The Enhanced Global Strategy for Further Reducing the Disease Burden due to Leprosy: 2011-2015 and the Updated Operational Guidelines were widely welcomed and endorsed. The overall goal is to provide access to quality leprosy services for all affected communities based on the principles of equity and social justice.

These Updated Operational Guidelines seek to help managers of national health services to implement the Enhanced Global Strategy comprehensively in their own countries. This will be achieved by developing detailed national policies applicable to their own situation, and revise the National Manual for Leprosy Control in their respective countries.

Enhanced Global Strategy for Further Reducing the Disease Burden Due to Leprosy
(2011-2015)

Operational Guidelines (updated)
Enhanced Global Strategy for Further Reducing the Disease Burden Due to Leprosy
(2011-2015)

Operational Guidelines (Updated)
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Foreword

Though there has been substantial reduction in the disease burden of leprosy due to registered prevalence brought about by a well-designed strategy and unified effort, new cases will continue to appear, possibly in smaller numbers, for many more years or even decades to come. Today, the diagnosis and treatment of leprosy is simple and is available free of charge at the nearest health centre. There are increasing expectations that persons affected by leprosy and their families do not have to carry the devastating burden caused by the disease without hope.

Our challenge is to sustain the quality of leprosy services and to ensure that all persons affected by leprosy, wherever they live, have an equal opportunity to be diagnosed and treated by competent health workers without unnecessary delays and at an affordable cost. To achieve this goal, the major thrust of our efforts must focus on integrating leprosy into the general health services. Health workers at all levels must be taught the simple methods required to diagnose and manage leprosy. This will improve access to leprosy services and reduce the stigma and discrimination faced by persons affected by the disease.

The World Health Organization’s Global Strategy for Further Reducing the Leprosy Burden and Sustaining Leprosy Control Activities: 2006-2010 and the Enhanced Global Strategy for Further Reducing the Disease Burden Due to Leprosy: 2011-2015 focuses on sustaining the gains made so far and on reducing the disease burden further in all endemic communities. At the same time, particular attention should be given to ensuring that the
quality of services is not compromised. Every person affected by leprosy should have easy access to diagnosis and free treatment with multidrug therapy. We need to ensure that sustainable activities are carried out and quality services provided within an integrated set-up that includes an effective referral network to manage leprosy-related complications effectively.

The implementation of the Enhanced Global Strategy through these updated Operational Guidelines will require renewed commitment from all partners working towards the common goal of a world without leprosy. Together, we can further reduce the disease burden due to leprosy and ensure that the physical and social consequences of the disease continue to decline in magnitude throughout the world. It is hoped that these Guidelines will help towards a better understanding of the Enhanced Global Strategy and the principles behind it, and will contribute to improving the quality of care for persons affected by leprosy.

Dr Samlee Plianbangchang
Regional Director
Executive Summary

The Global Strategy for Further Reducing the Leprosy Burden and Sustaining Leprosy Control Activities: 2006-2010 and the Enhanced Global Strategy for Further Reducing the Disease Burden Due to Leprosy: 2011-2015 have been widely welcomed and endorsed. The overall goal is to provide access to quality leprosy services for all affected communities following the principles of equity and social justice. The purpose of these updated Operational Guidelines is to help managers of national health services to implement the Enhanced Global Strategy in their own countries. This will be achieved as they develop detailed national policies applicable to their own situation, and revise the National Manual for Leprosy Control in their respective Member countries.

Leprosy services have been integrated into the general health services in most of the leprosy endemic countries; far greater emphasis is given here to the need for an effective referral system, as part of an integrated programme. Good communication between all involved in the management of a person affected by leprosy and those disabled due to leprosy is essential. These Guidelines should help managers choose which activities can be carried out at the primary health-care level and for which aspects of care patients will have to be referred to them. This will depend on the nature of the complication and the capacity of the health workers to provide appropriate care at different levels of the health system.

The control strategy will continue to rely on early case finding and treatment with multidrug therapy. Therefore, the promotion of self-reporting is now crucial to case detection. The use of small-scale campaigns should be restricted to special situations or in exceptional circumstances as large case-finding campaigns have become less cost-effective. It is important to identify and remove
barriers that may prevent new cases from coming forward. The procedures for establishing the diagnosis of leprosy remain firmly linked to the cardinal signs of the disease, but the accuracy of diagnosis must be monitored. The Operational Guidelines suggest a greater emphasis on the assessment of disability at diagnosis, so that those at particular risk can be recognized and managed appropriately.

The treatment of leprosy with MDT has been a continuing success; neither relapse nor drug-resistance is a significant problem and the regimens are well-tolerated. Although not alarming as yet, sporadic reports of patients relapsing with *M. leprae* strains resistant to anti-leprosy drugs have been reported recently. The potential risk of emergence and transmission of rifampicin-resistant strains need to be contained by ensuring improved treatment regularity and rigorous adherence to MDT regimens. In addition, it is important to establish a global surveillance network to monitor drug resistance in leprosy and promote research on more effective and shorter treatment regimens against leprosy. Clear procedures are given for managing irregular treatment with MDT. Leprosy reactions are a serious complication affecting some patients. The *Guidelines* address this topic, emphasizing the need for early recognition and timely management of leprosy reactions and neuritis. A key decision for programme managers is to determine how and at which level of the health system should leprosy reactions be managed in their countries. Different Member countries must develop their own detailed guidelines on this issue.

Prevention of disability (PoD) and self-care practices are also described in some detail as there is a need for much greater coverage with basic PoD activities. The programmes need to consider these activities as an integral part of leprosy case management. This is also an important component of “quality leprosy services” emphasized in the *Enhanced Global Strategy*.

Rehabilitation may include a medical component (such as reconstructive surgery), but its scope is much broader. It is likely that some people affected by leprosy would benefit from socioeconomic rehabilitation, for example, vocational training or a loan. The *Operational Guidelines* also give some details on the importance of community-based rehabilitation as a sustainable and cost-effective approach to address rehabilitation needs of persons
affected by leprosy. Staff in the health services need to be familiar with what is being done in the locality, and know how and where to refer people who need these services.

Recording and reporting are essential to maintain quality standards in any programme. The indicators selected in the Enhanced Global Strategy are useful for monitoring and evaluation, and they determine which data must be recorded. The emphasis is now firmly on monitoring the occurrence of new cases and particularly on the number of new cases detected with grade-2 disabilities. The data needed to monitor the quality of activities have not been collected routinely by many programmes. The national programme managers must, therefore, decide for themselves which indicators will be used to ensure quality as these will vary from country to country.

Programme management is a broad subject; the topics covered in this Section are those that are central to the running of integrated leprosy control services, including supervision, supply of MDT, partnerships, training and programme evaluation.
1.1 What is the place and purpose of the updated Operational Guidelines?

The updated Operational Guidelines are a companion document to the Enhanced Global Strategy to Reduce the Disease Burden Due to Leprosy: 2011-2015, which has been extensively reviewed and revised on the basis of suggestions from a wide range of experts, national programme managers (NPMs) and partners. While the Strategy document presents an overview of the ethics and guiding principles of the Enhanced Global Strategy, the updated Operational Guidelines attempts to provide practical suggestions, based on current professional knowledge, for the implementation of activities in the field.

These updated Operational Guidelines have two functions:

- To define and explain terms, concepts and activities mentioned in the Strategy; and
- To indicate how the strategy should be implemented in the context of a national programme.

Since the Enhanced Global Strategy and the updated Operational Guidelines are global in scope, they cannot provide direction and guidance on every aspect of each National Programme. However, it is intended that national programme managers should be able to adjust these to the local realities and develop a comprehensive National Manual for Leprosy Control.

1.2 What is the target audience for the updated Operational Guidelines?

The target audience for the updated Operational Guidelines includes managers of national health services and mid-level
managers responsible for leprosy control activities in their countries. They will be required to implement the *Enhanced Global Strategy*.

**1.3 How can the Enhanced Global Strategy and the updated Operational Guidelines be applied to countries with widely differing health systems?**

On account of the wide variations in the way leprosy patients are managed by different health services-relating to health service coverage, varying endemicity, training, staffing levels, supervision, etc.-the same guidelines cannot be used in every situation. The *Operational Guidelines* are for use at two levels, “peripheral” and “referral”, in appropriate situations. The distinction between these two levels as used in this document should be adapted to the situation prevailing in each country.

“Peripheral-level guidelines” are provided for the general health workers running the integrated clinics, where they see and manage a wide range of health problems; leprosy being a relatively small part of their workload. “Referral-level guidelines” are for those staff at referral units, including field supervisors, who have had advanced training and experience in leprosy; and also for those with specialist skills to manage other leprosy-related consequences (ophthalmologists, orthopaedic surgeons, etc). As part of the process of integration, referral services need to be bolstered.

Where leprosy is a common occurrence and health workers are familiar with the disease many of the routine activities of diagnosis, treatment and disability prevention can be carried out in the peripheral clinics. However, health workers at that level must possess a fairly good knowledge of leprosy, even in an integrated setting. In this case, some activities mentioned in the “referral-level guidelines” may be appropriate for many peripheral clinics. Some issues may be laid down by the government, for example, who may diagnose and treat leprosy and who may diagnose and treat reactions.

**Example 1**: Disability grading is covered in Section 4.6. The guidelines given in that Section for peripheral-level health workers assume very little experience of leprosy and require a minimum level of skill to carry out the assigned tasks. In some programmes, certain peripheral-level workers are already doing disability grading
with a reasonable level of technical skill. In these programmes, therefore, it may be expected that the managers at the national level would decide that the so-called "referral-level" guidelines in this particular Section would apply to those peripheral staff.

**Example 2: Recognition of reactions and neuritis, and the use of steroids to treat such cases, is covered in Section 5.8. The peripheral-level guidelines assume no training in this area amongst peripheral health staff and give very simple guidelines—basically to refer cases on to the referral facility. If peripheral staff have received adequate training in this area, the "referral level" guidelines may be used.**

Referral will always be an essential component of an integrated health service (see Section 2.1). At any level, health staff must be ready to refer any patient who cannot be adequately managed from where he or she is. Staff at selected health centres, district hospitals or any other place identified as a referral unit should be adequately trained and be ready to receive those patients and use such occasions as a training opportunity for peripheral staff.

### 1.4 What does it mean to “reduce the disease burden due to leprosy”?

The “burden of leprosy” can be viewed in three ways:

*First,* the most relevant epidemiological measure of the burden of leprosy is the incidence of disease, which is the number of people developing leprosy during a set period of time—usually one year, in a specific population. Since incidence of disease is difficult to measure directly, the “New Case Detection Rate” is used as a proxy for incidence rate. It seems likely, however, that some new cases never come for diagnosis and treatment, so the number of cases detected is lower than the number of incident cases. The global incidence rate of leprosy seems to be declining slowly, but in many areas it remains static while it also seems to be rising in a few others. Changes in incidence take place slowly, over decades, and are related to factors such as immunization with BCG and economic development, as well as good leprosy control practices. By this measure, the “burden” of leprosy is declining slowly but new cases will continue to appear for many years. Thus, diagnostic and treatment services need to be maintained at appropriate levels.
Secondly, the burden may be related to the registered prevalence of disease, which is the number of people on treatment at a certain point in time. The prevalence of leprosy has decreased throughout the world over the last 20 years because of multidrug treatment (MDT) provided through the Leprosy Control Programme. By reducing the duration of treatment, MDT has greatly reduced the number of patients under treatment at any one time and, thereby, brought down the “burden” on the health services. However, the decline has slowed considerably in the last few years as most of the accumulated backlog has been dealt with. Today, the bulk of registered prevalence is made up of the number of new cases detected during the year and put on multidrug therapy.

The third way in which the “burden of leprosy” can be viewed is through the eyes of people affected by leprosy. Leprosy complications can lead to disability of the hands and feet and sometimes also to blindness. These physical problems are often overshadowed by the social rejection and mental suffering caused by the stigma that persists around this treatable disease in many communities. It is estimated that more than three million people are living with disability due to leprosy in the world. Many of these disabilities can be prevented and the Enhanced Global Strategy once again calls for increased efforts to reduce this “burden” by reducing the number of new cases presenting with disabilities through early detection, and by improving management of acute and chronic complications due to leprosy reactions, helping to rehabilitate those with disabilities, and fighting stigma and discrimination wherever it exists.

1.5 What are “quality leprosy services”?

The Enhanced Global Strategy emphasizes quality leprosy services as an essential component of an effective programme. Quality is based on appropriate training of staff at every level, regular technical supervision and monitoring of key indicators. The pursuit of quality predisposes the willingness of staff to make changes aimed at improving their skills and the functioning of the health services in which they work.

Quality leprosy services are accessible to all who need them in terms of
• **Coverage**: MDT treatment can be provided at the nearest health unit.

• **Absence of geographical, economic or gender barriers.**

Quality leprosy services are also patient-centred and observe patients’ rights, including the rights to timely and appropriate treatment, and to privacy and confidentiality.

They also address each aspect of case management, based on solid scientific evidence. These aspects are that:

• **Diagnosis** is timely and accurate, with supportive counselling (Section 4).

• **Treatment** with MDT is available free of charge and is user-friendly (Section 5).

• **Prevention of disability interventions** are carried out appropriately (Section 6).

• **Referral** for complications and rehabilitation is done as needed (Section 2 and 7).

• **Simple records** are maintained and reviews and evaluation encouraged (Section 8).

### 1.6 What are the “principles of equity and social justice” in this context?

Communities have wide-ranging health needs. Resources (staff, time, money) should be allocated fairly to different programmes, including the leprosy services, according to the disease burden so that each can function as effectively as possible. ‘Equity’ means that leprosy patients have the same opportunity to attend health services that are adequately equipped to deal with their problems. It also implies that leprosy services should be neither worse nor better than other health services available in a given community.

Social justice refers to an absence of discrimination for any reason, including type of disease, level of disability, race, gender, social class or religion, while incorporating the principles of privacy and confidentiality.
1.7 What measures can be taken to ensure equity and social justice?

At the national level

- Enact laws and policies, remove discriminatory laws and create mechanisms to ensure that the rights of the persons affected by leprosy are respected, fulfilled and protected.
- Work with like-minded partners across all development sectors (social welfare, education, law, and industry), groups of persons affected by leprosy and nongovernmental organizations (NGOs).

At the local level

- Use appropriate educational tools in the community to build positive attitudes, combat discrimination and stigma.
- Empower communities through education that makes them understand their rights as well as needs and through partnership that guarantees their participation in decision-making.
- Promote community-based rehabilitation activities in collaboration with other stakeholders, both from the health and non-health sectors.
Integration and referral

2.1 How does referral work in an integrated health service?

Effective leprosy control requires an integrated approach, which provides wider equity and accessibility, improved cost-effectiveness and long-term sustainability. This implies that leprosy control activities should be implemented by the general health services, including integrated referral facilities. Integration not only improves accessibility to treatment, but also reduces the stigma and discrimination faced by persons affected by leprosy.

Integration implies that day-to-day patient management, recording and reporting become the responsibility of general health staff. However, integration does not mean that specialist expertise is removed from the health service. On the contrary, this expertise must be available within the general health service at the central and intermediate levels for planning and evaluation, provision of training, technical supervision, advice, referral services (including those at hospitals) and research. A system should be in place for the referral of difficult or complicated cases to the hospitals or specialists (e.g., general medical officers with some additional training in leprosy, dermatologists or surgeons) and referral by specialists back to the peripheral health facilities for continuation of treatment. The specialized referral services for leprosy are part of the general health services, just as a surgeon in a district hospital is part of the general health services.

Depending upon local conditions (e.g., the availability and level of training of various categories of health staff), each country or region must decide at which level of the health system such
specialist expertise should be made available. Peripheral general health workers should be capable of diagnosing and treating leprosy under the technical supervision of specialized health workers who are positioned at the intermediate level. They should be aware of where specialized services for managing patients with special needs are available. They should also develop linkages with nongovernmental organizations for specialized interventions. This category of specialized staff will usually have responsibility for other diseases in addition to leprosy.

Where leprosy is relatively less common, the ability to suspect it and refer the patient to a referral unit is the most important skill required for peripheral general health workers. These referral units (including district hospitals and selected health centres) should diagnose leprosy and start treatment. Continuation of treatment could be delegated to the peripheral health facility serving the community to which the patient belongs. The community should be informed about symptoms of leprosy and the availability of services. In areas with small patient loads, management of nerve damage will have to be concentrated in referral units. Centres treating the difficult complications of leprosy and providing rehabilitative surgical services will be even more centralized, but could also provide some referral services through mobile units.

An adequate referral system means that specialist services should be accessible and available to any patient who needs them. The main obstacle to referral in many countries is the difficulty for the patient to reach the referral unit at the right time. In such situations, the visiting supervisor should prove useful in providing the necessary support services.

All peripheral health staff should know the clinics and health staff to whom they will refer patients, so that they can advise their patients accordingly, in order to minimize their difficulties. Good communication should be maintained to allow discussion of patients' progress and as an opportunity for further training. The convenience of mobile phones and text messaging can make this easy and timely.

Six basic principles for successful integration as advocated by WHO are:

(1) Health facilities should be identified as close to the patients' home as possible to provide leprosy services on all working days
(2) At least one trained staff member should be available at the health facility providing leprosy services.

(3) All health facilities where patients are under treatment should have an adequate stock of drugs.

(4) Information, education and communication (IEC) material should be available for the community member.

(5) A simple treatment register should be available.

(6) Referral services should be available and accessible, and general health staff should know when, where and how to refer patients.

**Peripheral level**

Staff at the peripheral level should develop effective links with the referral units they are most likely to use regularly. These include

- The visiting technical supervisor;
- Nearest health centre (with staff with additional training in leprosy) or district hospital;
- Eye clinic for anyone with eye problems;
- Leprosy or dermatology specialist: for diagnosis, skin smears, reactions; and
- Local rehabilitation networks for anyone with long-term disability.

**Referral level**

Staff at the referral level should be aware of specialist clinics and other professionals to whom they may refer patients. These professionals include the areas of

- ophthalmology for significant eye pathology;
- dermatology for diagnosis of difficult skin conditions;
- laboratory for skin smears and histopathology;
- physiotherapy for assessment and management of reactions;
- Podiatry for the feet and footwear;
- occupational therapy for rehabilitation and adaptations;
• reconstructive and plastic surgery;
• social worker for assessment and further referral; and,
• community-based rehabilitation specialists.

2.2 Which conditions in leprosy require referral?

Staff should refer patients whose condition they are not able to deal with – this may be either because they have not been trained to deal with the same or they do not have the necessary resources (drugs, equipment, other staff, etc.) to manage the condition.

**Routine referrals**: Non-urgent conditions include:

- Diagnosis: if leprosy is suspected but the diagnosis is uncertain (Section 4.4);
- Suspected relapse (Section 5.5);
- Any stable, long-standing disability which may be suitable for surgery or any other rehabilitation intervention (Sections 6 and 7);
- Non-medical referrals, for example, to a social worker or to a CBR programme, and,
- Other health problems unrelated to leprosy.

**Emergency referrals**: Conditions that require urgent treatment such as:

- Severe leprosy reactions (Section 5.8), including:
  - Severe reversal reactions.
  - Reversal reactions overlying a major nerve trunk.
  - Neuritis, including silent neuritis.
  - ENL reactions.
- Severe infection of the hand or foot (usually related to an ulcer with foul-smelling discharge): the hand or foot will be hot, red, swollen and probably painful.
- Eye involvement in leprosy–four specific problems which need urgent referral:
  - Recent loss of visual acuity.
  - A painful red eye.
- Recent inability to close the eye (lagophthalmos).
- A reaction in a leprosy skin patch on the face.
- Serious adverse drug reactions (Section 5.7).

National programmes should document and circulate contact details of clinics and consultants ready to see leprosy-related referrals in order to establish a more efficient system of referral.

2.3 How could partnerships strengthen the referral system?

There are several community-based organizations (CBOs), NGOs and private institutions that provide a whole range of leprosy services close to the community they serve. They can be highly effective focal points for specialized services and interventions. It is also important to develop public-private partnership with other sectors and within the community, including with organizations of persons affected by leprosy.
Enhanced Global Strategy for Further Reducing the Disease Burden Due to Leprosy
3.1 How should case detection be organized?

There are two methods of case detection, active and voluntary. The promotion of voluntary self-reporting is now crucial to case detection. Active case-finding methods, including large-scale campaigns, are generally not recommended as these have become less and less effective. The use of small-scale campaigns should be restricted to special situations or for exceptional circumstances. It should be a one-time activity with the principal aim of establishing sustainable services. National programmes should promote initiatives to encourage people suspected with leprosy to report voluntarily to the health facilities near their homes.

3.2 What is the role of household contact examination in case detection?

Household contacts of leprosy patients are at significantly greater risk of developing leprosy than contacts who are not living in the same household. When a new case is detected, household contacts of the patient should be examined for evidence of leprosy. They should then be educated on the early signs of the disease and their significance and requested to return if any suspect skin lesions or motor or sensory changes occur.

3.3 How can early case detection be promoted?

Efforts to increase case detection are focused on facilitating self-referral by people who develop leprosy. This is done by increasing awareness of the early signs and symptoms of leprosy among the general public. Barriers which prevent people reporting for examination should be removed; they are considered here under five headings.
Barriers include a lack of awareness of the fact that leprosy is treatable and that treatment is free and available locally. This can be addressed most effectively by public information campaigns through a variety of media channels, including traditional means of communication.

Secondly, fear is also a common barrier. This may be fear of the diagnosis, fear of future deformity, fear of being exposed as having leprosy, or fear that one’s family will suffer on account of the patient. The last two relate to negative attitudes or other forms of stigma and discrimination inherent in society. Such fears may persist long after the general attitude and perception has become more tolerant and instances of overt discrimination have become rare.

Fear and stigma are difficult to eradicate. They can only be addressed successfully through a combination of strategies that include the dissemination of factual information about leprosy and its treatment, context-specific media messages addressing misconceptions and traditional beliefs about leprosy, building a positive image about leprosy, and through the testimonies of people successfully cured from leprosy. Contact between the community and treated patients, successful self-care, rehabilitation aimed at empowerment and counselling of patients to build their self-esteem also help to create a positive image among the people about those affected by leprosy. At the same time, any negative attitudes, structures or arrangements in the health services should be addressed as a matter of urgency. Assurance of privacy and confidentiality and treatment with dignity are particularly important.

A third group of barriers include other disadvantages, some of which are culturally determined, such as gender, ethnic identity and poverty. These require specific approaches, which include awareness building and education, as well as advocacy for supportive legislation and services, and general poverty alleviation measures.

Physical barriers, such as the topography or difficult terrain where the patient is located, and long distances to the nearest health centre, also pose particular challenges - especially in areas with low health service coverage - and these form a fourth category. These necessitate flexible arrangements for diagnostic and treatment services. The final group of barriers, issues of security in areas of war or civil unrest, is the most difficult to address, but is nevertheless a grim reality in several leprosy-endemic countries.
3.4 What is the importance of community awareness in leprosy control?

The purpose of health action aimed at generating community awareness is to improve levels of understanding about the disease and the programme and the implications on the community in terms of benefits accrued and responsibilities that arise. It also aims to encourage the community members to accept an active role in the service. The expected outcome is an increase in the rate of self-referral and positive attitude of society towards persons affected by leprosy.

Public information and education in the field of leprosy control is aimed at building awareness among the people by:

- improving their understanding about the disease and the programme;
- stimulating civic concern about quality and responsibility;
- increasing demand and support for health service;
- dispelling myths and refuting misconceptions;
- making stigma and discrimination unacceptable;
- developing of a sense of community ownership;
- enabling the community to develop a positive attitude and behaviour for social action; and
- providing support to people affected by leprosy in enabling them to overcome barriers that prevent them from discharging their social responsibilities.

3.5 What are the key messages about leprosy for the general public?

Messages should be objective, positive, specific, and age-gender-location-language-and culture-sensitive. Reference should be on curability, availability of free-of-cost drugs, early signs, elimination of discrimination and stigma, and providing support and encouragement to persons affected.

The areas of focus are:

- **Curability of leprosy**: Leprosy is an infectious disease but the risk of developing the disease is low. It can be cured with drugs that are widely available and which are free of charge.
• **Early signs** of leprosy are pale or reddish skin patches with loss of sensation. Early detection with appropriate treatment helps to prevent disability from leprosy.

• **Fear**: The disease can be managed just like any other disease; affected people should not suffer any discrimination. Treated persons are no longer infectious.

• **Support**: Affected people need the support and encouragement of their family and community, first to take the MDT and any other treatment as prescribed, and secondly to be able to live as normal a life as possible.
4.1 What is a case of leprosy and when should leprosy be suspected?

A case of leprosy is a person with clinical signs of leprosy who requires chemotherapy (MDT).

Leprosy should be suspected in people with any of the following symptoms or signs:

- pale or reddish patches on the skin (the most common sign of leprosy);
- loss, or decrease, of feeling in the skin patch;
- numbness or tingling of the hands or feet;
- weakness of the hands, feet or eyelids;
- painful or tender nerves;
- swellings or lumps in the face or earlobes; and
- painless wounds or burns on the hands or feet.

Although the majority of leprosy patients have skin lesions which are visible, experienced field workers are aware that there is a great variety of skin lesions that are manifest in cases of the disease. Some skin lesions are very diffused and difficult to distinguish from normal skin. In these cases the other symptoms and signs become important for diagnosis.

4.2 How is leprosy diagnosed?

A reasonable degree of certainty is required before making the diagnosis of leprosy. A suspect should not immediately be
registered as a case because the diagnosis of leprosy has adverse social consequences.

Leprosy is diagnosed when at least one of the following cardinal signs manifest:

1. **Definite loss of sensation** in a pale (hypopigmented) or reddish skin patch.

2. A thickened or enlarged peripheral nerve, with loss of sensation and/or weakness of the muscles supplied by that nerve.

3. The presence of acid-fast bacilli in a slit skin smear.

**Definite loss of sensation** in a skin lesion may be detected by touching the skin lightly (use something like a piece of cotton wool). The person's skin is touched in different places. The person is then asked to point to each place that is touched. If the person cannot feel the points of contact within the skin patch but does point to other places where the skin is normal, diagnosis of leprosy is confirmed.

**Examination of the nerves** is an important part in the examination of a person affected with leprosy. But this requires experience and should be done only by staff specifically trained to do it.

**Skin smear examination** requires a suitably equipped laboratory with staff trained to perform this test. Leprosy skin smear services could be made available in selected units (such as those already doing sputum smears for the diagnosis of TB). In most patients, a skin smear is not essential in the diagnosis of leprosy, but in some cases of early MB leprosy it may be the only conclusive sign of the disease. The majority of people with leprosy have a negative smear.

**Peripheral level**

Examine the skin in sufficient light to identify all skin patches. Subsequently,

- note the number of patches,
- test for loss of sensation in the skin patches, and
- assess the disability grade (Section 4.6).
If there is definite loss of sensation in a skin lesion, make the diagnosis of leprosy, count the number of lesions to find the classification (Section 4.3) and start the person on MDT immediately (Section 5.1). If there is no loss of sensation, do not start treatment but refer the person for further examination.

Similarly one should be able to suspect nerve damage through elicitation of symptoms such as tingling in the limbs, weakness in the hands (inability to hold cup or button shirt) or lower limbs or eyes (watering, inability to close), and refer the person to referral centre for appropriate management.

**Referral level**

(1) Examine the whole skin in good light; identify all the skin patches. Note the number of patches. Note if there are nodules around the face or ears, areas of plaque or infiltration of the skin.

(2) Test for loss of sensation in the skin patches, as indicated above. **Definite loss of sensation in a skin patch is diagnostic of leprosy.**

(3) Examine the nerves for enlargement and test for loss of feeling and muscle weakness: this is to be done only by those trained.

Nerves which are commonly enlarged:

- The **great auricular nerve** on the side of the neck, below the ear, is sometimes visibly enlarged: gently feel it to make sure it is the nerve (solid) and not one of the veins in the neck (full of fluid).

- The **ulnar nerve** at the elbow, the **radial cutaneous nerve** and **median nerve** at the wrist, **common peroneal nerve** at the knee and **posterior tibial nerve** at the ankle, should be gently palpated for enlargement. This is a practical skill that must be learned and practised in a training session.

**Definite nerve enlargement, with loss of sensation or muscle weakness, is diagnostic of leprosy,** but it requires experience to do this examination properly.
Testing for sensory loss and muscle weakness in hands and feet:
- See Section 4.6 for all aspects of testing nerve function.

(4) If possible, arrange for a skin smear test, especially if there are nodular lesions or if most of the skin is infiltrated with very indistinct lesions and if there is no obvious loss of sensation. These features are more suggestive of multibacillary disease, in which the skin smear is often positive, but some of the other signs, such as loss of sensation, may not be present.

A positive skin smear in an untreated individual is diagnostic of leprosy.

4.3 How and why are leprosy cases classified?

Leprosy is a very variable disease, affecting different people in different ways, according to their immune response. Those at one end of the spectrum with a high level of immunity harbour a low number of bacilli and are termed paucibacillary or PB patients. Those with many bacilli in the body are referred to as multibacillary or MB cases. MB patients need more intensive treatment than PB patients - they need three instead of two antileprosy drugs taken for a longer duration of time. Classification in routine programmes is, therefore, a practical step which categorizes leprosy patients into two treatment groups.

A simple clinical rule is now used to divide patients into these two groups. The number of individual skin lesions is counted (this means that the whole body must be examined to make an accurate count):

- PB cases have up to five skin lesions in total.
- MB cases have six or more skin lesions.

If a skin smear is done and is positive, the patient must be classified as MB irrespective of the number of skin lesions. If the smear is negative, the classification is decided by the number of skin lesions. Other factors such as nerve involvement may be considered at the referral level for classifying the disease (e.g. multiple peripheral nerve involvement irrespective of the number of skin lesions).
The risk of nerve damage is greater in MB patients. Therefore, classification is helpful in assessing future risk (Section 6.1) and in guiding patient care.

4.4 What should be done when leprosy is suspected but the diagnosis is uncertain?

Generally, the most difficult cases to diagnose are people who present with one or two pale patches without loss of sensation or other signs of leprosy. In these cases, there are three options:

- Know where to refer cases that are difficult to diagnose; discuss cases with colleagues who have the experience of managing leprosy (Section 2.2).
- Consider the possibility of another skin disease and treat appropriately.
- Wait three to six months and review the skin lesions again; if it is a case of leprosy, loss of sensation may now be observed and MDT can be initiated.

If there is no loss of sensation in the skin lesions and no enlarged nerves but there are nevertheless suspicious signs, such as nodules or swellings on the face or earlobes, or infiltration of the skin, it is important to try and get a skin smear test done. In these circumstances a positive skin smear confirms the diagnosis of leprosy while a negative result (in the absence of other cardinal signs) would, in practice, rule out leprosy. An alternative diagnosis should then be considered.

In PB cases (where the skin smear will be negative), loss of sensation is almost always detected. In MB cases, normal sensation may still be present in a proportion of cases, but these patients often have one or more enlarged nerves and a positive skin smear. Signs of nerve involvement (enlarged nerves or signs of nerve damage such as numbness, tingling or weakness affecting hands or feet) may occasionally occur without any obvious skin lesions. In such cases, known as neural leprosy, the disease can only be diagnosed by someone having experience in assessing nerve involvement in leprosy.
4.5 How can the accuracy of leprosy diagnosis be ensured?

The diagnosis of leprosy is straightforward in the majority of cases. These cases should be diagnosed in clinics as near as possible to the patients’ homes and treatment with MDT should be started immediately or at least within a few days of diagnosis.

In some cases, the diagnosis is more difficult. As stated above (Section 4.4), the most difficult ones are early PB cases with one or two pale patches on the skin. Another difficult group (especially if skin smears are not available) of cases are early MB cases with very vague skin patches and no loss of sensation.

The following steps will help ensure accuracy in leprosy diagnosis:

1. Adherence to the criteria for case definition (Section 4.2).
2. Competent training about leprosy diagnosis for health workers (Section 9.8).
3. Regular and effective supervision, with on-the-job training (Section 9.4).
4. Clear lines of referral for suspect cases, when the diagnosis is uncertain (Section 2.2).
5. Availability of appropriate training and reference material (Section 10.1).

The quality of diagnosis should be monitored as part of regular technical supervision. If there are indications of substantial over-diagnosis, a validation exercise on a representative sample of cases can be conducted (Section 8.3) in order to understand the magnitude of the problem.

4.6 How is disability assessed and recorded in leprosy?

Disability is a broad term covering any impairment, activity limitation or participation restriction affecting a person.

Disability grading in leprosy

Every new case of leprosy must be assigned a “Disability Grade”, which depicts the condition of the patient at diagnosis. The grade
is on a scale of 0, 1 or 2. Each eye, each hand and each foot is given its own grade, so the patient actually has six grades, but the highest grade given is used as the Disability Grade for that patient.

*Grade-0* means no disability found.

*Grade-1* means that loss of sensation has been noted in the hand or foot (the eyes are not given a grade of 1). Loss of sensation in the hand or foot means that one of the main peripheral nerve trunks has been damaged by leprosy and this is more common in the later stages of the disease than during diagnosis. It should not be confused with the loss of sensation in a skin patch, which is caused by local damage to the small nerves in the skin and not to the main peripheral nerve trunks.

Persons with loss of sensation (grade-1 disability) on the soles of their feet, but no other abnormality, are at significant risk for developing plantar ulcers. Persons with grade-1 disability who routinely use appropriate shoes are protected from ulceration and have far fewer long-term problems with their feet. Therefore, measuring and recording grade-1 disability is an essential step in preventing damage to the feet of people affected by leprosy. It is, therefore, a key component of quality leprosy services.

*Grade-2* means that visible damage or disability is noted.

For the eyes, this includes the inability to close the eye fully or obvious redness of the eye (in leprosy, this is typically caused by either a corneal ulcer or by uveitis). Visual impairment or blindness also gives a disability grade of 2.

For the hands and feet, visible damage includes wounds and ulcers, as well as deformity due to muscle weakness, such as a foot drop or a claw hand. Loss of tissue, such as the loss or partial reabsorption of fingers or toes, is a late sign in leprosy, but it also gives a disability grade of 2 for that particular hand or foot.

**Peripheral level**

1. Check for grade-1 disability by asking the patient about loss of sensation in the hands and the feet.
2. Look for the signs of visible disability (grade-2):
   - Wounds or ulcers on the hands or feet.
   - Marked redness of the eye.
- Muscle weakness, causing:
  - Incomplete eye closure.
  - A claw hand.
  - A drop foot.

(3) Loss of tissue, such as fingers or toes shortened or missing

Any patient showing the above signs should be referred to a referral unit where prevention of disability (PoD) services are being provided. Visible disability should be recorded before referral.

**Referral level**

Examine carefully for any disability, recording the full results of the examination in the Patient Record Card for future reference.

**Eyes**

- Check the visual acuity of each eye separately, using a Snellen chart. If no chart is available, ask the person to count fingers at six metres. If the person cannot read the top line of the chart, or count fingers at six metres, they are visually impaired and have grade-2 disability in that eye.

- Look for an inability to close one or both eyes (lagophthalmos) and check for normal strength of eye closure.

- Look for any redness of the eye.

**Sensation in hands and feet**

Check the sensation in the palms of the hands and the soles of the feet, using a ballpoint pen:

- Explain the test to the patient.
- Ask them to close or cover their eyes.
- Touch the skin very lightly with the ballpoint.
- Ask the patient to point to the place you touched.
- Test a minimum of four points on each hand and foot.
- Note any areas where the pen is not felt.
NB: In the palm of the hand, the side with the little finger is supplied by the ulnar nerve. The part with the thumb, index and middle fingers is supplied by the median nerve. The sole of the foot is supplied by the posterior tibial nerve.

Check for muscle weakness

The three key muscles are:

(1) Thumb up (tests the median nerve):
   - Ask the person to put out their hand, palm up.
   - Support their hand in yours.
   - Ask them to point the thumb towards their own nose.
   - Test the strength of the thumb to stay in that position.

(2) Little finger out (tests the ulnar nerve):
   - Ask the person to put out their hand, palm up.
   - Support their hand in yours.
   - Ask them to move the little finger out.
   - Test the strength of the little finger to stay in that position.

(3) Foot up (tests the peroneal nerve):
   - Ask the person to sit down.
   - Support the person’s lower leg in your hand.
   - Ask them to point the foot up to the roof.
   - Test the strength of the foot to stay in that position.

Muscle strength is recorded as “strong” (S), “weak” (W) or “paralysed” (P). “Strong” (S) means that the muscle being tested is of normal strength; “weak” (W) means that the muscle can move, but is definitely weak; and “paralysed” (P) means that the muscle cannot move at all.
4.7 What are the key messages for someone newly diagnosed with leprosy?

When someone is newly diagnosed with leprosy, he/she should receive help and counselling so that the disease can be treated expeditiously in the best possible manner. It is important that the person realizes:

- that he/she should lead a normal life.
- where to get answers to any questions about leprosy.
- leprosy is caused by a germ and is curable:
  - the treatment is for either 6 or 12 months.
  - common side-effects include reddening of the urine and darkening skin is inevitable.
  - tablets must be taken every day at home.
  - a new blister-pack is needed every 28 days.
- consultations and treatment are free of charge:
  - discuss how often the person should attend, once a moth or less frequently.
- leprosy is no longer infectious once treatment has begun:
  - persons in close contact with the patient may develop leprosy and hence they should be brought in for examination at the earliest.
- the skin patches take time to disappear.
- leprosy reactions can occur, and can be treated:
  - patches can suddenly become red and swollen again
  - there may be pain or numbness in the limbs
  - there may be weakness of hand or feet
  - there may be eye problems: loss of vision, pain or redness.
- new disability can occur at any time but it can be treated.
- existing disability may or may not improve with treatment.
- when problems occur, treatment may be available locally, or the patient may need to be referred to another clinic for specialist care.
- various skills will need to be learnt to help prevent and manage disability.
5.1 What is MDT and what steps need to be taken when starting treatment?

Multidrug therapy (MDT) is a combination of drugs that is very safe and effective in treating leprosy to prevent the emergence of drug resistance. Under no circumstance should leprosy be treated by a single drug. It is distributed free of charge to all who need it. The drugs are taken orally. MDT is given out in convenient blister packs which provide supplies for four weeks of treatment (in these guidelines the four-week period is referred to as a “month”). There are different packs with the same drugs but in smaller doses for children. MDT is safe for women and their babies during pregnancy and breastfeeding. MDT can be given to HIV-positive patients, those on antiretroviral treatment and to patients on treatment for tuberculosis (TB). If a leprosy patient is treated for TB, the MDT regimen should omit rifampicin as long as the TB regimen contains rifampicin.

PB patients need two drugs for six months while MB patients need three drugs for 12 months (See Section 5.2 for drugs and dosage). Every effort must be made to ensure regularity of drug intake so that PB cases complete their treatment in six months and MB cases in 12 months.

There are various groups of people who need MDT, recorded as either New or Other:

- **New cases** include people with signs of leprosy who have never received treatment before.
- **Other cases** include:
- **Relapse cases** are treated exactly the same way as new cases (either PB or MB) *(Section 5.5).*
- People who return from default receive exactly the same treatment as new cases (either PB or MB) *(Section 5.4).*
- **Cases which have been transferred in:** These people should come with a record of the treatment they have received till date. They require only enough treatment to complete their current course.
- People with a **change in classification** from PB to MB need a full course of MB treatment.

**NB:** None of the “Other cases” should be recorded as “New cases”.

When it is determined that a patient needs to be treated with MDT, the following steps must be taken:

- Fill in the Patient Record Card and the Leprosy Treatment Register *(Section 8.4).*
- Determine which type of MDT is required: PB or MB *(Section 4.3).*
- Determine which dose level is required: adult or child *(Section 5.2).*
- Counsel the person (and the parents, if it is a child) to indicate:
  - the need for regular treatment.
  - the possibility of complications of leprosy which may need other treatment.
  - that the clinic is always ready to assist them if they have any problems.
- Give the first dose of treatment and explain how to continue the treatment at home.

As long as accessibility is not a problem, the drugs administered once a month should be supervised; in other words, the health worker should make sure that the drugs have actually been taken. The other drugs are taken at home. The supervised dose is most conveniently arranged by having the patient attend the clinic each month. This monthly visit is also useful for monitoring the regularity of treatment and to identify
complications (such as neuritis, reaction, etc) at an early stage. Supervision of the monthly dose is important to ensure regularity of treatment, eventual cure and prevention of relapse.

5.2 Which drugs are included in MDT and what are the doses for adults and children?

MDT treatment is provided in blister packs, each containing drugs for four weeks’ treatment. Specific blister packs are available for multibacillary (MB) and paucibacillary (PB) leprosy as well as for adults and children.

<table>
<thead>
<tr>
<th>The standard adult treatment regimen for MB leprosy is:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Rifampicin:</strong> 600 mg once a month</td>
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<tr>
<td><strong>Clofazimine:</strong> 300 mg once a month, and 50 mg daily</td>
</tr>
<tr>
<td><strong>Dapsone:</strong> 100 mg daily</td>
</tr>
<tr>
<td><strong>Duration:</strong> 12 months (12 blister packs)</td>
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</table>

<table>
<thead>
<tr>
<th>The standard adult treatment regimen for PB leprosy is:</th>
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<tbody>
<tr>
<td><strong>Rifampicin:</strong> 600 mg once a month</td>
</tr>
<tr>
<td><strong>Dapsone:</strong> 100 mg daily</td>
</tr>
<tr>
<td><strong>Duration:</strong> Six months (six blister packs)</td>
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</table>

<table>
<thead>
<tr>
<th>Standard child (age 10-14) treatment regimen for MB leprosy is:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Rifampicin:</strong> 450 mg once a month</td>
</tr>
<tr>
<td><strong>Clofazimine:</strong> 150 mg once a month, and 50 mg every other day</td>
</tr>
<tr>
<td><strong>Dapsone:</strong> 50 mg daily</td>
</tr>
<tr>
<td><strong>Duration:</strong> 12 months (12 blister packs)</td>
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</tbody>
</table>

<table>
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<tr>
<th>The standard child (age 10-14) treatment regimen for PB leprosy is:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Rifampicin:</strong> 450 mg once a month</td>
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</tr>
<tr>
<td><strong>Duration:</strong> Six months (six blister packs)</td>
</tr>
</tbody>
</table>

The appropriate dose for children under 10 years of age can be decided on the basis of body weight [Rifampicin: 10 mg per kilogram body weight; Clofazimine: 1 mg per kilogram per body weight daily and 6 mg per kilogram monthly; Dapsone: 2 mg per kilogram body weight daily. The standard child blister pack may be broken up so that the appropriate dose is given to children under 10 years of age. Clofazimine can be spaced out as required].
Rarely, it may be considered advisable to treat a patient with a high Bacterial Index (BI) for more than 12 months. This decision may only be taken by specialists at referral units after careful consideration of the clinical and bacteriological evidence.

5.3 What should be done when a person does not regularly attend clinic for treatment?

Every effort should be made to persuade newly diagnosed patients to complete their treatment as prescribed (Section 5.1); discuss attendance at the clinic; and if there is likely to be any difficulty, work out ways in which it can be made easier for the patient.

There are several reasons why someone may not attend clinic regularly. These include:

- Poor accessibility of the clinic (it may be located at a distance, or the journey involved may be difficult, or the timing could be inconvenient).
- Difficulty in taking time off from work or nomadic lifestyle.
- Lack of understanding about the disease and the importance of regular treatment.
- Stigma, often fed by negative attitudes and fear in the community.
- A poor relationship with the health worker.

As soon as someone misses an MDT appointment, action should be taken to find out why the patient has not attended the clinic and, if necessary, to remind the patient of the importance of taking treatment regularly and finishing the full course of MDT. If this proves insufficient, a home visit by a local community worker should be arranged to find out why the patient has stopped visiting the clinic and, if necessary, motivate him or her to resume treatment. Such a home visit should be undertaken preferably within one month of the date of the first missed visit.

If the person has difficulty in attending the clinic, it may help if arrangements are made for them to receive several blister packs at once so that the visits to the clinic are made less frequent. It is advisable in such cases to involve another responsible person.
to supervise the treatment (a community volunteer, a family member or neighbour) to help the patient to continue the treatment properly from home (this is called Accompanied MDT, or A-MDT). Counselling and information about the importance of regularity of drug intake is essential. They should also be advised to report to the clinic in case of any problem.

5.4 Who is a defaulter and what should be done for people who return to the clinic after defaulting?

Although every effort must be made to ensure that PB patients complete their treatment regimen in six months and MB patients in 12 months, the treatment regimen for PB leprosy must be completed within a maximum period of nine months. Similarly, the treatment regimen for MB leprosy must be completed within a maximum period of 18 months.

A defaulter is an individual who fails to complete treatment within the maximum allowed time-frame. Thus, whenever a PB patient has missed more than three months of treatment or an MB patient more than six months of treatment, it is not possible for them to complete the regimen in the maximum time allowed and they should be declared as defaulters from treatment. This should be indicated in the Leprosy Treatment Register under the heading “Treatment Outcome”.

If a patient returns after default, examine him/her in the same way as you would examine a new patient and record your findings.

If the returning patient was previously a PB case:

- Count the number of patches to confirm the original classification (Section 4.3).
- If the classification is now MB (more than five lesions), register the patient as a return from default, not as a new case, and treat with a full course of MB-MDT (12 months).
- If the classification remains PB, register the patient as a return from default, not as a new case, and give a full course of PB-MDT.
- If there are signs of a reaction (Section 5.8), manage appropriately.

If the returning patient was previously an MB case:
• Register the patient as a return from default, not as a new case and not as a relapse (a relapse can only occur after fully completing the first course of MDT).
• Treat with a full, 12-month course of MB-MDT.
• Remember that a reaction may mimic a return of the disease (Sections 5.8 and 5.9).

Any defaulter, particularly one who remains very irregular on treatment and repeatedly defaults despite every effort on the part of the health staff, may be referred to a more experienced person so that the latter can decide if further treatment is required and how much of it.

5.5 What is a relapse? How is it recognized and managed?

Relapse is defined as the re-occurrence of the disease at any time after the completion of a full course of treatment with WHO-recommended MDT. Relapse is diagnosed by the appearance of definite new skin lesions and/or an increase in the bacterial index (BI) of two or more units at any single site compared to BI taken from the same site at the previous examination. Care should be taken to exclude patients suffering from leprosy reactions (Section 5.8).

MDT is a very effective treatment for leprosy. If a full course of treatment has been administered properly, relapse is generally rare, although continued vigilance is important as sporadic reports of relapses due to drug resistance have been recently reported. Patients who start treatment with a high BI are more likely to suffer a relapse later; most relapses occur long after the treatment was given, sometimes more than 10 years later. Fortunately, the use of a combination of drugs has limited the development of drug resistance in leprosy, so generally relapse cases can be treated effectively with the same drug regimen – MDT.

PB relapses are difficult to differentiate from reversal reactions (Section 5.9). If there are signs of recent nerve damage, a reaction is very likely. The most useful distinguishing feature is the time that has passed since the person was treated: if it is less than three years a reaction is most likely while if it is more than three years, a relapse becomes more likely. A reaction may
be treated with steroids, while a relapse will not be greatly affected by a course of steroids. Therefore, using steroids as a “therapeutic trial” can clarify the diagnosis.

MB relapses should be investigated by using skin smears, histopathology and, where possible, for drug sensitivity using recently standardized molecular tests.

**Peripheral level**

Suspected relapses should be referred for further investigation at a referral centre.

**Referral level**

Suspected PB relapse: PB relapse is diagnosed by the appearance of a definite new skin lesion and/or a positive skin smear. The diagnosis of a PB relapse can never be absolutely certain. A skin smear should be carried out, if at all possible, to ensure that an MB case is not being misclassified as PB. The evidence for either a relapse or a reaction must be weighed and a decision made. If it is decided to treat someone as a case PB relapse, they are given a normal six-month course of PB-MDT.

MB relapse is diagnosed by the appearance of definite new skin lesions and/or an increase in the bacterial index (BI) of two or more units at any single site compared to BI taken from the same site at the previous examination. Care should be taken to exclude patients suffering from leprosy reactions. The MB relapses are generally treated with 12 months’ MB-MDT.

5.6 Is drug resistance a problem?

The current treatment based on WHO-recommended multidrug therapy for MB and PB leprosy is unlikely to have any major, immediate changes. However, this situation may be threatened by the emergence of rifampicin resistance. Limited availability of mouse-foot pad inoculation technique means there has been very little information till recently on drug resistance. With the recent development of DNA sequencing methods, several reports of rifampicin, dapsone and ofloxacin resistance have been published.
which underscores the importance of this condition and highlights the need for its systematic monitoring. The problem of drug resistance may not be serious at present, but it is important that we collect data more systematically and monitor trends carefully so that effective measures to combat this problem can be developed in the future. This requires improved reporting of relapses at the national level and highlights a need to standardize case ascertainment and definitions.

5.7 What complications occur in leprosy and how are they managed?

The complications of leprosy come under five headings:

- Leprosy reactions (Section 5.8).
- Effects of nerve damage (Section 6.2).
- Adverse effects of MDT.
- Complications of advanced disease.
- Psychosocial problems.

Adverse effects of MDT

MDT is remarkably safe and serious adverse effects are very rare.

<table>
<thead>
<tr>
<th>Minor problems</th>
<th>Drug</th>
<th>Management</th>
</tr>
</thead>
<tbody>
<tr>
<td>Red urine</td>
<td>Rifampicin</td>
<td>Reassurance</td>
</tr>
<tr>
<td>Brown discolouration of the skin</td>
<td>Clofazimine</td>
<td>Counselling</td>
</tr>
<tr>
<td>Gastrointestinal irritation</td>
<td>All three</td>
<td>Give drugs with food</td>
</tr>
<tr>
<td>Anaemia</td>
<td>Dapsone</td>
<td>Give iron and folic acid</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>More serious problems</th>
<th>Drug</th>
<th>Management</th>
</tr>
</thead>
<tbody>
<tr>
<td>Itchy skin rash</td>
<td>Dapsone</td>
<td>Stop dapsone, refer</td>
</tr>
<tr>
<td>Allergy, urticaria</td>
<td>Dapsone or Rifampicin</td>
<td>Stop both, refer</td>
</tr>
<tr>
<td>Jaundice</td>
<td>Rifampicin</td>
<td>Stop rifampicin, refer</td>
</tr>
<tr>
<td>Shock, purpura, renal failure</td>
<td>Rifampicin</td>
<td>Stop rifampicin, refer</td>
</tr>
</tbody>
</table>
Other drugs are available for use if one or more of the standard drugs have to be stopped, but serious adverse drug reactions are complex problems and must be managed by specialists.

Complications of advanced disease

Most late complications are easily prevented by MDT and are rarely seen these days, but it is important to refer patients with unusual complications:

Eye problems

Leprosy can lead to blindness because of damage to the cornea, or due to damage to the internal structures of the eye. Refer to an eye specialist any patient who reports decreased vision or has a red or painful eye.

Facial and other deformities

The sunken nose, loss of eyebrows and the so-called ‘leonine’ face which used to be characteristics of untreated MB leprosy are cosmetic problems and visible disfigurements that lead to severe stigma and discrimination. Fortunately, these instances are now rare. Plastic surgery is needed to correct these lesions.

Internal medical conditions

Chronic untreated leprosy (fortunately no longer reported) and chronic ENL reactions (still a serious complication in a small proportion of patients) may lead to internal medical complications. Such patients need referral to the appropriate specialists.

Psychosocial problems

Psychosocial problems are related to widely-held beliefs and deep-rooted prejudices concerning leprosy and its underlying causes, and not merely to the problem of disability. People with leprosy often suffer from low self-esteem and depression, as a result of rejection and hostility they endure at the hands of the family and community. Such negative attitudes are also observed among staff of the health services, including doctors. These need to be addressed with urgency. People suffering from psychosocial problems may need to be referred for counselling or other help.
5.8 What are leprosy reactions? How are they suspected and managed?

The long-term problems related to leprosy (deformity and disability resulting in stigma and suffering for the patient and family) are due to damage from leprosy reactions. Early recognition and effective management of reactions are thus very important. Longer-term assistance for people with nerve damage is covered in Sections 6 and 7.

A leprosy reaction is the sudden appearance of symptoms and signs of inflammation in the skin lesions of a person with leprosy. There is redness, swelling and sometimes tenderness of the skin lesions. New skin lesions may appear. There may also be swelling, pain and tenderness of nerves, often accompanied by loss of function; sometimes loss of nerve function occurs without other signs of inflammation, making it much less obvious – so called “silent neuritis”.

Recent (within the last six months) loss of function in one or more peripheral nerves is the main reason for steroids to be prescribed in leprosy. Monitoring nerve function on a regular basis and using the checklist in Section 4.6 enables new nerve damage to be detected in time and treated.

**Peripheral level**

Reactions requiring treatment with steroids may be suspected when patients have symptoms suggestive of new nerve damage, such as numbness, or muscle weakness in the hands or feet. They should be referred to a specialist unit where they can be monitored and treated effectively.

The following signs also indicate that a reaction is severe and the patient must be referred:

- Red, painful, single or multiple nodules in the skin with or without ulceration.
- Pain or tenderness in one or more nerves, with or without loss of nerve function.
- Silent neuritis – nerve function impairment, without skin inflammation.
- A red, swollen skin patch on the face, or overlying another major nerve trunk.
• A skin lesion that becomes ulcerated, or that is accompanied by a high fever.
• Marked oedema of the hands, feet or face.
• Pain and or redness of the eyes, with or without loss of visual acuity.
• Painful swelling of the joints with fever.

Reactions which show none of these signs of severity, but which are limited to mildly inflamed skin lesions, may be treated symptomatically with aspirin.

Referral level

MB patients with nerve damage present at the time of diagnosis are at high risk of further nerve damage (Section 6.1) and should be examined regularly for the same. Monitor nerve function on a monthly basis (or at least every three months) using the checklist in Section 4.6. Recent nerve function impairment (appearing within the last six months) is the most important sign of a reaction requiring treatment with steroids.

There are two types of reaction: reversal reaction (or Type 1) and Erythema Nodosum Leprosum (ENL or Type 2). Both types can occur before the start of treatment, during treatment, or after treatment has been completed. Both types can be divided into mild or severe: only severe reactions are treated with corticosteroids. Patients with single skin lesions are unlikely to get reactions, but most other patients have some risk of getting a reversal reaction. Only a much smaller group of MB patients with a high load of bacilli are at risk of developing an ENL reaction.

Distinguishing between the two types of reactions is usually not difficult: in a reversal reaction, the leprosy skin lesions themselves become inflamed, red and swollen. On the other hand, in an ENL reaction, new inflamed, red nodules (about 1–2 cm across) appear under the skin of the limbs or trunk, while the original leprosy skin patches remain as they were. In addition, ENL reactions cause a general feeling of fever and malaise while reversal reactions cause less systemic upsets.
Signs of a severe reversal reaction
If any of the following signs is found, the reaction should be treated as severe:

• Loss of nerve function, that is, loss of sensation or muscle weakness.
• Pain or tenderness in one or more nerves.
• Silent neuritis.
• A red, swollen skin patch on the face, or overlying another major nerve trunk.
• A skin lesion anywhere that becomes ulcerated.
• Marked oedema of the hands, feet or face.

Severe reversal reactions should be treated with a course of steroids, usually lasting three to six months. Steroids should be prescribed by someone properly trained in using these drugs. There are a number of important side-effects associated with steroids and, therefore, a careful assessment must be made of any patient requiring them.

Signs of a severe ENL reaction
If any of the following signs is found, the reaction should be treated as severe:

• Pain or tenderness in one or more nerves, with or without loss of nerve function.
• Ulceration of ENL nodules.
• Pain and or redness of the eyes, with or without loss of visual acuity.
• Painful swelling of the testes (orchitis) or of the fingers (dactylitis).
• Marked arthritis or lymphadenitis.

ENL reactions are complex medical problems requiring careful management by experienced clinicians. Short courses of steroids are often used, but other drugs are also useful.
5.9 How is a relapse distinguished from a reaction in leprosy?

Various criteria may help in distinguishing a relapse from a reaction:

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Relapse</th>
<th>Reaction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time since completion of treatment</td>
<td>More than three years</td>
<td>Less than three years</td>
</tr>
<tr>
<td>Progression of signs and symptoms</td>
<td>Slow</td>
<td>Fast</td>
</tr>
<tr>
<td>Site of skin lesions</td>
<td>In new places</td>
<td>Over old patches</td>
</tr>
<tr>
<td>Pain, tenderness or swelling</td>
<td>No</td>
<td>Yes - skin and nerves</td>
</tr>
<tr>
<td>Damage</td>
<td>Occurs slowly</td>
<td>Sudden onset</td>
</tr>
<tr>
<td>General condition</td>
<td>Not affected</td>
<td>Inflammation</td>
</tr>
</tbody>
</table>

**Peripheral level**

Refer such patients for specialist assessment.

**Referral level**

The assessment of any patient who has previously been treated for leprosy should be carried out as follows:

Take a full history of the current problem, including:

- When did the new symptoms appear?
- Where and when previous treatment was taken?
- Did new lesions appear quickly or over a long period?
- What is the relationship with the old skin patches?
- Has there been any pain, tenderness or swelling?
- Has there been any recent loss of function in any nerves?

Carry out a full examination of the skin and of nerve function in order to identify any signs of a recent reaction.

Arrange for a skin smear test to be done; an MB relapse is associated with an increase in the bacillary load. Obviously, if no previous smear has been done, it is impossible to identify
an increase. In this case, the presence of solid staining bacilli in the smear provides support to the diagnosis of a relapse.

If no firm conclusion can be made after all these investigations, a trial of steroids may be considered. A reaction would begin to settle in 10-14 days while a relapse would be unchanged by such treatment.

5.10 What are the key messages for someone who is completing treatment successfully?

Most patients in this situation will have no further problems. However, after being congratulated for completing treatment, they need to be made aware of possible complications:

- Recurrence of the disease (relapse) is rare, but if they suspect the disease has returned, they should opt for further examination. If leprosy recurs, it can be treated again.

- Reactions can occur, even after treatment has been successfully completed. If any unusual symptoms occur (including weakness, numbness or pain in the limbs, or loss of vision or other eye problems) the person should return for examination and treatment. This is especially important for MB patients.

- If some disability is already present, make sure the person knows what they need to do at home to manage the problem (Sections 6.3, 6.4 and 6.5). Arrange for any follow-up or referral that may be necessary.
6.1 Are some patients more at risk of nerve damage than others?

The longer the delay between the appearance of the first symptoms of leprosy and the start of treatment, the more likely that nerve damage will occur. For this reason, every effort should be made to inform the public that early diagnosis and treatment of leprosy prevents the occurrence of long-term complications.

It is important to realize that significant nerve damage does also occur during MDT and after the patient has completed the full course of MDT; the risk declines steadily over the following three years. MB cases with impaired nerve function at diagnosis are at much higher risk of nerve damage than other patients and, therefore, should be monitored more closely (Section 5.8).

6.2 What are the effects of nerve damage in leprosy?

Recent nerve damage (present for less than six months) can usually be reversed by steroids, but in many cases the damage has occurred long ago and no further recovery is expected. Such persons need to learn how to minimize any adverse effects and how to prevent any worsening of the damage.

There are five common, physical problems that affect everyday life for people who have had leprosy. Many have to cope with more than one of these problems:

(1) Problems with eye closure: Lack of muscle strength to shut the eye causes the cornea to be exposed. This causes dryness and damage to the cornea leading to ulceration.
These ulcers heal, but healed ulcers interfere with vision, leading eventually to blindness. The aim of PoD interventions is to preserve sight.

(2) **Loss of sensation in the hand:** Numbness is usually accompanied by loss of sweating and, therefore, extreme dryness of the skin. Together, these lead to recurrent injury, cracking and ulceration. These in turn lead to chronic infection, stiffness and loss of tissue, making the hand more and more disabled. PoD interventions aim at keeping the skin in good condition and avoiding injury, if necessary by adjusting routine activities.

(3) **Weakness and deformity of the hand:** Muscle weakness is a disability by itself, but over time it often leads to the formation of contractures and fixed deformity. PoD activities help to preserve strength and prevent contractures and deformity.

(4) **Loss of sensation and ulceration of the foot:** The same problems of dryness, recurrent injury (especially from walking), cracking and ulceration occur in the insensitive foot. Late complications include chronic infection (osteomyelitis), sometimes necessitating amputation. PoD interventions target the condition of the skin and the provision of appropriate footwear to help prevent injury. Changes to routine activities may also be advised.

(5) **Weakness and deformity of the foot:** Muscle weakness affecting the toes is quite common, but it does not usually affect walking. A foot-drop leads to problems with walking.

### 6.3 What can be done for people with disabilities due to leprosy?

There are three categories under which useful interventions can be described:

**Home-based self-care (see also Section 6.4):**

- These are activities performed by the person at home.
- Self-care succeeds when people fully take charge of their own care.
- Daily dressing of wounds can be done at home, using local material.
Simple interventions organized at the local clinic:

- The clinic can help with some simple PoD activities.

Referral services for more complex interventions:

- Some interventions require inputs from specialists.

**Home level**

Activities to prevent disability which can be performed by the person at home

- **Problems with eye closure:**
  - Inspect the eye in a mirror every day to check for redness.
  - Learn to blink frequently to keep the eyes moist and exercise the lids.
  - Wear a hat or sunglasses to prevent dust from getting into the eyes.
  - Use a sheet or mosquito net to cover the head at night.

- **Problems with the hand:**
  - Inspect daily for signs of injury.
  - Loss of feeling is associated with dryness of the skin, so the insensitive hand must be soaked in water for about 30 minutes every day, to maintain skin elasticity. Use a rough stone to smoothen the callus, and then apply oil or petroleum jelly when the skin is still wet to prevent the skin from drying out.
  - Use a clean cloth to cover any open wound.
  - If there is weakness of the muscle in the hand, passive stretching and active exercises will help prevent contractures and may lead to some strengthening.

- **Problems with the foot:**
  - Inspect daily for signs of injury.
  - Soak and oil the feet. As for the hands use a rough stone to rub away the callus.
  - Walk as little as possible and walk slowly. Rest frequently.
- If ulcers are present, rest is essential.
- Use a clean cloth to cover open wounds.
- If there is a foot-drop, passive stretching will help prevent a contracture of the Achilles tendon.

“All simple ulcers will heal, if given sufficient rest. No ulcer will heal if not rested sufficiently.”

### Peripheral level

These include activities which can be done in the peripheral clinic.

General health workers cannot be taught all of these interventions as a matter of routine. When they have a patient with certain disability problems, however, they can arrange to see that person with their supervisor so that specific interventions relevant to that person can be discussed (Section 9.4). Leprosy-related disabilities are long-term problems and individual health workers should learn how to manage the specific problems seen in their own patients.

Provide any help that may be needed by the person to carry out the home-based self-care tasks mentioned above.

- Problems with eye closure:
  - Provide saline drops for use if the eyes are very dry.
  - Treat conjunctivitis with antibiotics and an eye pad.
  - Refer more serious eye problems to an eye clinic.
- Problems with the hand:
  - Review, guide and refer if required.
- Problems with the foot:
  - Organize appropriate footwear (Section 6.5)
  - Review, guide and refer if required.
Referral level

These are interventions which can usually only be done at a referral centre.

- Problems with the eyes:
  - Any acute eye problem should be managed at an eye clinic.
  - Corrective surgery may be helpful in severe cases of lagophthalmos.
  - Remember that cataract is the commonest cause of blindness in elderly people, whether or not they have leprosy. Leprosy does not prevent routine cataract surgery.

- Problems with the hand:
  - Help the person adapt tools to avoid injury to insensitive hands
  - Remove thick callus and trim ulcers with a scalpel blade
  - If there is weakness or a contracture, make a splint to wear at night
  - An invasive infection (the hand is hot, red and swollen) is an emergency and must be referred for intensive antibiotic treatment and surgery
  - Surgery may be useful in some cases of weakness or claw-hand.

- Problems with the foot:
  - Remove thick callus and trim ulcers with a scalpel blade.
  - Chronic ulcers may be helped by orthotics, or by surgery.
  - For a foot-drop, make a spring-loaded device to keep the foot in the correct position while walking.
  - An invasive infection (the foot is hot, red and swollen) is an emergency and must be referred for intensive antibiotic treatment and surgery.
  - Foot-drop surgery.
6.4 How can people be encouraged to practice self-care at home?

There are many ways in which the complications of leprosy can be minimized by practicing good self-care at home, as indicated earlier. People need to be informed clearly about the actions they can take at home that are appropriate for their particular situation.

The health worker may be the main source of advice but others can be recruited to help:

Ø Family members can help and encourage the person to do what is needed on a regular basis.
Ø Other people affected by leprosy can provide guidance on how they have been able to look after themselves at home.

Self-care groups have been started in some communities. A number of people with self-care needs meet together regularly to discuss the practicalities of self-care. These groups are often surprisingly supportive and can be very motivating for members.

6.5 What is the value of appropriate footwear for people affected by leprosy?

Loss of feeling on the sole of the foot and ulceration are very common in people affected by leprosy, so the use of appropriate footwear is very important to prevent disability.

The best solution for a person affected by leprosy is to wear locally available and socially acceptable shoes whenever they are on their feet and walking. It is of no help to use shoes only for special occasions.

Most people do not require specially-made footwear; the right shoes found in the market can be just as effective. Sports shoes or running shoes are often very appropriate; alternatively, sandals or shoes with a firm under sole and a soft insole may be used. They should preferably have hard outsole and soft insole; fit comfortably; velcro straps are easier to use than other types of fastenings and heel straps are needed for sandals.
7 Rehabilitation

7.1 What is rehabilitation?

"Rehabilitation includes all measures aimed at reducing the impact of disability for an individual, enabling him or her to achieve independence, social integration, a better quality of life and self-actualization."

UN Standard Rules for Equalization of Opportunities for Persons with Disabilities (PWD)

7.2 What is the role of health workers in rehabilitation?

**Peripheral level**

Health staff may not have the time or expertise to be involved in rehabilitation activities. However, they need to be able to identify physical, functional or socioeconomic problems resulting from disability, know about available services for rehabilitation, and how to refer people to make use of such services. Health workers may need to play an advocacy role to ensure that those affected by leprosy have access to health-care services, including rehabilitation facilities, in the same way as other people.
The following are examples of interventions that may be available.

<table>
<thead>
<tr>
<th>Problems</th>
<th>Rehabilitation interventions</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Anatomical:</strong></td>
<td></td>
</tr>
<tr>
<td>Anaesthesia of hands and feet</td>
<td>Self care</td>
</tr>
<tr>
<td>Deformity of the hand</td>
<td>Reconstructive surgery and physiotherapy</td>
</tr>
<tr>
<td>Foot-drop</td>
<td>Ankle-foot orthosis, reconstructive surgery</td>
</tr>
<tr>
<td>Amputation</td>
<td>Prosthesis</td>
</tr>
<tr>
<td><strong>Psychological:</strong></td>
<td></td>
</tr>
<tr>
<td>Depression</td>
<td>Counselling</td>
</tr>
<tr>
<td><strong>Functional:</strong></td>
<td></td>
</tr>
<tr>
<td>Limitation of fine hand movements</td>
<td>Occupational therapy</td>
</tr>
<tr>
<td>Mobility limitations</td>
<td>Crutches or wheelchairs</td>
</tr>
<tr>
<td><strong>Social participation:</strong></td>
<td></td>
</tr>
<tr>
<td>Stigma in the family</td>
<td>Counselling</td>
</tr>
<tr>
<td>Exclusion from community functions</td>
<td>Education and advocacy</td>
</tr>
<tr>
<td>Children with disability</td>
<td>Promoting inclusive education</td>
</tr>
<tr>
<td><strong>Economic:</strong></td>
<td></td>
</tr>
<tr>
<td>Loss of employment placement</td>
<td>Vocational training and/or</td>
</tr>
<tr>
<td>Poverty</td>
<td>Microcredit for self-employment</td>
</tr>
</tbody>
</table>

### 7.3 What is Community-based rehabilitation?

Leprosy may lead to physical, functional, social and/or economic problems. Physical rehabilitation includes physiotherapy and occupational therapy, orthotics and prosthetics services, assistive and protective devices, and sometimes corrective surgery. Social
and economic rehabilitation aims at social integration, equal opportunities and economic advancement.

A comprehensive approach to rehabilitation is needed to maximize the benefit for the individual, family and society at large. Considering the limited availability of specialized institutional services, the World Health Organization introduced a strategy called ‘Community-based Rehabilitation’ (CBR). CBR is defined as “a strategy within general community development for the rehabilitation, equalization of opportunities and social inclusion of all people with disabilities” (ref. to Joint Position Paper on CBR 2004). The CBR approach emphasizes community participation and empowerment of the individuals involved. Poverty has been identified as a root problem that causes and aggravates disability. Addressing poverty is, therefore, an essential part of rehabilitation.

Although most basic rehabilitation activities can be carried out within the person’s own community, many persons with disabilities have to be temporarily referred to specialized services. Cooperation is needed between specialized services and CBR programmes. Networking among existing services should be actively promoted. CBR is a team effort and requires the full participation of the clients, their families and communities in the rehabilitation process. Organizations of people with disability need to be involved actively in the planning and management of rehabilitation services.

Persons affected by leprosy who are in need of rehabilitation should have access to any existing (general) rehabilitation services. Similarly, where leprosy-specific rehabilitation services are available, people with other disabilities should be given access. This facilitates integration, helps to break down stigma and promotes sustainability of rehabilitation services.

7.4 What actions are needed to promote inclusion of persons affected by leprosy in CBR?

There cannot be one model of community-based rehabilitation because socioeconomic conditions, terrain, culture and political systems differ. Some of the following steps may assist in formulating a viable CBR strategy:
• Developing a national plan on community-based rehabilitation with a clear policy, objectives and a coordinated implementation plan involving other relevant sectors and partners.
• Preparing guidelines for mobilizing local resources and providing special services, interventions from government and nongovernmental organizations.
• Establishing a network of services.
• Developing the capacity of service-providers.
• Promoting team approach for providing service.
• Introducing locally-specific techniques to train and develop skills and knowledge of people with disabilities and their families.
• Promoting opportunities for educational, functional and vocational training and job placements.
• Involving people with disabilities and their families in the decision-making process.
8.1 What are the main indicators for monitoring progress and how are they used?

The following are the main indicators used for monitoring the epidemiological trends of leprosy:

- Number and rate per 100 000 population of new cases detected per year.
- Number and rate of new cases with grade-2 disabilities per 100 000 population per year.
- The proportion of patients who complete their treatment on time as proxy-to-cure rate.

The number of new cases indicates the extent of leprosy in an area. This shows how much MDT should be supplied to that area during the following year. Given the consistent procedures for case detection, annual figures over a period of several years will reveal whether there is an increase or decrease in numbers, which may in turn indicate whether activities aimed at controlling the disease are effective. If the population of the area is known, it is possible to calculate the case detection rate (the number of new cases per 100 000 population) which can be compared with other areas.

The number of new cases with grade-2 disabilities detected in a population gives an indication of under-detection due to various reasons. The changes in the rate of new cases with grade-2 disabilities per 100 000 population is expected to reflect changes in the new case detection rate.
The proportion of new patients who complete their treatment on time is an indication of how well the leprosy patients are being served by the health services. The information required to calculate this indicator can be collected either through the routine reporting system from all health facilities or from a representative sample of health facilities as part of supervision. The rate is calculated separately for PB and MB patients, in what is known as a “cohort analysis”. A cohort is simply a group of patients who all started treatment in the same batch, usually in the same year.

The calculation of the completion rate is as follows:

1. The report date will normally be at the beginning of a new reporting year and the annual report will refer to the year just completed (Year “Y”). For completion statistics, the PB cohort will be from year Y-1; the MB cohort will be from year Y-2.

2. Identify all the PB patients who are new cases in the register (Sections 5.1 and 8.4) and who started MDT in year Y-1. Note this number.

3. From this cohort, count the number who completed treatment within nine months of registration.

4. The PB treatment completion rate is calculated as follows:

\[
\frac{\text{Number of new PB cases who completed MDT}}{\text{Number of new PB cases who started MDT}} = \times 100
\]

5. Identify all the MB patients who are new cases in the register and who started MDT in the year Y-2. Note this number.

6. From this cohort, count the number who completed treatment within 18 months of registration.

7. The MB treatment completion rate is calculated as follows:

\[
\frac{\text{Number of new MB cases who completed MDT}}{\text{Number of new MB cases who started MDT}} = \times 100
\]

8. Note that each cohort includes all new cases that started treatment during the year, including any who became defaulters or who died before completing treatment.

For example, the report for the year Y= 2010 will include completion statistics for PB cases registered in 2009 (year Y-1) and MB cases registered in 2008 (Year Y-2).
8.2 What are the main indicators for evaluating case-detection activities?

The following indicators may be used for evaluating case-detection activities. The information used to calculate these indicators is usually collected and reported routinely.

**Number and proportion of new cases with grade-2 disabilities (Section 4.6)**

The proportion of new cases with grade-2 disabilities among all new cases detected during the year is used to assess the delay in diagnosis as an indicator of quality of case-detection activities.

**Number and proportion of child cases (under 15 years of age) among new cases**

If the transmission of leprosy is being reduced in an area, it is expected that the number of children affected will decrease. Monitoring this indicator over several years may show a trend. It is also required for correctly replenishing the stock of child doses for MDT.

**Number and proportion of female cases among new cases**

Many programmes diagnose leprosy more frequently in men than in women, but there is concern that women may have less access to health care in some situations. Thus a ratio of 2 males to every 1 female is commonly seen. If the ratio is higher, steps should be taken to ensure that women have adequate access to diagnostic services.

**Number and proportion of multibacillary cases among new cases (Section 4.3)**

This is a useful guide to the cases at risk of developing complications and is needed for accurately replenishing the stock of MDT.

8.3 What are the indicators for assessing the quality of leprosy services?

Each programme may have to define its own national minimum quality standard for leprosy services, taking into consideration the capacity and competence of the health staff and the availability of resources. Quality of leprosy services can be assessed using a wide range of
tools, from routinely collected epidemiological indicators to highly sophisticated health systems research studies. Depending on the capacity of the programme to collect and analyse data, further indicators can be measured and reported giving a better indication of the quality of services being provided. Quality of services should be viewed as part of the responsibilities of every health facility providing leprosy services and should be adhered to by all staff of the facility. The following indicators for quality of leprosy services may be collected, usually on a representative sample basis or as part of an integrated supervision process.

The proportion of new cases correctly diagnosed (Section 4.5)
The accuracy of diagnosis should be assessed through regular technical supervision. If there is any suggestion of significant over-diagnosis, a sample of new cases should be reviewed within three months of the diagnosis being made. The proportion of new cases included in the review would depend on the total number of cases and the resources available (staff and funds) for the review. This would identify problem areas where additional training and supervision are needed, but would not impede treatment at all.

The proportion of treatment defaulters (Section 5.4)
This only requires examination if the completion rate is low. The proportion of patients who default and who are transferred out are calculated in exactly the same way as the cure rate. If transfer out is the main reason for non-completion of treatment, the situation needs to be investigated to find out whether the transferred patients are really continuing treatment at a new clinic, or whether in fact they simply stop taking treatment.

The number of relapses reported during the year (Section 5.5)
Relapse cases occur sporadically and are generally not part of any defined cohort, so these figures are difficult to analyse. If higher numbers are reported from any particular area, further investigations must be carried out.

The proportion of patients who develop new or additional disability during MDT (Section 4.6)
Possible methods of calculating this indicator are given below:

This indicator is a measure of how well new nerve damage is detected and treated by the programme. There are two ways in which information may be gathered in the clinic in order to calculate
this indicator: the EHF (eye-hand-foot) score and the Impairment Summary Form (ISF). Both scoring systems can also be used after completion of treatment to monitor PoD activities.

(1) The **EHF score** is calculated from data already being recorded routinely. It is the sum of all the individual disability grades for the two eyes, two hands and two feet. Since the disability grade can be scored as either 0, 1 or 2, it follows that the EHF score ranges from 0 to 12. A score of 12 would indicate grade-2 disability of both eyes, both hands and both feet.

The EHF score has been shown to be more sensitive to change over time than the disability grade itself. The simplest way to use the EHF score to measure the development of new or additional disability during MDT is to calculate the score at diagnosis (this examination is already done in the initial assessment of the disability grade) and then repeat the examination at the time treatment is completed. The two scores can then be compared. When the cure rate is calculated for any cohort, the proportion in which the EHF score increased can be calculated at the same time - an increase in the score would indicate some new or additional disability.

(2) The **Impairment Summary Form (ISF)** may be used to monitor impairments and disabilities in patients, and to calculate the proportion of patients who develop new or additional disability during MDT. The ISF contains greater detail about each individual patient’s impairments and disabilities. Hence, if used effectively it allows a higher quality of care to be maintained if used effectively. The ISF is described in more detail in the *ILEP Learning Guide Four: How to prevent disability in leprosy*.

### 8.4 What records are used in clinics treating leprosy?

Information about new leprosy patients is needed for two reasons:

- Details about the individual are recorded in the **Patient Record Card**. Over the following months and years, any health worker treating that person will be able to read the medical history, which is very important when considering how to manage a new problem. Good records are essential for quality health care. Good records do
not have to be very detailed; they may be quite simple but they should be accurate and neat in order to be useful to other health workers who will read them.

- Data about new leprosy patients is entered into the Leprosy Treatment Register, which is essential for planning, and for the calculation of essential indicators and monitoring.

Use the Patient Record Card to record the following basic information on each patient:

**Minimum data to be recorded on Leprosy patient record card**

<table>
<thead>
<tr>
<th>Minimum data to be recorded on Leprosy patient record card</th>
<th>At diagnosis</th>
<th>During follow-up and at RFT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Sex</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Address</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Patient status (new/return from default/transfer in/relapse)</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Duration of symptoms</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Number of skin lesions with sensory loss</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>*Enlarged nerves</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Classification</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Eye (l/r): disability grade (0, 1, 2)</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Hand (l/r): disability grade (0, 1, 2)</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Foot (l/r): disability grade (0, 1, 2)</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>*Skin smear (if available)</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>*Signs suspicious of reaction?</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Date of starting MDT</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Date of completing MDT or other treatment outcome (default, died, transferred out, change of classification)</td>
<td></td>
<td>✓</td>
</tr>
</tbody>
</table>

* These items may be omitted in peripheral units

A body chart may be used to show where skin lesions occur
Note that clinics with only occasional patients may not need a Leprosy Treatment Register; the treatment can be noted on the Patient Record Card. If no printed record card is available, a blank sheet of paper may be used. However, some kind of record is essential for good patient care, effective supervision and monitoring.

The **Leprosy Treatment Register** should list every patient receiving MDT at a particular clinic. This register should have the following information:

- Names of every patient who is started on MDT.
- Treatment patients are receiving (PB or MB) and the dose (adult or child).
- Type of patient (New or Other: Section 5.1).
- The disability grade (Section 4.6).
- The date of starting treatment.
- Date of attendance whenever the patient comes for MDT and the number of blister packs given (this will indicate when the person is expected to attend again).

The Register should record each visit of each patient to receive MDT. It should be easy to note from the register when any patient is overdue for an appointment—in other words, when any patient has run out of MDT at home. Each month, the register should be examined to find out which patients (if any) did not attend to collect their MDT during the last month. A note should be made if more than one month’s treatment has been given. Every effort should be made to help patients take treatment regularly.

When a patient collects the last dose of MDT (the sixth dose of PB-MDT, or the twelfth dose of MB-MDT), they should be marked as “Treatment completed” and their entry closed in the treatment register. They should be informed that they are cured after completion of this last dose and the importance of returning for treatment in case of further complications should be stressed. The other treatment outcomes that may be recorded include: “Transferred out” (i.e., a patient who has started treatment and has been transferred to another reporting unit and for whom the treatment outcome is not known at the time of evaluation of the treatment results), “Defaulted” (Section 5.4) and “Died” (i.e., a patient who has died for any reason during the course of MDT).
The cohort analysis (Section 8.1) is carried out using the Leprosy Treatment Register.

Some countries prefer to maintain a Master Register at the district level with all details of all patients being treated in the district. These include, in addition to personal details such as name, address, sex and classification, the disability status and treatment outcome. Such a register is usually maintained by a district supervisor, who compiles the reports from this register.
Organizational issues for programme managers

9.1 What are underserved populations?

The underserved populations refer to groups of people who live in geographical areas that are difficult to access, such as forests, riverbanks, deserts and mountains, or regions that on account of special conditions are denied an equal opportunity for access (e.g., tribal areas, nomadic populations, slum-dwellers, immigrants, people internally displaced due to war, civil disturbance, social unrest, economic or climatic crisis and others with no settled habitat, or those who live in special facilities such as prisons). These groups may find it difficult to secure adequate health care because of poor health infrastructure, lack of information or discrimination due to their social, political, cultural and economic backgrounds, or because of limited transportation facilities.

9.2 How can access to leprosy services be improved in underserved population groups?

Leprosy services should start with programmes identifying such groups and identifying their healthcare needs. A review of existing governmental or nongovernmental developmental agencies in an area may provide an opportunity to network with them for introducing sustainable and cost-effective leprosy control services in the area.

Action should be taken at the organization, patient, provider and community levels.

Actions at the organization level

- Intervention should be sensitive to the needs and priorities of the specific population groups and should be sustainable and integrated within other health programmes.
• Appropriate use of all available technology to reach remote locations (e.g. media, including telemedicine).
• Support from mobile units in areas where the existing services are sparsely distributed, or there are geographical barriers to access.

**Actions at the patient level**
• Provide appropriate information and education, preferably in local languages.
• Introduce convenient service hours.
• Ensure adequate supply of MDT and supportive drugs and materials.

**Actions at the provider level**
• Training initiatives to build local capacity.
• Involve community leaders, representatives of local government and persons affected by leprosy in the planning and decision-making process.
• Be sensitive to local culture, and matters of interpretation and translation, and wherever possible encourage recruitment of local staff.

**Actions at the community level**
• Train community members and involve them as volunteers in disseminating health education messages, referral of suspects, organizing health camps, ensuring regular treatment and supporting persons with disabilities in managing self-care. In underserved areas it is necessary to implement strategies that promote self-reliance and self-help, and which involve community-based organizations so that the activities can be sustained.

### 9.3 How can programmes improve access to leprosy services in urban areas?

“Urban” refers to “populations that live and work usually in an incorporated area, such as a city or town, with similar environmental conditions”\(^1\). Some of the characteristics of urban areas are:

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\(^1\) Linden E. The exploding cities of the developing world. Foreign Affairs (75) 1, 1996
A population of 100,000 or more with a high population density.

A large group of homeless persons and a significant slum population.

Noticeable barriers to access to services, including health care for the poor.

Dependence on the private sector for health-care needs.

Inequalities in health among sections of the population in urban settings reflect the inherent inequalities in economic, social and living conditions. Integrated approaches are needed to promote changes in health-care practices, particularly among marginalized populations living in slums, which may require the following actions:

- Make health care, including leprosy control, an integral part of urban health plan.
- Promote local ownership – involve local leaders and persons affected by leprosy in coordination and decision-making.
- Expand public-private partnerships with government sectors, private and nongovernmental organizations, community-based organizations (clubs, associations, unions, dermatologists, etc.) and representatives of persons affected by leprosy.
- Facilitate target messaging: disseminating correct information to the target groups using appropriate media network.
- Ensure access to referral services for specialist care.

9.4 How should technical supervision be organized?

Supervision is a way of ensuring staff competence and effectiveness through observation, discussion, support and on-the-job training. Its aim is to ensure that:

- the technical skills required for leprosy control activities are present;
- any obstacles faced by the peripheral health worker are identified and removed;
- plans for future work and improved performance are made;
• health workers are supported and motivated in their work; and
• additional information, not available under the routine reporting system, is collected and analysed.

The central figure in supervision is a designated individual located at the first referral level (usually with other responsibilities in an integrated setting), who visits individual clinics on a regular basis—there are many different titles for such a person, but the key element is a personal link with the staff of the peripheral clinics where the majority of patients are seen. Training in supervisory skills and attitudes is essential for effective supervision. The supervisor should be aware of his own tasks and responsibilities, and also of the people he has to supervise.

One of the most important aspects of a supervision visit is to see and examine patients with the clinic staff. The supervisor will also use methods such as document review (records and registers), observation of skills and activities, and interviews with health workers.

In order to carry out supervision in a systematic manner, the supervisor uses a “checklist”. Items to be included in the checklist are listed under “Quality leprosy services” in Section 1.5 and “Six basic principles for successful integration” in Section 2.1. In some countries the district-level supervisor maintains a District Leprosy Register (Section 8.4), which is very useful for monitoring programme performance and reporting.

Before each visit, the supervisor should review the assessment made during the last visit to note any points that may need further attention. After each visit, a description of the findings, both positive and negative, with recommendations, should be included in the feedback to the supervised staff and to their direct superior.

9.5 How can programme managers ensure easy access to MDT?

This can be achieved through:

• Correct estimation of drug requirement and regular ordering, based on epidemiological data.
• Integrating MDT supply with the general drug supply system.
• A system of monitoring drug supply distribution to ensure that adequate quantities of drugs are available at all levels.
• Making MDT available free of charge to all patients.

9.6 How can partnerships be developed to enhance leprosy control activities?

Partnerships have always played an important role in leprosy control. The World Health Organization and national and international NGOs provide a significant supportive function in partnership with national governments. Among the NGOs involved, the members of the International Federation of Anti-Leprosy Associations (ILEP), The Nippon Foundation (TNF), Novartis Foundation for Sustainable Development and the World Bank have played a conspicuous role.

Partnership can be defined as “interorganizational relationships involving activities (beyond that which contracts or authority alone would demand) aimed at achieving shared goals based on close working relationships”. There are other definitions of partnership but they all usually include these common themes: commitment to shared objectives; mutuality, equality and open dialogue; a sense of trust and respect between the partners; and reciprocal obligations and accountability. Partnership does not mean that partners should agree on all aspects, but implies that there is a willingness on both sides to “give and take” so as to reach consensus. Partnerships will be most effective when the objectives are clearly expressed and agreed by all partners, the role of each partner is agreed and acknowledged, and activities and problems widely discussed and negotiated.

The role of the partners in the short to medium term will focus on strengthening the national capacity to provide quality leprosy services, to provide technical advice, funding for core activities, free MDT drug supply and logistics, and global advocacy. It is important that the partners involved in leprosy control continue to collaborate and coordinate their activities to increase their effectiveness. The government, particularly the Ministry of Health (MoH), is the owner of the programme, and should coordinate national and international donor support to the country.
Effective donor coordination is an important requirement for a consistent and uniform implementation of the programme activities throughout the country. All partners should know how their resources are utilized, and should, therefore, be involved in the planning and evaluation process. It is necessary that the MoH and its partners, including WHO and ILEP Members, reach consensus on the implementation of the Strategy, long-term planning and annual plans of action, and on budgets. This will be greatly helped by organizing joint programme reviews by the MoH and all partners.

Besides NGOs and international multilateral and bilateral organizations, there are also government departments other than the MoH that have to be involved in sustaining effective leprosy services, such as the departments of education, social welfare, finance, and communications and publicity. A great degree of collaboration and coordination is required between the various departments, NGOs and other partners. At the national level, coordination should primarily be the responsibility of the MoH.

9.7 What is the role of persons affected by leprosy in leprosy control?

Persons affected by leprosy have a substantial role to play in leprosy control, especially in the area of advocacy, awareness generation and rehabilitation. Organized efforts by persons affected by leprosy are definitely needed to promote a positive perception and attitude about the disease among the public. This will also bring about essential changes in the legal provisions in many countries which are perceived to be discriminatory in nature; and ensure that leprosy control continues to occupy an important place in the health policy framework of the country.

9.8 What type of training should be provided to general health workers?

Training of general health workers should enable them to:
- correctly diagnose and classify a case of leprosy,
- treat a leprosy patient with the appropriate MDT regimen,
- manage or refer cases with complications,
- maintain simple patient cards and a treatment register, and submit reports regularly,
• keep adequate stocks of drugs for MDT,
• provide appropriate information about the disease to patients, community members and decision-makers, and
• recognize patients in need of rehabilitation and refer them to the appropriate services.

In an integrated setting, it is important to ensure that this training is included in the core curriculum of all health workers.

9.9 What is programme evaluation and how is it carried out?

Evaluation is the systematic assessment of a programme’s performance after the completion of a specified period of implementation. It compares achievements with the intended outcomes that have been defined in the strategic plan (annual plan or medium-term plan of three, five or more years). In order to carry out an effective evaluation, it is essential that such a plan is developed at the national level, including well-defined outcome indicators.

Evaluation will mainly consider the effectiveness of the programme, but it can also take into account a number of other aspects of quality, including efficiency, equity, relevance, sustainability, quality of care and impact on the target population. The aim of evaluation is to determine if an ongoing programme is on the right track or needs to be adjusted, and to provide recommendations regarding the future direction of the programme.

The programme at the national level must plan and organize the evaluation missions. It has to define the terms of reference and choose the evaluation team. Team members can be:

• **Internal**: The programme’s own staff, who are directly responsible for its implementation and management.
• **External**: Experts from outside the programme (they may be national or international experts).
• **Mixed**: Participatory evaluation by internal and external evaluators.

When planning the evaluation mission, the national level authority should take into consideration the interests of all concerned stakeholders, particularly the people affected by leprosy.
Enhanced Global Strategy for Further Reducing the Disease Burden Due to Leprosy
10 Addenda

10.1 Further reading

Many of the items mentioned in this Section are freely available on the WHO website: http://www.who.int/lep or on the ILEP website: http://www.ilep.org.uk.

WHO

- I can do it myself: Tips for people affected by leprosy who want to prevent disabilities. WHO, 2007 (SEA-GLP-2007.2)

International Leprosy Association (ILA)

International Federation of Anti-Leprosy Associations (ILEP)
• Learning Guide One: How to diagnose and treat leprosy. 2001
• Learning Guide Two: How to recognise and manage leprosy reactions. 2002
• Learning Guide Three: How to do a skin smear examination for leprosy. 2003
• Learning Guide Four: How to prevent disability in leprosy. 2006
• Technical Guide: Facilitating the integration process. 2003
• Technical Guide: Training in leprosy. 2003
• Technical Guide: Meeting the needs of people affected by leprosy through CBR. 2006
• Joint WHO/ILEP Technical Guide: CBR and Leprosy: Meeting the rehabilitation needs of people affected by leprosy and promoting quality of life. 2007

Others
• van Hees C & Naafs B. Common skin diseases in Africa. 2001
• Cross H. Wound care for people affected by leprosy. ALM 2003
10.2 Glossary

Case of leprosy: A case of leprosy is a person with clinical signs of leprosy who requires chemotherapy (MDT)

CBR: community-based rehabilitation

CBO: community-based organization

Corticosteroids: A group of drugs known for their ability to suppress inflammatory response

Defaulter: An individual who fails to complete treatment within the prescribed timeframe

Disability: A broad term covering any impairment, activity limitation or participation restriction affecting a person

EHF score: The sum of the individual disability grades for each eye, hand and foot

Impairment: A problem in body function or structure, such as a significant deviation or loss

Indicator: A measurable aspect of a programme, which can indicate the level of performance and changes in performance

IEC: information, education and communication

ISF: Impairment Summary Form

MDT: multidrug therapy

Monthly dose: MDT is frequently referred to as being given on a "monthly" basis; in fact, MDT blister packs actually provide 28-days, or 4 weeks, of treatment. Appointments must, therefore, be scheduled every four weeks, not strictly on a monthly basis.

Multibacillary (MB): A leprosy patient with six or more skin patches

NGO: nongovernmental organization
<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nerve function loss</td>
<td>A loss of normal nerve functioning, demonstrated by loss of sensation (loss of feeling or numbness) in the skin served by the nerve and/or weakness of muscles supplied by the nerve</td>
</tr>
<tr>
<td>New case</td>
<td>A case of leprosy who has never been previously treated with anti-leprosy chemotherapy</td>
</tr>
<tr>
<td>Orthotics</td>
<td>Specially shaped inner sole of a shoe, used to correct an abnormality of the foot, including a tendency to ulceration</td>
</tr>
<tr>
<td>Paucibacillary (PB)</td>
<td>A leprosy patient with up to five skin patches</td>
</tr>
<tr>
<td>Reaction</td>
<td>The sudden appearance of symptoms and signs of inflammation in the skin of a person with leprosy</td>
</tr>
<tr>
<td>Relapse</td>
<td>The re-occurrence of the disease at any time after the completion of a full course of treatment</td>
</tr>
<tr>
<td>RFT</td>
<td>Release from treatment; this occurs when treatment with MDT has been successfully completed</td>
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</table>
The Enhanced Global Strategy for Further Reducing the Disease Burden due to Leprosy: 2011-2015 and the Updated Operational Guidelines were widely welcomed and endorsed. The overall goal is to provide access to quality leprosy services for all affected communities based on the principles of equity and social justice.

These Updated Operational Guidelines seek to help managers of national health services to implement the Enhanced Global Strategy comprehensively in their own countries. This will be achieved by developing detailed national policies applicable to their own situation, and revise the National Manual for Leprosy Control in their respective countries.