5. **Operational aspects**

The present strategy for the control of leprosy, based on early detection and effective chemotherapy in order to interrupt the chain of transmission of the disease in the community and to avoid permanent disabilities, remains unchanged. Given the effectiveness of the standard WHO MDT regimens for paucibacillary and multibacillary leprosy, and WHO’s goal of elimination of leprosy as a public health problem by the year 2000, leprosy control programmes of the highest quality become even more important.

5.1 **Classification**

The current system for classifying patients as either paucibacillary or multibacillary based on skin smears has proved satisfactory. In this system, patients showing negative smears at all sites are classified as having paucibacillary leprosy, while those showing positive smears at any site are classified as having multibacillary disease. The Study Group therefore recommended that this system should be continued. However, it is possible in most cases to distinguish multibacillary and paucibacillary leprosy on clinical grounds, and approaches based on clinical classification may be required where reliable facilities for the bacteriological examination of skin smears are not available. When classification is in doubt, the patient should be treated as having multibacillary disease.

5.2 **Laboratory facilities**

5.2.1 **Facilities for bacteriological examination**

A service for the bacteriological examination of skin smears is not a prerequisite for initiating an MDT programme. However, with the widespread implementation of MDT, many leprosy control programmes have established or improved their services for processing skin smears. To ensure that the services offered are of high quality, however, they must be regularly monitored by reference laboratories. Provision of suitable laboratory equipment and training will be necessary in countries where such services do not exist.

In view of the increasing prevalence of human immunodeficiency virus (HIV) and hepatitis B infection in many countries where leprosy remains endemic, the number of skin-smear sites and the frequency of smear collection should be limited to the minimum necessary for diagnostic purposes. To prevent cross-infection, technicians should take care to avoid injury when taking skin smears (46).

5.2.2 **Referral facilities for mouse-footpad studies**

Unless the patient is part of a special study, routine drug-susceptibility
studies in the mouse-footpad model are generally not useful for leprosy control programmes.

5.2.3 **Other laboratory facilities**

Whenever possible, the laboratory facilities of primary health care services should be used for routine screening for contraindications to MDT and evaluating any cases of drug toxicity that arise.

5.3 **Re-treatment of multibacillary cases previously treated only with dapsone monotherapy**

Relapse of multibacillary patients previously treated only with dapsone monotherapy continues to be a significant source of new cases in many leprosy control programmes (47–49). Re-treatment of such patients with the standard WHO MDT regimen for multibacillary leprosy would probably prevent nearly all such relapses. The Study Group therefore recommended that multibacillary patients previously treated with dapsone monotherapy and showing negative skin smears should be given a 2-year course of the standard WHO MDT regimen for multibacillary leprosy wherever resources permit, provided that this activity does not prevent newly diagnosed cases from receiving treatment.

5.4 **Drug delivery**

The recommended regimens require that the monthly doses of rifampicin and clofazimine for multibacillary patients and of rifampicin alone for paucibacillary patients be administered under direct supervision: a health worker should be present when the patient ingests the drug. All registered and newly diagnosed cases must be started on an appropriate MDT regimen immediately. Because the WHO MDT regimens are “robust” (i.e. their efficacy is not impaired by minor modifications and their application requires little in the way of infrastructure), it is possible to devise new treatment delivery systems outside the conventional medical network in certain countries where primary health care services are limited and communications are difficult. If normal monthly supervision by a health worker is not possible, every effort should be made to find a responsible person, such as a village chief or schoolteacher, to supervise the monthly drug intake. Continuity, regularity, and completion of chemotherapy continue to be the keys to the success of the MDT regimens.

To be effective, treatment must be given regularly. Multibacillary patients should receive 24 monthly doses of combined therapy within 36 months and paucibacillary patients six monthly doses within 9 months. If any patients drop out before completion of therapy, they should be re-evaluated when retrieved to determine whether further treatment is needed.
There should be an efficient system for identifying patients who drop out of treatment, which should include home visits to the patients. Leprosy patients should have access to the nearest hospital, whether general or specialized, for the treatment of complications and side-effects of drugs. They should also be monitored for side-effects periodically and should be seen by medical officers at specified intervals.

5.5 Management of reactions and prevention of deformity

If deformity is to be prevented, reactions must be promptly diagnosed and treated. This is a vital part of every leprosy control programme, since patient compliance will often depend on how well reactions are managed.

Usually the diagnosis of reactions is relatively straightforward but occasionally, in patients who have completed treatment, differentiation of a reversal (type I) lepra reaction from relapse may be difficult. Guidelines exist (50) to assist programme staff in this regard and a referral source for evaluation of problematic cases should be available.

Reversal reactions and erythema nodosum leprosum (ENL) can be treated using corticosteroids, or in some cases, clofazimine. For patients with severe ENL, however, thalidomide is the most effective drug. Corticosteroids and clofazimine are readily available, and thalidomide should be made available at referral centres. Detailed guidelines for their use should be given during training and in field manuals. It must be pointed out, however, that because of its teratogenic effects, thalidomide should never be given to women of childbearing age. All patients must be fully informed of its side-effects and this drug must be given only under close supervision at the nearest referral centre. If supervision and appropriate use of thalidomide cannot be assured, it should not be used.

Clinical trials have shown that, in general, patients with reactions or neuritis can be treated successfully using standard courses of corticosteroids. The Study Group noted that such standard courses (36) have safely been used by appropriately trained health workers, even under very difficult field conditions, and therefore recommended their use. On the basis of experience with tuberculosis, the Study Group considered that, when treatment with corticosteroids was started after a patient had completed MDT, there might be some risk of relapse in multibacillary patients. It therefore recommended that, wherever possible, 50 mg of clofazimine daily be started as a prophylactic measure if the duration of steroid therapy is expected to exceed 4 months, and be continued until the course of steroids is completed. However, these patients should not be re-entered into the case registry.

The Study Group also recommended that care for iridocyclitis, lagophthalmos and other eye problems and access to specialized ophthalmology services should be available to all leprosy patients. Care and advice about measures to prevent injuries to insensitive hands and feet are also required.
5.6 **Follow-up after completion of therapy**

Because the risk of relapse after completion of the WHO MDT regimens has been shown to be negligible, it is no longer necessary to continue routine annual surveillance of patients. Instead, the Study Group recommended that patients should be taught, at the time of release from treatment, to recognize the early signs of possible relapse or reactions and to report promptly for treatment.

Health services, for their part, must ensure that health workers are aware of the possibilities of reactions and relapse after completion of MDT. They must also be able to diagnose and treat these conditions and to refer patients when necessary.

5.7 **Health education and medical care**

Acceptance of MDT by health professionals and patients has generally been excellent, as has community participation. For MDT regimens to be implemented successfully, however, a good health education programme must be developed and/or maintained, using all available resources, including the mass media.

Before starting MDT, patients should be informed of the possible side-effects of the treatment they will receive, the possibility of leprosy reactions or disabilities occurring, and what to do if such problems arise. Patients should also be advised about the consequences of interrupting or stopping MDT. This information is essential to ensure that patients cooperate with health workers. Throughout their treatment, patients should be advised about how to take care of insensitive hands, feet and eyes.

5.8 **Household contacts of patients**

Household contacts of leprosy patients are at significant risk for the development of the disease. Thus, contacts of newly diagnosed cases should be examined for evidence of leprosy at that time. They should then be advised of the early signs of the disease and told to return if any suspect skin, motor, sensory or other lesions occur. Chemoprophylaxis with rifampicin or other antileprosy drugs is not recommended for contacts of leprosy patients in leprosy control programmes.

5.9 **Training**

With the introduction of MDT, training is needed for all categories of staff, especially those working in the primary health care delivery system. The training should be planned and organized so that each category of personnel is able to perform certain tasks competently within the overall context of the programme. Adequate training for all management personnel involved in the programme is crucial. Several training modules
for managers of leprosy control programmes are available from WHO. Training of medical students and organization of refresher courses for physicians on MDT for leprosy should also be encouraged.

A working manual should be prepared for the guidance of all personnel engaged in the programme. The manual should give, in simple language, detailed instructions regarding drug combinations, treatment delivery, and possible side-effects that may arise. The chain of referral and appropriate action to be initiated should be precisely indicated. The manual should be updated as necessary.

5.10 **Drugs and drug supplies**

Availability of an uninterrupted supply of drugs is the most important prerequisite for an MDT programme.

Drugs for MDT regimens should be ordered at least 6 months in advance to ensure that the necessary amounts are obtained in time. This means that every leprosy control programme should have a long-range plan of its drug needs. In addition, every programme should try to keep a reserve stock of at least 6 months’ supply of drugs in order to prevent an interruption of MDT in the event of a delay in the drug supply.

Since substandard products exist on the world market, care should be taken to ensure that the drugs procured by the programme are of adequate quality. All drugs should be properly stored to prevent deterioration and the stock managed so that supplies are utilized before their expiry date. Blister packs containing a month’s supply of drugs should be used wherever possible, since they are convenient for the health workers and may aid patient compliance.

5.11 **Planning and human and financial resources**

In general, experience has shown that MDT can be readily implemented, with some programme modifications, wherever monotherapy is now utilized. Countries planning to increase MDT coverage must first mobilize the necessary human and financial resources.

Proper planning and precise formulation of projects with intermediate objectives and operational targets will be necessary.

5.12 **Monitoring and evaluation**

A suitable, uniform system of collecting, recording and transmitting data to programme managers is indispensable and will greatly assist in

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1 Available on request from Leprosy Control, Division of Control of Tropical Diseases, World Health Organization, 1211 Geneva 27, Switzerland.
assessing the impact of MDT. In order to monitor compliance, a record should be kept of the number of patients who drop out of treatment.

A system for evaluation should be developed when the programme is planned. Progress should then be continuously measured in relation to specific targets at different stages of the programme. Periodic evaluation by independent teams should be encouraged.

5.13 Treatment of patients with human immunodeficiency virus (HIV) infection or tuberculosis

HIV infection is a significant problem in many countries where leprosy is endemic. As yet, leprosy has not been found to be more common in such countries, but occasionally, patients may be encountered who both are HIV-positive and have active leprosy. The information available (51) indicates that the initial response of such patients to MDT is similar to that of other leprosy patients and treatment of reactions does not require modification.

Patients suffering from both leprosy and tuberculosis will also occasionally be encountered. They will require standard antituberculosis therapy in addition to MDT for their leprosy. At present only rifampicin will be common to the two regimens and it must be given in the doses required for tuberculosis.

6. Research trends and needs

6.1 New bactericidal drugs

Progress continues in all areas of leprosy research but particularly in chemotherapy. The availability of three powerful new bactericidal drugs has led to considerable work to define their role in the treatment of this disease. Ji et al. recently reported the results of mouse-footpad studies, which showed that a single combined dose of minocycline and clarithromycin is only slightly less bactericidal than rifampicin, while adding a single dose of ofloxacin yields a combination similar to rifampicin in terms of activity. They suggested that this three-drug combination could be given once monthly for treating multibacillary patients infected with rifampicin-resistant *M. leprae*, and that this same combination or perhaps just minocycline plus clarithromycin could be given together with rifampicin once monthly to treat other multibacillary patients (52).

Although there is less need for new drugs now than in 1981, the potential for finding new drugs is greater. This is because thousands of preparations are currently being screened for antituberculosis activity, some of which are likely to be effective against *M. leprae*. Such drugs may permit the duration of therapy to be reduced further. A drug to eliminate persistent *M. leprae* would also be extremely useful.