FOR THE INTRODUCTION OF NEW MDT REGIMENS FOR THE TREATMENT OF LEPROSY

1 INTRODUCTION

In June 1997, the WHO Expert Committee on Leprosy made several recommendations on possible ways to improve the treatment of leprosy (1). Two have been endorsed by WHO and one or both are being implemented in many national programmes.

One recommendation relates to shortening the duration of the Multiple Drug Treatment (MDT) regimen for multibacillary (MB) patients. On the basis of the available information, the WHO Expert Committee concluded that it is possible that the duration of the current MDT regimen for multibacillary leprosy could be shortened to 12 months.

The Committee also considered the results of a multi-centre, double-blind field trial in India (2), which revealed that the use of a single dose of the combination of 600 mg Rifampicin, 400 mg Ofloxacin and 100mg Minocycline (ROM) is almost as effective as the standard WHO MDT of six months duration, in treating Paucibacillary (PB) leprosy patients who have a single skin lesion. Based on that information, the WHO Expert Committee considers that this single dose ROM combination is an acceptable and cost-effective alternative regimen for the treatment of single skin lesion PB leprosy.

The ILEP Medico-Social Commission has studied the Expert Committee's report and concluded that the recommendations should be supported when adopted by national programmes. There are several major advantages in shortening the duration of treatment for MB patients and for PB patients with single skin lesions. It is likely to reduce the cost to the patient, both in financial terms (reduction in the number of required clinic attendances) and in psycho-social terms (reduction of the period as a registered leprosy patient). It may lower costs for the programme (drugs and staff time). The proportion of defaulters is also likely to be lower. However, the Commission felt that the report fails to give detailed recommendations on how to implement the changes in the regimens and how to maintain an acceptable standard of quality in service provision. Control programmes should bear in mind that implementation of the shortened MDT therapy for MB leprosy and the introduction of ROM for single skin lesion PB leprosy have several consequences which have to be anticipated.

This Technical Bulletin therefore gives advice on some of the operational aspects which must be considered before implementing the WHO Expert Committee recommendations.

2 THE 12 MONTHS MDT REGIMEN FOR THE TREATMENT OF MB LEPROSY

The following operational guidelines should be considered when the 12 month MDT regimen is adopted by national programmes:

2.1 Operational precautions related to patient management

- Criteria for Release From Treatment (RFT).

  All MB patients who have received 12 monthly doses of MDT within a period of 18 months should be released from treatment (RFT). Some national leprosy control programmes (e.g. Ethiopia) have defined 15 months as the maximum period in which to take the 12 monthly doses. A maximum period of 18 months was seen by them as too lenient as it may facilitate defaulting.

  Those patients who fail to complete 12 doses within the defined period of 18 months (except where this differs from specific national recommendations) should be allowed to start another course of MDT according to the national guidelines.

- Patient education.

  Patients should be well informed on the change in the duration of treatment. Conflicting information within the patient's

family and community (e.g. contacts who have been treated with the earlier 24 months regimen) will cause confusion and doubt.

All programmes should develop or revise their patient leaflets which give information on the treatment, possible complications and the potential sequelae of the disease. These leaflets should be used as a tool to support patient education.

- Management of reactions.

  Shortening the duration of treatment means that the period to actively detect reactions is reduced. It is therefore important to ensure alertness regarding the detection of reactions after RFT.

  Also, shortening the MDT duration from 24 to 12 months may increase the occurrence of Erythema Nodosum Leprosum (ENL) or type 2 reactions. Clofazimine has a known suppressive effect on ENL reactions and the withdrawal of this drug after 12 months might result in more patients suffering from ENL.

  The active surveillance of patients after RFT is not an option as it will neutralise most of the advantages of shortened treatment (e.g. reduction in staff time, stigma) if health workers have to follow-up RFT patients. In preference, patient self care after RFT should be through the intensification of patient education. During the time in which the patient is under treatment, efforts must be made to make the patient aware of the possibility that reactions might occur at any time, even after release from treatment and of the action to take should reactions develop. Staff should ensure that patients, particularly those at higher risk of developing a reaction after RFT (e.g. those who have already had one episode in 12 months), can recognise early signs and return promptly for treatment. The programme must ensure that sufficient supplies of corticosteroids are available to treat those patients who develop a reaction.

- Management of relapses.

  Although in theory, the relapse rate may increase if the duration of treatment is shortened, it is expected that this rate will remain within acceptable limits and the benefits of the shortened MDT regimen outweigh the disadvantages. The risk of developing rifampicin resistance probably remains negligible if all MDT components are taken by the patient.

  Among highly smear-positive MB patients (with a BI of 4 or more), relapse rates could be much higher. However, for general programmes with limited specific diagnostic capacities (no specialist clinical skills, reliable skin smear or biopsy facilities), the ILEP Medico-Social Commission does not advise the use of two MB regimens. Instead, the Commission favours the 12 months MDT regimen plus a concerted effort to inform patients of the (remote) possibility of a relapse after RFT, which may occur even 4 years or more after RFT. Giving information to patients before RFT is essential to prevent delays in the detection of relapses.

  In individual cases, a dermatologist or a leprologist may decide for a particular reason (e.g. high BI of 4 or more), to continue MDT up to 24 doses. Treatment results of this category of patient should be analysed separately. It is recommended that these patients be excluded from the standard cohort analysis.

- Management of disabilities.

  Patients with irreversible impairments and disabilities will have a shorter exposure to care activities if no specific measures like care after cure services are available. Thus, Programme managers are advised to encourage leprosy programme staff and general health workers to intensify their guidance to patients on self-care. Moreover, clear referral guidelines should be given to health staff on the prevention of disability.

2.2 Operational precautions related to programme management

- Information to general health workers in public and private sector.

  Programme managers need to inform all levels of staff, both in the public as well as in the private sectors, on the new policies regarding treatment duration. This is to prevent health professionals giving conflicting information to patients, generating confusion among patients and in the community. It must be anticipated that clinicians and other health professionals might, for various reasons, be reluctant to introduce the new changes.

- Improve the Information, Education, Communication (IEC) skills of health workers.

  Clearly, the introduction of a shorter duration of treatment means that more responsibility for self-care and self-monitoring is put on the shoulders of the patient. This requires effective education of the patient, facilitated by good

communication skills in health workers. The training of health workers should therefore not only focus on the acquisition of technical skills but as much on IEC skills, preferably in an integrated way.

- Revision of training materials.

  Manuals and training modules need to be revised. A circular with the revised treatment guidelines and recommendations on their implementation should be distributed at short notice to all health workers.

- Adjusting information systems: recording and reporting.

  Cohort analysis must be used to monitor the quality of case holding and to provide an indicator of the quality of the leprosy control programme. Although the cohort intake period will remain the same if the criteria for successful treatment completion is 12 months within 18 months, the evaluation of annual cohorts can already be done 30 months after the beginning of the cohort period, instead of 48 months, as it is usually the case now. Programme managers and field staff must know the criteria for successful treatment completion, i.e. 12 months MDT within a period of 18 or 15 months.

3 THE SINGLE DOSE ROM FOR THE TREATMENT OF SINGLE SKIN LESION LEPROSY

While the advantages of a single dose ROM regimen are obvious, some potential operational problems should not be underestimated. The World Health Organization recommends that this single dose regimen is only adopted in the national guidelines of programmes detecting a large number (1,000 or more) of single skin lesion PB patients annually. ILEP Members should only introduce ROM when it is part of the national guidelines. It is important to gain experience in national centres of excellence.

The adoption or not, of the ROM regimen is clearly a strategic decision that should be taken at national level. There is a danger that, if a single dose treatment is available, the field workers could have a tendency to mis-classify or mis-diagnose leprosy. The following precautions should be introduced:

3.1 Operational precautions related to patient management

- Reliability of diagnosis: examination of the body surface and determination of nerve involvement.

  The whole skin surface and all peripheral nerves of the patient must be examined. If for any reason, the whole body surface cannot be examined, there is a danger that some patients with more than one skin lesion would be considered as single lesion cases, and would consequently receive insufficient therapy.

  The same danger exists if the field workers are not able to correctly diagnose peripheral nerve involvement (thickened nerves, loss in sensation and / or loss of motor function in extremities).

  Therefore, the ILEP Medico-Social Commission recommends that ROM is only given to patients:

  - When a full examination of the body surface has been carried out.
  - When a proper nerve assessment is done.
  - When the reliability of the diagnosis is monitored by programme managers.
  - Where possible, skins smears could be examined in order to exclude positive patients from the single dose treatment.

- Contraindications to the use of ROM.

  Tetracyclines are known to cause deposits in teeth and bones. They can cross the placental barrier and pass into the milk of breast-feeding mothers. It is not known whether these are real problems when Minocycline is given in a single dose, but prudence is imperative. Teratogenic consequences of Ofloxacin cannot be excluded, either. ROM is therefore also contra-indicated for pregnant women. **For these reasons, ROM must not be given to pregnant or breast-feeding women or to children up to 5 years of age (inclusive)**. For these patients, the standard WHO MDT regimen for PB leprosy of six months duration is preferable.

  For adult, the following dosage is recommended: Rifampicin 600 mg, Ofloxacin 400 mg, Minocycline 100 mg.

  For children between 6 and 14 years of age, the following dosage is recommended: Rifampicin 300 mg, Ofloxacin 200 mg, Minocycline 50 mg.

3.2 Operational precautions related to programme management

- Drug supply.

  The logistics must be in place to ensure that the ROM drugs will be available where and when the patients will be diagnosed.

- Adaptation of Information systems: recording and reporting.

  If the single dose treatment is adopted, the recording and reporting form should be adapted. Single skin lesion patients should be given a separate category.

- Follow up after RFT.

  Active follow-up of the patients who have been treated with single dose therapy is not necessary. As with other patients, they should be told to report voluntarily if there is any problem or new lesions. Patients with new lesions appearing after treatment with a single dose of ROM should be given standard WHO therapy. If patients develop a reversal reaction, this would entail treatment with prednisolone; the standard six-month MDT for PB leprosy should also be given. A single lesion case, treated with ROM who has clinical signs of activity after a one-year delay can be considered as a treatment failure and should be given the standard WHO six month MDT regimen for PB leprosy.

References

1 WHO Expert Committee on Leprosy, *Seventh report*, WHO, Geneva, 1998 (WHO Technical Report Series 874).

2 *Single Dose Rifampicin, Oflaxicin and Minocycline (ROM) Therapy for Single Leprosy Lesions,* Leprosy Review Vol. 69, No. 1, March 1998.