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SPECIAL ARTICLE

Basic requirements for implementation of multidrug therapy—ILEP Medical Bulletin

In 1982 the World Health Organisation (WHO) officially recommended that leprosy should be treated with multidrug therapy (MDT). Experience in using the WHO recommended MDT regimens has shown that they are effective, safe and acceptable to patients and field staff.

However, only 39·5% of the 4·3 million leprosy patients registered for chemotherapy at the end of 1988 were on MDT while a cumulative number of one million patients had completed treatment with MDT. Apparently far too many leprosy patients do not have access to the benefits of MDT. To a great extent, this regrettable situation can be attributed to the fact that in many countries the health services cannot fulfil the complex and demanding requirements for the introduction of MDT which were identified some eight years ago.

A working group of the ILEP Medical Commission's Leprosy Control Expert Discipline, in which programme managers from various parts of the world participated, met in Brussels in September 1989 in order to review these requirements and to formulate recommendations which are more appropriate to the real field situation in many leprosy endemic countries. The recommendations were endorsed by the Medical Commission in December 1989 and were slightly adapted after the Interface Meeting of the ILEP member associations and the Medical Commission in June 1990. They represent the consensus of the members of the working group and the Medical Commission.

These recommendations concern basic rather than optimal requirements, which are intended especially for those programmes which otherwise could not implement MDT.

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The following are the suggested recommendations and are reprinted in full with the permission of ILEP, from a *Medical Bulletin*, Issue No. 1, revised July 1990.

1 INTRODUCTION

The current strategy for leprosy control is early diagnosis and the provision of effective chemotherapy in order to cure the patient, to interrupt transmission and to prevent leprosy-related disabilities.

At present, regular and complete course with multidrug therapy (MDT) of all known

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leprosy cases and early diagnosed new cases is the best available effective approach to achieve leprosy control and its use must be the top priority for leprosy control programmes. Using this approach will decrease the need for social, psychological and economic rehabilitation of the leprosy patient.

Until now on the global scale the coverage of MDT has been too slow. There has been hesitation to use MDT especially because the requirements proposed for its introduction were too demanding for the health services in many leprosy-endemic countries. In order to assist ILEP members to quickly expand the coverage of MDT in their own projects as well as those of national and local governments, the basic rather than the optimal requirements which should be met before MDT is implemented have been identified as follows.

2 THE MDT REGIMEN

2.1 MDT should be given to all patients in need of chemotherapy.

2.2 In principle there is no longer a place for dapsone monotherapy. Where dapsone monotherapy is used, every effort must be made to transfer the patients to MDT.

2.3 The WHO recommended MDT regimens for Multibacillary (MB) and Paucibacillary (PB) leprosy are recommended for routine field conditions. Experience has shown that they are effective, safe and operationally feasible. They are acceptable to patients and field staff.

This does not imply that where some countries have already introduced other multidrug regimens which have proven to be equally effective and safe that these are to be changed.

2.4 Experience with the WHO MDT regimens has shown that 24 monthly doses in 36 months for MB patients and 6 monthly doses in 9 months for PB patients is adequate thus continuation of treatment beyond these periods is not necessary in the vast majority of the cases.

The available evidence indicates that the risk of relapse after MDT is low. Moreover, as it is always possible to adequately retreat relapsed cases, the possibility of relapse after treatment should be accepted; this is so for other diseases.

2.5 The principle of monthly supervised intake of drugs should be adhered to and ideally supervision should be done at the peripheral health service and by a health worker. However, if a health worker is unavailable a village leader, teacher, family member, etc. could be given this responsibility.

In particular cases such as migrant workers, inaccessible roads due to the rainy season, etc., patients could be entrusted with more than one month's supply of drugs. In such cases the provision of blister calendar packs is indicated.

2.6 The following are reasons for stopping MDT:

—severe liver disease,
—severe toxic or allergic side-effects to the drugs.

In cases of leprosy patients also suffering from tuberculosis, both diseases should be treated simultaneously.

3 THE BASIC REQUIREMENTS WHICH MUST BE MET BEFORE IMPLEMENTING MDT

MDT can be introduced into and successfully implemented in all existing health infrastructures in leprosy-endemic countries if the following basic requirements are fulfilled:

3.1 Political and professional commitment

In principle, commitment at all administrative levels is essential to expand the coverage of MDT.

In practice, the commitment of one or two key professional individuals in the health service to introduce MDT at a local level is the basic requirement.

3.2 A plan of action

This can be a simple statement of objectives, main activities with targets and timetable, a statement of the finances needed and information on who is responsible for the allocation of resources.

3.3 Operational guidelines

This can be a simple document which includes information on:

—Job descriptions,
—Supervisory schedules,
—Criteria for the diagnosis and classification of patients,
—Criteria for the selection of patients for MDT, this includes criteria for screening old patients currently on register,
—Treatment regimens,
—Management of patients during treatment including periodicity of examination, absentee tracing, prevention of disability and management of complications (including referral procedure),
—Procedure at release from treatment,
—Recording and reporting of patient data.

3.4 Competent staff

Staff responsible for leprosy control should be able to diagnose leprosy, treat patients and give health education on regularity of drug intake and disability prevention to patients. Their training should be task-orientated according to appropriate job descriptions.

Well trained paramedical workers can diagnose leprosy, give treatment with MDT and give adequate health education. As treatment has a fixed duration the paramedical worker can release patients from treatment. Thus it is not absolutely necessary for every patient to be seen by a doctor.

At the regional/provincial and/or district levels, staff with adequate knowledge and skills in the field of management of leprosy control should be available for supervision, training and referral.

3.5 Availability of drugs

There must be an adequate logistical system to guarantee a secure and uninterrupted drug supply.

3.6 Collection of basic data

The following is the minimum data required:

—Number of patients registered for chemotherapy (MB and PB),
—Number of patients registered for MDT (MB and PB),
—Proportion of patients who have successfully completed MDT within the required time period (MB and PB).

Although the availability of the following data is not a pre-requisite for the introduction of MDT, collection of this information is recommended in order to monitor the effectiveness of case finding and disability prevention activities:

—Proportion of cases with disabilities (grade 2) among newly detected cases,
—Proportion of patients who developed new disabilities among those on register/or MDT.

3.7 Case detection activities

With the introduction of a good quality service, voluntary self-reporting should be the basis of conducting cases. Active case finding can be limited to the examination of the patients' contacts.

This can be a useful occasion also to improve the motivation of the patient through fostering the support of the family.

3.8 Diagnosis

The vast majority of leprosy patients who report voluntarily to the health service can be diagnosed using clinical skills only.

With the application of well-defined criteria, a number of programmes base the classification into MB and PB leprosy on clinical findings alone. (To help field programmes, the ILEP Medical Commission intends to convene a working group to define the most appropriate criteria for this purpose.)

If there is doubt about the classification of leprosy, the MDT regimen for MB leprosy should be given to the patient.

3.9 Laboratory Services

Skin smear examination is necessary in the diagnosis of early lepromatous cases and is useful in monitoring the classification which was made on clinical grounds. Therefore it is recommended that reliable skin smear services should be established.

In practice, however, skin smear services in most programmes are not reliable. As already discussed in section 3.8, almost all patients can be diagnosed using clinical skills only. The availability of skin smear services is thus not an absolute prerequisite for starting MDT on the condition that if there is doubt about the classification of leprosy, the MDT regimen for MB leprosy should be given to the patient.

3.10 Care activities

Early diagnosis and adequate treatment with MDT are the most important means of preventing disabilities.

Whilst the early detection of neuritis and the treatment of reactions is extremely important, the lack of this service should not be a block to the introduction of MDT.

The main responsibility for the prevention of new/increasing disabilities should be given to the patient. Health education in self care practices should be given to those patients at risk of developing disabilities.

Though the early detection of neuritis and the treatment of reactions are extremely important, the provision of this care is not an absolute requirement to the introduction of MDT. However, it is strongly recommended that these services should be established as soon as possible.

3.11 Surveillance after MDT treatment

It is recommended that passive surveillance only is carried out. Each patient should be aware at the time of release from treatment of the need to contact the health service if problems are experienced.

3.12 Rehabilitation services

The availability of rehabilitation services although important and desirable is not a prerequisite for introducing MDT. However, if rehabilitation services exist for the physically or socially handicapped, every effort should be made to make these services available for leprosy patients as well.

4 THE FRAMEWORK FOR IMPLEMENTATION OF MDT

ILEP Members should aim at the implementation of MDT through the General Health Services (based on the primary health care approach). This would give a wider and more comprehensive coverage and provide greater continuity of service. Where this is not yet possible, vertical services may still be appropriate but consideration should be given to combining the leprosy service with other vertical health programmes as a transition towards full integration. Within the integrated programme a specialized component should be available at the more central levels for supervision, training and referral. ILEP Members can play a crucial role in expanding the coverage of MDT. Member-Associations should consider the following proposal:

Acceptance of the global goal of **'MDT for all leprosy cases by the year 2000'.**

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This document was originally produced by a working group of the Leprosy Control Expert Discipline co-ordinated by the Damien Foundation Belgium in September 1989. It was endorsed by the ILEP Medical Commission in December 1989 and revised following the 2nd ILEP Interface meeting in June 1990.