

**Enhanced
global strategy
for further
reducing the
disease burden
due to leprosy**

Questions and answers

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Questions and answers



**World Health
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FOREWORD



The drafting of a disease control strategy requires that the process be dynamic, making relevant changes and adjustments as per the current epidemiology of the disease and advancements in technology. In addition, the environmental changes and new political realities must be taken into consideration. WHO's strategies for leprosy control over the past three decades present good examples of such adaptation to new realities in dealing with an ancient disease.

In the 1950s, with the advent of an anti-mycobacterial agent – dapsone – the strategy of isolation and containment was replaced with a strategy of domiciliary treatment. In the 1980s, with the emergence of dapsone-resistance, a new treatment regimen, consisting of a powerful combination of two to three anti-mycobacterial agents was recommended. The regimen known as multidrug therapy (MDT) proved to be effective in curing leprosy at any stage and also prevent emergence of drug resistance strains of *Mycobacterium leprae*. This ushered in new hope and a new strategy to reduce the prevalence of the disease to very low levels, calling it elimination of leprosy as a public health problem.

The target of achieving a leprosy prevalence level below 1 per 10 000 population (defined as elimination of leprosy as a public health problem) was reached at the global level in 2000 and in almost all endemic countries at the national level (except for a few countries) in 2005. With elimination, new challenges and new strategies emerged. As the prevalence and new case detection rates continued to decline, integration of leprosy control into the general health services became the key part of the strategic changes during this decade. The success also led to a sense of complacency; sporadic reports of resistance to multidrug therapy began to appear in the scientific literature and many countries faced loss of leprosy expertise.

The current strategy, the “Enhanced Global Strategy for Further Reducing the Disease Burden Due to Leprosy 2011-2015”, focuses

on reducing new cases and the occurrence of grade-2 impairments and disabilities. In addition, the emphasis is also on ensuring sustainability and quality of leprosy services. The strategy has specifically addressed issues such as gender equity, human rights and initiatives to reduce stigma and discrimination faced by persons affected by leprosy and their families.

It is important to explain to all stakeholders the changes in WHO's strategies, technical improvements in case management and other new concepts currently being applied to reduce the disease burden due to leprosy. This "Questions and Answers" booklet is an attempt to provide clarifications and justification for decisions taken and for introducing changes. The booklet answers questions on the strategy for leprosy control, epidemiology of the disease, case management, including management of complications and many other frequently asked questions. It is hoped that the booklet will be of interest to a wide range of decision-makers, health professionals as well as members of the community.



Dr Samlee Plianbangchang
Regional Director

STRATEGIC ISSUES

Q 1: HOW HAS THE CURRENT GLOBAL STRATEGY FOR LEPROSY BEEN DEVELOPED?

The current global strategy is the continuation of WHO's earlier strategies for leprosy control and elimination. During the 1950s, with the introduction of dapsone, the institutional treatment approach changed to domiciliary treatment of patients. With the introduction of multidrug therapy (MDT) in the 1980s, and its widespread implementation in the 1990s, a more ambitious concept of eliminating leprosy as a public health problem was introduced. The elimination strategy aimed at reducing the prevalence of cases registered for treatment to less than one case per 10 000 population at the global level. The goal was reached at the global level in 2000 and at the national level in most of the endemic countries in 2005.

Since 2006, two more five-year initiatives were launched. The current one being the "Enhanced Global Strategy for Further Reducing the Disease Burden Due to Leprosy 2011-2015". Both these strategies focus on reducing the disease

burden in terms of reducing the occurrence of new cases and occurrence of grade-2 impairments and disabilities. The current global strategy was developed in 2009 by WHO in collaboration with national leprosy programme managers, nongovernmental organizations such as the International Federation of Anti-Leprosy Associations (ILEP), and people affected by leprosy.

Q 2: WHAT OTHER ISSUES ARE ADDRESSED IN THE CURRENT STRATEGY?

In addition to reducing the occurrence of new cases and physical impairment and disabilities in new cases, the emphasis is on ensuring sustainability and quality of leprosy services. The strategy has specifically addressed issues such as gender equity, human rights and initiatives to reduce stigma and discrimination faced by persons affected by leprosy and their families.

Q 3: WHAT ELEMENTS OF LEPROSY CONTROL WILL BE ENHANCED DURING THE IMPLEMENTATION OF THE CURRENT STRATEGY?

The main elements of leprosy control which the current strategy aims to enhance are:

- sustaining political commitment;
- strengthening referral services within the integrated health systems;
- introducing innovative approaches for early case detection;
- improving management of acute and chronic complications, including prevention of disabilities and rehabilitation;
- supporting initiatives to promote community-based rehabilitation;
- establishing surveillance systems to monitor development and transmission of drug-resistance and initiate research to develop alternative treatment regimens;

- developing sustainable training strategies to sustain expertise in leprosy even under very low endemic situations; and
- strengthening supportive working arrangements with partners at all levels.

Q 4: WHAT HAS BEEN ACHIEVED SINCE THE INTRODUCTION OF MDT?

The following are some of the notable achievements since MDT was first introduced:

- more than 16 million persons affected by leprosy have been diagnosed and cured;
- there has been significant improvement in the coverage of antileprosy services particularly in previously inaccessible and underserved population groups;
- early case finding and treatment has prevented transmission of infection and the relapse rate after MDT has been extremely low;
- early case finding and treatment has prevented impairments and disabilities among an estimated two million individuals;
- there is a higher level of awareness regarding human rights issues related to stigma and discrimination faced by affected persons;
- much progress has been made in developing effective partnerships with national and international agencies, which has resulted in improved levels of collaboration among partners at global and national levels.

Q 5: WHAT ARE THE REMAINING CHALLENGES FACED BY THE PROGRAMMES IN ENDEMIC COUNTRIES?

Although considerable progress has been made in controlling and reducing the disease burden in medical terms, much needs to be done to reduce the disease burden due to physical, mental and socioeconomic consequences

of leprosy on the affected individuals and communities. The major challenges currently faced are:

- removing the sense of complacency that seems to have set in control programmes after initial success;
- in most endemic countries referral systems are weak;
- developing effective tools/tests to detect cases early, including tools/tests for early recognition and management of leprosy reactions;
- much needs to be done in the field of prevention of disabilities and rehabilitation;
- sustaining basic expertise in clinical leprosy against the backdrop of declining trends;
- improving information, education and communication (IEC) components of the programme to be locally relevant, cost-effective and sustainable;
- developing alternative treatment regimens to combat the threat of drug-resistance;
- developing effective vaccines for the prevention of leprosy.

Q 6: WHAT IS MEANT BY THE DISEASE BURDEN DUE TO LEPROSY?

The burden of disease can be measured in terms of new cases reported, the number of cases registered for treatment, the number of cases with impairments and disabilities, the number of children affected, and the number of affected people requiring rehabilitation due to consequences of the disease. Some of these can be measured, for others it may be difficult. The global strategy is set to monitor the burden in terms of number of new cases reported annually and among them the number presenting with visible (grade-2) disabilities.

Q 7: WHAT IS THE CURRENT TARGET SET FOR LEPROSY CONTROL PROGRAMMES?

The recent global strategy has agreed to set a target of 35% reduction per population in grade-2 disabilities among

new cases, taking the proportion for grade-2 disabilities among new cases registered in 2010 as the baseline. The target will be monitored at both global and national level from 2011 to 2015.

The most recently concluded Expert Committee on Leprosy in its eighth report has recommended a more ambitious target of reducing the incidence of grade-2 disabilities among new cases to less than one per million population by 2020.

INTEGRATING LEPROSY INTO GENERAL HEALTH SERVICES

Q 8: WHY IS IT CRUCIAL TO INTEGRATE LEPROSY WITHIN THE GENERAL HEALTH SERVICES?

Integration improves the coverage of leprosy services and makes it an integral part of the basic health services provided to communities. This will:

- improve patients' access to leprosy services and thereby ensure timely treatment;
- remove the "special" status of leprosy as a complicated and feared disease and help ensure that leprosy is treated as just another straightforward, curable disease;
- ensure that MDT services are provided on a daily basis at the nearest health centre;
- expand the network of people who are able to diagnose and cure leprosy as well as provide basic information about the disease;
- ensure equitable access to leprosy services for all groups (including women, tribal, rural, and other underserved or minority groups); and
- consolidate the substantial gains made in reducing the leprosy burden in communities.

Q 9: WHAT ARE THE BASIC REQUIREMENTS FOR INTEGRATION IN THE FIELD?

WHO has made integration part of its Global Strategy to sustain leprosy control services in all countries. The basic five-step principles advocated by WHO are simple:

- every health facility in an endemic area should provide MDT services¹ on all working days;
- at least one trained staff member should be available in every health facility;
- adequate amounts of MDT drugs should be available, free of cost, for patients;
- information, education and communication (IEC) materials should be available for education and counselling of patients, families, and the community;
- a simple treatment register should be available.

These concepts are well understood and are being implemented in most of the endemic countries on the basis of their own situation analysis and plans of action.

Q 10: WHAT IS MEANT BY EASY ACCESS TO MDT SERVICES AND WHY IS IT IMPORTANT?

Easy access to services means that leprosy services are:

- not very far from the patient's home;
- not too expensive (considering all "costs" - bus fares, travelling time, loss of wages, consultation costs, social costs, etc.);
- open on every working day;
- welcoming and can be approached without fear or prejudice;
- readily available in terms of diagnosis, treatment and advice.

Easy access is particularly important in the case of leprosy as the disease:

¹ MDT services includes: suspecting a case of leprosy, diagnosis, treatment with MDT, patient and family counselling, community education, and referral for complications.

- generally affects the poor who cannot afford to travel far to seek treatment;
- affects people at their most productive age, i.e. mainly young adults who run the risk of developing disabilities if they delay starting treatment;
- generates fear and shame so that people tend to hide it or ignore it.

The nearer the health facility, the easier it is to secure advice and treatment.

Q 11: WHAT TYPE OF TRAINING SHOULD BE PROVIDED TO GENERAL HEALTH WORKERS?

Training of general health workers should enable them to:

- suspect a case of leprosy;
- diagnose and classify a case of leprosy on clinical grounds;
- 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.

Q 12: IS THERE ANY ROLE FOR SPECIALIZED/VERTICAL ELEMENTS IN AN INTEGRATED PROGRAMME?

Integration does not mean completely abolishing the specialized elements. These must exist at the national and intermediate levels to play a vital role in providing referral, training, coordination and services for monitoring and supervision of the programme.

COMMUNITY AWARENESS AND PARTICIPATION

Q 13: WHY DO WE NEED TO CHANGE THE IMAGE OF LEPROSY?

There are significant numbers of undetected leprosy cases in communities. These cases are not coming forward for a variety of reasons; including poor awareness of the availability of free and effective treatment, fear of leprosy, and deep-rooted social stigma. It is expensive and time-consuming to detect them through active case-finding.

It is crucial to change the negative perception of leprosy and encourage patients to come forward for treatment as soon as they note a suspicious skin patch. Moreover, as leprosy services are being progressively integrated into existing health facilities, the change in perception is critical in ensuring effective provision of these services at the local level.

A compelling and meaningful campaign should motivate:

- *people with skin lesions* – to seek timely diagnosis and treatment;

- *health workers* –to “think leprosy” when examining patients with skin problems;
- *community leaders* – to fight against discrimination;
- *community members* – to accept leprosy as a simple curable disease and encourage people to seek and comply with treatment; and
- *decision-makers* – to give their support for elimination and to make leprosy services readily accessible.

Q 14: WHAT ARE THE MOST IMPORTANT MESSAGES ABOUT LEPROSY FOR THE COMMUNITY?

The communication approach must be positive about cure and also emphasize free treatment: fear-based appeals simply do not work. It is important that the messages are simple, clear, and positive to help dispel fear of the disease. Some examples of messages could be:

- Leprosy is caused by a germ. It is neither hereditary nor a curse.
- Leprosy can be easily diagnosed from clinical signs alone. A pale or reddish skin patch that lacks sensation is a tell-tale sign of the disease.
- MDT kills germs and stops the spread of leprosy after the first dose. Patients on treatment do not spread leprosy.
- MDT is available free of charge at all health facilities.
- Leprosy can be completely cured.
- Early and regular treatment prevents deformities.
- Patients who complete treatment are totally cured, even if they have residual skin patches or disabilities.
- Patients can lead completely normal lives during and after their treatment.

Q 15: WHAT ARE THE KEY CHANNELS FOR AN EFFECTIVE COMMUNICATION CAMPAIGN?

A coherent communication campaign and plan should be developed to ensure that the materials reach their target

audiences. Television and radio are important to ensure high visibility and to spark enthusiasm for early diagnosis and treatment and to eliminate stigma and discrimination among the general population. Given the limited access to mass media among rural communities, posters, displays, songs, and materials that can be used during interpersonal contacts and community mobilization events will be pivotal. Posters, stickers and billboards placed strategically in public places serve as reminders, motivate people to go to a health centre, or simply prompt spontaneous conversations about leprosy. Interpersonal communications, especially using established social structures and hierarchies, lend credibility to the message and can be used to provide more detailed information. They also provide a context for social acceptance of the disease and for support of patients.

In addition to “advertising”, positive messages can easily be packaged into entertainments, such as “soap operas”, radio dramas, and street plays. Eliciting the support of well-known personalities in sports, culture, or religion can give a strong boost to any campaign and has already been used successfully in Brazil, India and Myanmar.

Achieving an effective balance between exposure, coverage, costs, and reach is a challenging but vital task. Typically, there should be short periods of intense exposure to the message, followed by low-level maintenance periods.

Whenever possible, it is worth pretesting the materials in local communities with the relevant target groups to ascertain whether the message is clear, perceived as compelling and credible, correctly understood, and attractively presented.

Q 16: WHEN SHOULD THE COMMUNICATION CAMPAIGNS BE LAUNCHED?

The communication campaign should not be launched before the health services are in a position to receive, diagnose, and treat new cases. It is crucial to avoid creating expectations that cannot be met; otherwise the programme will lose credibility – possibly forever.

A “positive” image for leprosy can be established only if we can deliver satisfactory services to the communities. This means that people must have easy access to diagnosis and treatment, that health care staff have been trained to correctly recognize leprosy, that adequate quantities of drugs for MDT are in stock, and that costs incurred by the individual in seeking treatment (e.g. lost wages, or travelling costs) are acceptable. Once communities witness the dramatic impact of leprosy treatment, there is a real change in their approach to the disease.

Q 17: WHY SHOULD COMMUNITIES BE ACTIVELY INVOLVED IN LEPROSY CONTROL ACTIVITIES?

It is important that local communities accept leprosy control activities as their own programme and actively support it. By involving members of the community and promoting their participation, awareness of the disease will increase, and this will also help to reduce the stigma associated with leprosy. Trained, voluntary health workers from the community will play a key role by providing correct information and advice to other community members. They will also be able to help patients with their treatment by reminding them about the importance of taking it regularly.

Q 18: HOW CAN COMMUNITY AWARENESS AND INVOLVEMENT IN THE PROGRAMME BE IMPROVED?

Methods to improve community awareness include identifying and involving specific groups from the community, designing core messages, using most appropriate media and methods to relay messages and developing criteria for assessing impact of various approaches. The mass media are very useful for widespread dissemination of information. However, attitudinal and behavioural changes can be brought about only through interpersonal interactions.

Q 19: HOW DO INFORMATION, EDUCATION AND COMMUNICATION (IEC) ACTIVITIES ASSIST IN LEPROSY CONTROL PROGRAMMES?

A lack of proper understanding of leprosy and the unconstrained propaganda of traditional myths and beliefs lead to negative social attitudes.

IEC activities will assist in:

- dispelling myths and misconceptions;
- making stigma and discrimination unacceptable;
- improving understanding of the disease and its consequences;
- developing a sense of community responsibility and ownership;
- facilitating support for persons affected by leprosy in leading a normal life within communities.

URBAN AREAS

Q 20: HOW CAN THE PROGRAMME IMPROVE ACCESS TO LEPROSY SERVICES IN URBAN AREAS?

Urban populations pose unique challenges for health service management. The challenges include social, cultural and economic inequalities and constraints that make vulnerable population segments unaware or unable to access services. The situation is further complicated by rapid industrialization, increasing density of migrant populations in slums, multiplicity of health care providers and lack of coordination among them.

The major focus within urban areas should be on improving services for people living in the slums. Many health outcomes are more severe in slums than in their neighbouring urban or rural areas. The core principles of leprosy control in an urban situation should include focusing on early diagnosis and treatment with MDT, coordinated involvement of all partners and particularly in building public–private partnerships. This will ensure sustainability, high-quality care, easy accessibility and increased coverage through outreach programmes.

GENDER ISSUE

Q 21: DOES LEPROSY AFFECT WOMEN MORE THAN MEN?

Men are in general more likely to be affected by leprosy than women for reasons that are not clearly understood. In many societies discrimination against women based on socio-cultural norms often put women at a disadvantage. It limits their access to resources and health care services, decision-making power and to opportunities across all spheres of life. Health care providers need to identify women's pattern of service use, levels of participation and perception of quality of care. Health staff need to be trained to be gender sensitive and improve women's involvement when defining priorities for leprosy control services.

ROLE OF PEOPLE AFFECTED BY LEPROSY

Q 22: IS THERE A NEED TO INVOLVE PERSONS AFFECTED BY LEPROSY IN LEPROSY CONTROL ACTIVITIES?

Persons affected by leprosy have a major role to play in leprosy services as the direct beneficiaries of the programme and main stakeholders. Their involvement will be essential in the areas of advocacy, awareness creation, prevention of disabilities, rehabilitation and case finding. Their involvement will be important in promoting a positive attitude about the persons affected and to bring about changes in the legal and other measures that are discriminatory in nature.

REFERRAL SYSTEM

Q 23: HOW CAN REFERRAL SYSTEMS BE STRENGTHENED?

The referral system should include a network of individuals and institutions capable of providing higher level of expertise for patient care. Besides direct patient care, referral institutions can serve other functions, such as training and research, technical support and quality-assurance to lower levels of health services.

Q 24: HOW CAN LEPROSY EXPERTISE BE MAINTAINED WHEN THE DISEASE BURDEN DECLINES?

Decreasing disease burden may bring about a number of issues, such as, reduced political commitment and resources, changes in health priorities and most importantly loss of clinical expertise in leprosy. These will compromise the quality and sustainability of the programme in achieving further reduction in the disease burden. Global, regional and national efforts should be made at identifying suitable institutions and establishing training programmes for different categories of health personnel. In the majority

of endemic countries dermatologists provide significant support to the programme, particularly in the urban areas. They will be an important resource for national efforts to sustain clinical expertise in leprosy.

Q 25: WHICH CONDITIONS IN LEPROSY REQUIRE REFERRAL?

Health workers should refer patients whose condition they are not able to deal with, because they have not been trained to deal with the same or they do not have necessary resources to manage the condition or the condition needs hospitalization.

Non-urgent referrals:

- difficult to diagnose: if leprosy is suspected but needs further investigations to confirm the diagnosis;
- suspected relapse;
- any disability that may be suitable for surgery;
- to social worker or for CBR programme;
- other health problems unrelated to leprosy.

Emergency referrals:

- severe leprosy reactions;
- acute neuritis;
- severely infected ulcer or wound;
- eye complications such as, recent loss of visual acuity, painful red eye;
- serious adverse drug reaction.

National programmes should list contact details of facilities and experts ready to treat leprosy-related referrals and circulate among health staff in order to establish a more efficient system for referral.

DISEASE PREVENTION

Q 26: HOW EFFECTIVE IS THE PRIMARY BCG IMMUNIZATION IN PREVENTING LEPROSY?

All studies have shown protection against both MB and PB disease attributable to BCG immunization. Given that BCG has been and is very widely used around the world, the vaccine must be making a substantial contribution to leprosy reduction. However, repeat BCG vaccination later in life has not been found cost-effective in most populations.

Q 27: CAN ANY ANTILEPROSY DRUG BE USED FOR CHEMOPROPHYLAXIS?

Chemoprophylaxis of contacts or of the total population has been evaluated in several studies. The first studies were carried out with dapsone or injectable long-acting acedapsone, and more recently with rifampicin and a combination of rifampicin, ofloxacin and minocycline (ROM). New evidence from a large randomized controlled trial

demonstrates that a single dose of rifampicin is effective in reducing new cases in close contacts.

Q 28: CAN LEPROSY BE PREVENTED AMONG HOUSEHOLD CONTACTS?

Given the high risk of household contacts, it is important to examine the options available for preventing leprosy among contacts in some situations. Well-resourced programmes and those detecting significant number of new cases among household contacts may be able to consider immunoprophylaxis with BCG or chemoprophylaxis with a single dose of rifampicin of identified contacts. Such a decision needs to consider the complexities of such policies, such as training and supervision of field staff, appropriate budget support, concern over contraindications, for example BCG vaccination should not be given to HIV-positive individuals, and single dose rifampicin should not be given to tuberculosis cases or individuals with liver disease. In addition, there is the question of ethics and confidentiality if some cases may not wish their diagnosis to be known to their contacts.

PREVENTION OF DISABILITIES AND REHABILITATION

Q 29: HOW MANY PEOPLE SUFFER FROM IMPAIRMENTS AND DISABILITIES DUE TO LEPROSY?

Currently there is no reliable information on the number of people affected at the global and country levels. It is estimated that globally there are around 2 million people with grade-2 disabilities attributed to leprosy. Between 25 000–50 000 new people develop leprosy-related disabilities every year. These numbers would be higher if grade-1 disabilities are also included.

Q 30: HOW CAN IMPAIRMENT AND DISABILITIES BE PREVENTED IN LEPROSY?

Prevention of disabilities begins with diagnosing leprosy sufficiently early, recognizing and treating reactions and neuritis, identifying patients at risk of developing secondary disabilities and intervening in time. In this regard collecting information on grade-1 disabilities (loss of sensation in hands, feet and eyes) is important so that patients are

supported through preventive measures such as footwear, protective devices and advice on self-care.

Q 31: WHAT IS SELF-CARE?

Self-care measures include care of dry, anaesthetic skin of palm and soles in order to prevent wounds, ulcers and skin cracks and prevention of occupational injuries including burns while handling hot objects. Care of eyes, where indicated should be part of self-care.

Q 32: WHAT IS COMMUNITY-BASED REHABILITATION (CBR) IN LEPROSY?

The strategy of CBR intends to enhance the quality of life for people with disabilities through community initiatives. Local resources can be used to promote the rehabilitation of people with disabilities in their own communities. Involving family and community members and people affected by leprosy is a key strategy to empower people with disabilities. This will facilitate community action to ensure that they have the same rights and opportunities as all other community members in accessing health care, education, skills training, employment, social mobility and political empowerment.

Q 33: WHAT CAN BE DONE WITH THE RESIDENTIAL CARE INSTITUTIONS FOR LEPROSY-AFFECTED PEOPLE THAT ARE STILL ACTIVE IN MANY ENDEMIC COUNTRIES?

Persons newly diagnosed with leprosy should not be admitted for long-term institutional care. Any admission, if necessary, should be for short-term care, for example for specific medical indications needing hospitalization. Persons who are already living in such institutions for a long time will find it extremely difficult to start living independently. If such institutions decide to close, suitable alternative arrangements will be needed for their accommodation and care.

EPIDEMIOLOGICAL ISSUES

Q 34: WHAT ARE THE DIFFERENCES BETWEEN DISEASE CONTROL, ELIMINATION AND ERADICATION?

The following are the internationally accepted definitions for infectious diseases, although the definition of control and elimination apply for non-infectious diseases as well.

Control: The reduction of disease incidence, prevalence, morbidity or mortality to a locally acceptable level as a result of deliberate efforts; continued intervention measures are required to maintain the reduction. Example: leprosy.

Elimination of disease: Reduction to zero of the incidence of a specified disease in a defined geographical area as a result of deliberate efforts; continued intervention measures are required. Example: neonatal tetanus.

Elimination of infections: Reduction to zero of the incidence of infection caused by a specific agent in a defined geographical area as a result of deliberate efforts; continued

measures to prevent re-establishment of transmission are required. Example: poliomyelitis.

(Leprosy elimination as a public health problem has used the special definition of reducing the prevalence of registered cases of leprosy to less than 1 in 10000 population.)

Eradication: Permanent reduction to zero of the worldwide incidence of infection caused by a specific agent as a result of deliberate efforts; intervention measures are no longer needed. Example: smallpox.

Extinction: The specific infectious agent no longer exists in nature or in the laboratory. Example: none.

Q 35: WHERE DID LEPROSY ORIGINATE?

The emerging science of microbial phylogeography indicates that leprosy probably originated in East Africa and then spread to other parts of the world through migration of early humans and trade routes. The most recent spread to the new world occurred only after the discovery of the Americas in late 15th century.

Q 36: WHAT IS THE CAUSATIVE AGENT OF LEPROSY?

Leprosy is the first disease to be causally associated with an infectious agent – *M. leprae*. The discovery was made by Dr Hansen in 1873, almost nine years before the discovery of *M. tuberculosis*, the causative agent for tuberculosis.

M. leprae is a rod-shaped organism. Like other species of mycobacteria, *M. leprae* divides by binary fission; it is Gram positive and strongly acid-fast. It is non-cultivable in any known laboratory media. In experimental models, both mice and nine-banded armadillos have been used for in vivo studies. It is an obligate intracellular parasite. *M. leprae* is the only species of mycobacteria to infect peripheral nerves.

In foot-pads of normal mice *M. leprae* have an exceptionally slow generation (doubling) time of 11–13

days compared with other mycobacteria (*M. tuberculosis* has a doubling time of about 20 hours).

Q 37: HOW IS LEPROSY TRANSMITTED?

Although mice and armadillos can be infected with *M. leprae* under laboratory conditions, it has long been thought that *M. leprae* infects only humans in nature and that human, in particular, untreated MB cases, were the only important source of infection for humans. There is now evidence that leprosy is a zoonosis in a region of the southern United States of America, where autochthonous leprosy cases have been reported.

Infection is thought to occur primarily by the respiratory route, but there is also evidence that infection may occur through injured skin. The incubation period from infection to clinical manifestations is variable, but appears to be shorter for paucibacillary (2–5 years) than multibacillary (5–10 years or more) disease.

Q 38: HOW INFECTIOUS IS LEPROSY?

A leprosy patient's infectiousness is related to the size of the bacillary population in the body. It has been shown that a single dose of rifampicin decreases the load of viable bacilli to such low levels that it is no longer possible to cultivate the organism in an animal model. In public health terms, it is reasonable to conclude that infectiousness becomes negligible after starting treatment with multidrug therapy.

Q 39: WHAT ARE THE RISK FACTORS FOR CONTRACTING LEPROSY?

In endemic populations leprosy occurs at all ages although rare among the very young. In most populations cases are more commonly reported in males than females. Contact with a known case (especially multibacillary case) is recognized as a major risk factor. In addition, absence of a history of BCG vaccination and low socioeconomic

status are considered risk factors. There is some evidence to suggest that host genetic factors may contribute to the risk of developing leprosy. Rarely AIDS patients who have been treated with anti-retroviral drugs may developed leprosy, so called re-constititional disease.

Q 40: Q40. HAS THE HIV PANDEMIC AFFECTED LEPROSY IN THE SAME WAY AS TUBERCULOSIS?

Most studies do not show an increase in leprosy cases among HIV-positive individuals and AIDS patients or any clinical alternation of leprosy among patients coinfectd with HIV.

Q 41: WHAT IS THE IMPORTANCE OF CONTACT SURVEILLANCE?

Individuals living in households with MB patients are at a 5 to 10-fold increased risk of leprosy and those living with PB patients are at a 2 to 3-fold increased risk than individuals not living in such households. Household contact my contribute a significant proportion of all new cases in relatively low endemic situations, while in higher endemic areas the distinction between contact and non-contact may be less clear. Thus, on detection of a new case, the patient's household contacts should be examined for evidence of leprosy and educated to report any suspect signs/symptoms to the nearest health facility.

Q 42: WHY IS THE DECLINE IN INCIDENCE IN LEPROSY SLOWER THAN THE DECLINES OBSERVED IN PREVALENCE?

The sharp decline in the prevalence of leprosy was mainly due to the introduction of shorter treatment regimens which rapidly cleared the large pool of patients registered for treatment. However, some of the reduction in prevalence can be attributed to the decline in incidence. The slow decline in the incidence, on the other hand is based on finding and treating new cases in the community at an early stage. By the time any new case is identified, he or she

has had a lengthy period during which to infect many of their close contacts. Secondly, there may be other sources of infection which are yet to be recognized.

Q 43: WHAT IS EXPECTED FROM STUDIES ON THE *MYCOBACTERIUM LEPRAE* GENOME?

The genome sequence of a strain of *M. leprae* originally isolated in Tamil Nadu, India was completed in 2001. The genome sequence of this strain contains 3.27 Mb base pairs, which is much lower than the corresponding genome of *M. tuberculosis* which contains 4.42 Mb base pairs. The comparative analysis suggests that both mycobacteria were derived from a common ancestor and, at one stage, had gene pools of similar size. The downsizing seen in the *M. leprae* genome may account for loss of many metabolic, respiratory, catabolic and other essential activities. This may explain *M. leprae* being an obligatory parasite, its slow growth, long doubling time and its inability to grow in any known artificial media.

The genome can assist in understanding the epidemiology of leprosy and improve its control in several ways:

- possible strain variations can help in understanding transmission patterns, geographical spread and differences between relapse and re-infection;
- development of new generation of vaccines;
- developing specific skin tests for early diagnosis;
- understanding neurotropism and nerve damage;
- new drug targets for treating leprosy;
- molecular tests for drug-resistance genes;
- new approaches for in vitro cultivation of *M. leprae*.

CURRENT GLOBAL SITUATION

Q 44: IS LEPROSY STILL ENDEMIC IN MANY COUNTRIES?

Leprosy remains endemic in all countries of the South-East Asia and African Regions, and in most countries of the Eastern Mediterranean Region. In the Region of the Americas, locally transmitted leprosy is found in all countries (except Canada and Chile), and several island countries of the Caribbean. In the European Region, a small number of cases are being reported in several southern and east-European countries. In the Western Pacific Region, leprosy is endemic in most countries, except in New Zealand and some small island nations.

Q 45: WHAT IS THE CURRENT LEPROSY SITUATION IN THE WORLD?

The global registered point prevalence at the beginning of 2011 was 192 246 cases and 228 474 new cases were detected during 2010. Of these about 95% of new cases were detected from only 16 endemic countries². These are (in order of ranking): India, Brazil, Indonesia, Bangladesh, Democratic Republic of Congo, Ethiopia, Nepal, Nigeria, Myanmar, United Republic of Tanzania, Sudan, Sri Lanka, Philippines, China, Madagascar, Mozambique and Angola.

² Date are from before South Sudan joined as a WHO member country.

DIAGNOSIS AND CASE MANAGEMENT

Q 46: WHEN SHOULD LEPROSY BE SUSPECTED?

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

- pale or reddish patches on the skin;
- loss or decrease of feeling in the skin patch;
- numbness or tingling of the hands and feet;
- weakness of the hands, feet or eyelids;
- painful or tender nerves;
- swelling or lumps in the face or ear lobes;
- painless wounds or burns in the hands or feet.

Q 47: HOW IS THE DIAGNOSIS OF LEPROSY CONFIRMED?

Leprosy diagnosis is confirmed when at least one of the following cardinal signs is present:

- definite loss of sensation in a pale or reddish skin patch;
- a thickened peripheral nerve with loss of sensation and/or weakness of the muscles supplied by that nerve;
- the presence of acid-fast bacilli in a slit skin smear.

Q 48: HOW IS LEPROSY CLASSIFIED?

Leprosy clinically manifests in a variety of clinical forms related to the type and strength of the host's immune response. A strong cellular immune response is effective in curtailing *M. leprae* multiplication and is thus associated with paucibacillary (PB) disease. A weak cellular response allows bacilli to replicate to large numbers in the body, leading to multibacillary (MB) disease forms. The MB leprosy includes polar lepromatous (LL), borderline lepromatous (BL) and mid-borderline (BB) cases in the Ridley-Jopling classification. The PB leprosy includes indeterminate (I), polar tuberculoid (TT) and borderline tuberculoid (BT) cases in the Ridley-Jopling classification.

Q 49: WHAT CLASSIFICATION IS USED TO DECIDE THE TREATMENT REGIMEN FOR A PATIENT IN THE FIELD?

The clinical classification system is used in the field for choosing an appropriate treatment regimen. This is, particularly so when reliable facilities for skin smear examination are not available. Patients are classified into two groups:

- one to five skin lesions – PB leprosy; and
- six or more skin lesions – MB leprosy.

If bacteriological examination of skin smear shows a positive result then patients are grouped into MB leprosy, irrespective of less number of skin lesions.

MULTIDRUG THERAPY (MDT)

Q 50: WHAT WAS THE GUIDING PRINCIPLE IN THE DEVELOPMENT OF MDT?

MDT was developed against a background of growing primary and secondary resistance to dapsone. It is based on two or three drugs (rifampicin, clofazimine, and dapsone), used in combination to prevent the development of resistance. Once-monthly treatment with an antibiotic (rifampicin 600 mg) is the cornerstone of all MDT treatment regimens. Leprosy should never be treated with any single antileprosy drug.

Q 51: WHAT ARE THE RECOMMENDED STANDARD TREATMENT REGIMENS FOR LEPROSY?

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

The standard adult treatment regimen for MB leprosy is:

Rifampicin	600 mg once a month
Clofazimine	300 mg once a month, and 50 mg daily
Dapsone	100 mg daily
<i>Duration</i>	12 months.

The standard adult treatment regimen for PB leprosy is:

Rifampicin	600 mg once a month
Dapsone	100 mg daily
<i>Duration</i>	6 months.

The standard child treatment regimen for MB leprosy is:

Rifampicin	450 mg once a month
Clofazimine	150 mg once a month, and 50 mg every other day
Dapsone	50 mg daily
<i>Duration</i>	12 months.

The standard child treatment regimen for PB leprosy is:

Rifampicin	450 mg once a month
Dapsone	50 mg daily
<i>Duration</i>	6 months.

Children under 10 years should receive appropriately reduced doses of the above drugs.

Rifampicin	10 mg per kg body weight once a month.
Dapsone	2 mg per kg body weight per day.
Clofazimine	6 mg per kg per month and 1 mg per kg body weight per day (to be spaced out as required per week, for example given as one, two or three times a week).

Q 52: WHAT IS THE EVIDENCE THAT MDT IS EFFECTIVE IN MB AND PB LEPROSY?

Clinical trials have established the efficacy of the individual drugs within MDT for the treatment of leprosy. The efficacy of MDT has been clearly demonstrated by the extremely low relapse rate (average 0.1% per year for PB and 0.06% per year for MB) following successful completion of treatment; these figures are based on reports from a number of countries and information available at WHO. In

addition, the low frequency of side-effects has made MDT highly acceptable to patients.

Q 53: IS THERE ANY EVIDENCE THAT THE DRUGS INCLUDED IN MDT CAN ANTAGONIZE EACH OTHER'S ANTIBACTERIAL ACTIVITY?

All experimental and clinical evidence indicates that there is no antagonism among the drugs included in MDT.

Q 54: DOES MDT HELP IN REDUCING THE FREQUENCY AND SEVERITY OF LEPROSY REACTIONS?

Evidence shows that there is some reduction in the frequency and severity of reversal reactions (Type 1) and erythema nodosum leprosum (ENL) reactions (Type 2) in leprosy patients on MDT. It is possible that this is attributable to the early arrest of the progress of leprosy and the anti-inflammatory effect of clofazimine, particularly in MB patients.

Q 55: WHY IS RIFAMPICIN GIVEN ONLY ONCE A MONTH?

Rifampicin is an exceptionally potent bactericidal agent against *M. leprae*. A single dose of 600 mg is capable of killing more than 99.9% of viable organisms. The rate of killing is not proportionally enhanced by subsequent doses. It is also known that rifampicin exerts a delayed antibiotic effect for several days, during which the organism is incapable of multiplying. The high bactericidal activity of rifampicin makes a single monthly dose of the drug feasible and cost-effective for leprosy control programmes.

Q 56: WHY IS CLOFAZIMINE GIVEN ONCE A MONTH IN ADDITION TO THE DAILY DOSE?

Clofazimine is a repository drug, i.e. it is stored in the body after administration and is then slowly excreted. A loading dose of 300 mg is given once a month to ensure that the optimal amount of clofazimine is maintained in the body tissue, even if the patient occasionally misses his or her daily dose.

Q 57: CAN MDT PREVENT THE DEVELOPMENT OF RESISTANCE OF *M. LEPRAE* TO ANTILEPROSY DRUGS?

Yes. MDT was developed mainly because of the widespread emergence of dapsone resistance, and the regimens were designed on the principle that they would be effective against all the strains of *M. leprae* regardless of dapsone susceptibility. It is estimated that a patient with advanced, untreated, lepromatous leprosy harbours about 10^{11} or $11 \log$ live organisms. Of these, an estimated 1 in 10^7 are naturally resistant to rifampicin, 1 in 10^6 to dapsone, and 1 in 10^6 to clofazimine. Organisms that are resistant to one drug will be susceptible to the other drugs in MDT, as their mechanisms of action are different.

As of today, most of the cases who relapsed after treatment with MDT have relapsed with drug-sensitive organisms and re-treatment with the same MDT regimen has been effective in them. However, recently sporadic cases of relapses with drug-resistant organisms, to dapsone, rifampicin and/or ofloxacin have been reported, which is a cause for serious concern.

Q 58: WHY IS SURVEILLANCE OF DRUG RESISTANCE IN LEPROSY IMPORTANT?

The emergence and transmission of rifampicin-resistant strains of *M. leprae* is the most serious among the various potential threats that could hinder the ongoing efforts to control leprosy. Following the recent developments of DNA sequence methods, several reports of rifampicin, dapsone and ofloxacin resistance have been published. These findings are important to set up a surveillance system, in order to monitor trends and develop effective counter-measures to combat the problem of drug-resistance.

Q 59: CAN MDT ELIMINATE PERSISTING *M. LEPRAE*?

Persisting *M. leprae* are, by definition, those viable organisms that are fully susceptible to the antileprosy drugs but survive despite adequate treatment with these drugs. This phenomenon probably occurs because the organisms

are in a low or dormant metabolic state. So far, there is no drug that can kill these persisting organisms, although rifampicin is known to be capable of killing persisting organisms in tuberculosis – another mycobacterial disease. The role of persisters in the occurrence of relapse among leprosy patients treated with MDT is still not clearly understood but because of the evidence of very low relapse rates it is believed that it does not play a major role.

Q 60: WHAT ARE THE COMMON ADVERSE DRUG REACTIONS REPORTED WITH MDT?

MDT is remarkably safe and severe adverse reactions are rare:

Minor adverse drug reactions:

Rifampicin	Reddish urine
Dapsone	Anaemia
Clofazimine	Brown discolouration of skin

Serious adverse drug reactions:

Rifampicin	Allergy, jaundice, purpura, shock and renal failure
Dapsone	Allergy
Clofazimine	Intestinal obstruction

Q 61: IS MDT CONTRAINDICATED IN PATIENTS SUFFERING FROM TUBERCULOSIS?

MDT is not contraindicated in patients suffering from tuberculosis (TB). An appropriate anti-TB regimen should be given, in addition to MDT, to patients who have both leprosy and TB. Rifampicin is common to the treatment of both leprosy and TB and must be given in the doses required for TB.

Q 62: IS MDT CONTRAINDICATED IN PATIENTS SUFFERING FROM HUMAN IMMUNODEFICIENCY VIRUS (HIV) INFECTION?

MDT is not contraindicated in patients suffering from HIV infection. Management of leprosy – and of leprosy reactions

– in patients infected with HIV is the same as that of any other patient. The response of such patients to MDT is also similar to that of other leprosy patients.

Q 63: IS MDT SAFE DURING PREGNANCY AND LACTATION?

Since leprosy is exacerbated during pregnancy, it is important that MDT be continued. All evidence so far indicates that MDT is safe during pregnancy. Small quantities of antileprosy drugs are excreted through breast milk but there is no report of adverse reaction as a result of this except for mild discolouration of the infant's skin caused by clofazimine.

Q 64: HOW LONG DOES IT TAKE FOR SKIN DISCOLOURATION CAUSED BY CLOFAZIMINE TO DISAPPEAR?

The discolouration caused by clofazimine starts to appear by the third month of MB-MDT treatment and reaches its maximum intensity by the end of a full course of treatment (12 blister packs). After discontinuation of MDT, the discolouration starts to diminish noticeably in six months; it is completely reversible, and the skin returns to its normal colour within a year.

Q 65: WHY IS MDT CONSIDERED TO BE ONE OF THE MOST EFFECTIVE AND COST-EFFECTIVE INTERVENTIONS IN PUBLIC HEALTH?

Since its introduction in 1981, MDT has remained highly effective for the treatment of leprosy in widely varying field conditions for the following reasons:

- it cures leprosy and stops transmission;
- relapse rates are low (less than 1%);
- there are very few reported instances of resistance to the combined drugs;
- side-effects are negligible;
- disabilities are prevented through early cure;
- health workers can be easily trained to administer the drugs;

- it easy to administer as it is taken orally;
- it is conveniently available in blister-packs containing four weeks' treatment;
- the drugs can be stored under ordinary storage conditions.

Q 66: HOW CAN MDT BE PROVIDED IN A PATIENT-FRIENDLY AND FLEXIBLE MANNER?

MDT treatment can be provided in a flexible and patient-friendly manner because it is:

- available in monthly blister packs;
- very effective (very few relapses);
- safe (few major side-effects);
- standard for all patients and so rarely needs to be changed or modified;
- effective even if an occasional dose is missed;
- easy for patients to understand which drugs they need to take and when;
- easy to store and take at home.

Q 67: WHAT ARE THE AVAILABLE SECOND-LINE ANTILEPROSY DRUGS?

There are three second-line drugs available for treatment of leprosy:

- ofloxacin – a fluoroquinolone;
- clarithromycin – a macrolide;
- minocycline – a tetracycline.

Q 68: WHAT ARE THE OTHER ANTILEPROSY DRUGS UNDER DEVELOPMENT?

There are several drugs with promising antimycobacterial activity, notable among these are:

- moxifloxacin – a fourth generation fluoroquinolone;
- rifapentine – a semi-synthetic rifamycin derivative;
- diarylquinoline – an adenosine-5'-triphosphate (ATP) synthetase inhibitor.

Q 69: WHAT ARE THE TREATMENT REGIMENS FOR PATIENTS WHO CANNOT TAKE ANY OF THE DRUGS IN MULTIDRUG THERAPY?

PATIENTS WHO CANNOT TAKE RIFAMPICIN

Special treatment regimens are required for individual patients who cannot take rifampicin because of side-effects or intercurrent diseases, such as chronic hepatitis, or who have been infected with rifampicin-resistant *M. leprae*. The following 24-month regimen is recommended:

- a daily administration of 50 mg of clofazimine, together with two of the following drugs – 400 mg ofloxacin, 100 mg of minocycline or 500 mg of clarithromycin – for 6 months; followed by a daily administration of 50 mg clofazimine, together with 100 mg of minocycline or 400 mg of ofloxacin for an additional 18 months. If available, ofloxacin may be replaced by moxifloxacin 400 mg as it has stronger bactericidal activity against *M. leprae*.

PATIENTS WHO CANNOT TAKE CLOFAZIMINE

Multibacillary leprosy patients who refuse to take clofazimine because of skin discolouration, also need a safe and effective alternative treatment. In such patients, clofazimine in the normal 12-month multidrug therapy for multibacillary patients may be replaced by ofloxacin, 400 mg daily or by minocycline, 100 mg daily for 12 months. Similarly, ofloxacin may be replaced by moxifloxacin 400 mg.

In 1997, the WHO Expert Committee on Leprosy also recommended the following alternative 24-month (ROM) regimen for multibacillary adult leprosy patients who refuse to take clofazimine: 600 mg rifampicin once a month, 400 mg ofloxacin once a month and 100 mg minocycline once a month for 24 months.

PATIENTS WHO CANNOT TAKE DAPSONE

If dapsone produces severe toxic effects in any leprosy patient suffering from either PB or MB leprosy, it must be

stopped immediately. No further modification of the regimen is required for patients with MB leprosy. However, clofazimine in the dosage employed in the standard multidrug therapy for MB leprosy should be substituted for dapsone in the regimen for PB leprosy for a period of six months.

Q 70: WHAT TYPES OF PATIENTS ARE AT RISK OF DEVELOPING RELAPSE AFTER MDT?

Relapse after MDT remains low even after three decades of its introduction and widespread use. Re-treatment of relapsed cases with another course of MDT is highly effective. Several risk factors have been suggested for relapse in leprosy, including persisters, re-infection, drug-resistance, inadequate/irregular therapy, use of monotherapy, high initial bacterial index (BI), number of skin lesions, lepromin negativity and coinfection with HIV. There are reports suggesting that the risk of relapse is higher among patients with pre-MDT average BI of 4+ or more.

Q 71: 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 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 with BI taken from the same site at the previous examination. Care should be taken to exclude patients suffering from leprosy reactions.

If a full course of treatment has been taken properly, relapse is generally rare, although continued vigilance is important as sporadic instances of relapses due to drug-resistance have been reported. Most relapses occur long after the treatment was completed, some times more than 10 years later. Generally relapse cases can be treated effectively with another course of MDT.

PB relapses are difficult to differentiate from reversal reactions. If there are any signs of recent nerve damage a reaction is very likely. The most useful feature is the time that has lapsed since the person completed treatment: if it is less than three years a reaction is most likely while if it is more than three years, a relapse becomes a more likely diagnosis. A reaction may be treated with a course of steroids while a relapse will not be affected by a course of steroids. Therefore, using steroids as a “therapeutic test” can clarify the diagnosis. MB relapse should be investigated by using skin smears, histopathology and where possible for drug sensitivity using recently standardized molecular tests.

Q 72: SHOULD INDIVIDUALS PREVIOUSLY CURED WITH DAPSONE MONOTHERAPY BE RE-TREATED WITH MDT?

WHO does not recommend re-treating of individuals who are already cured of leprosy unless there is definite evidence that the disease has relapsed. Only those presenting with such signs should be given an appropriate course of MDT.

Q 73: WHAT ADVICE SHOULD BE GIVEN TO PATIENTS AT THE TIME OF COMPLETING TREATMENT?

All patients should be reviewed at the end of treatment to confirm treatment completion and assess any new nerve function impairments that may have developed during treatment. Patients should be counselled at this point on the risks of reactions and relapse and recommended actions. Advice on self-care and prevention of disabilities as appropriate should be re-emphasized.

MANAGEMENT OF LEPROSY REACTIONS

Q 74: WHAT ARE LEPROSY REACTIONS?

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, pain and sometimes tenderness of the skin lesions. New skin lesions or inflamed reddish nodules 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, which is known as “silent neuritis”.

There are two types of reactions: reversal reaction (Type 1) and erythema nodosum leprosum (ENL or Type 2) reaction. Both types can occur before the start of treatment, during treatment, or after treatment has been completed. In the reversal reaction, the leprosy skin lesions themselves become inflamed, red and swollen, often new skin lesions may also appear. In an ENL reaction, new inflamed, red nodules appear under the skin of the limbs and trunk, while the original leprosy skin lesions remain unaffected.

In addition, ENL reactions cause general malaise with fever and body pain while reversal reaction causes less systemic symptoms.

Q 75: WHAT TYPE OF REACTIONS NEED URGENT TREATMENT WITH STEROIDS?

Most episodes of mild leprosy reactions, those without any sign or symptom of neuritis or ulcerating skin lesions or severe constitutional symptoms or involvement of other organ system can be treated symptomatically with aspirin or paracetamol orally.

Severe leprosy reactions demand urgent action and treatment with steroids as early as possible to prevent nerve damage.

The signs of severe reversal reaction are:

- recent loss of nerve function, that is, loss of sensation and muscle weakness with or without pain or tenderness;
- pain or tenderness in one or more nerves;
- a red, swollen skin patch on the face or overlying any major nerve trunk;
- ulcerating skin lesions;
- marked oedema of hands, feet or face.

The signs of severe ENL reaction are:

- pain or tenderness in one or more nerves with or without loss of nerve function;
- ulceration of ENL nodules;
- pain and tenderness of the eyes;
- painful swelling of testes or the fingers;
- Marked arthritis or lymphadenitis.

Q 76: HOW SHOULD LEPROSY REACTIONS BE MANAGED?

Severe reactions require urgent treatment as they can lead to irreversible deformities. Thus, early diagnosis and the timely initiation of anti-inflammatory measures are

crucial. MDT should be continued at full dosage without interruption. Aspirin or paracetamol should be given to reduce pain and fever, and rest is essential.

In specific cases, corticosteroids (e.g. prednisolone) should be prescribed at the following dosage:

- 40 mg daily for weeks 1 and 2
- 30 mg daily for weeks 3 and 4
- 20 mg daily for weeks 5 and 6
- 15 mg daily for weeks 7 and 8
- 10 mg daily for weeks 9 and 10, and
- 5 mg daily for weeks 11 and 12.

It is important that the patient is examined every week and that the dose of corticosteroids is reduced every two weeks. Maximum dosage of prednisolone is 1 mg/kg of body weight.

In some cases presenting with severe reactions, steroids may be given beyond the recommended 12 weeks period for up to 6 months after the case being reviewed by an expert.

Q 77: HOW SHOULD SEVERE ENL REACTIONS BE MANAGED?

WHO GUIDELINES FOR MANAGEMENT OF ENL REACTION:

GENERAL PRINCIPLES:

- Severe ENL reaction is often recurrent and chronic and may vary in its presentation.
- The management of severe ENL is best undertaken by a physician at a referral centre. The dose and duration of anti-reaction drug treatment may be adjusted by the physician according to the needs of the individual patient.

DEFINITION - SEVERE ENL REACTIONS INCLUDE:

- numerous ENL nodules with high fever;
- ENL nodules and neuritis;

- ulcerating and pustular ENL;
- recurrent episodes of ENL;
- involvement of other organs (e.g. eyes, testes, lymph nodes, joints).

MANAGEMENT WITH CORTICOSTEROIDS

- if the patient is still on antileprosy treatment, continue the standard course with MDT;
- use adequate doses of analgesics to control fever and pain;
- use standard course of prednisolone at a daily dosage not exceeding 1 mg/kg body weight for a total duration of 12 weeks. In certain cases the treatment may be extended up to six months after getting an expert opinion.

MANAGEMENT WITH CLOFAZIMINE AND CORTICOSTEROIDS – is indicated in patients with severe ENL who are not responding satisfactorily to treatment with corticosteroids or when the risk of toxicity with corticosteroids is high:

- If the patient is still on antileprosy treatment, continue the standard course with MDT.
- Use adequate doses of analgesics to control fever and pain.
- Use standard course of prednisolone at a daily dosage not exceeding 1 mg/kg body weight.
- Start clofazimine 100 mg three times a day and continue for a maximum of 12 weeks.
- Complete the standard course of prednisolone. Continue clofazimine as below.
- Taper the dose of clofazimine to 100 mg twice a day for 12 weeks and then 100 mg once a day for 12–24 weeks.

MANAGEMENT WITH CLOFAZIMINE ALONE – is indicated in patients with severe ENL when use of corticosteroids is contraindicated:

- if the patient is still on antileprosy treatment, continue the standard course with MDT;

- use adequate doses of analgesics to control fever and pain;
- start clofazimine 100 mg three times a day and continue for a maximum of 12 weeks;
- taper the dose of clofazimine to 100 mg twice a day for 12 weeks and then 100 mg once a day for 12–24 weeks.

NOTES:

1. If the MDT treatment is already completed, management of ENL should follow the guidelines. There is no need to restart MDT.
2. The total duration of a standard course of corticosteroids (prednisolone) is 12 weeks.
3. The total duration of treatment with high dosage clofazimine should not exceed 12 months. It takes about 4–6 weeks for clofazimine to take full effect in controlling ENL.
4. Another drug claimed to be useful in ENL is pentoxifylline, alone or in combination with clofazimine/prednisolone.
5. Because of the well known teratogenic side-effects, WHO supports the use of thalidomide for the management of severe ENL in leprosy only under strict medical supervision in a referral centre.

Q 78: SHOULD A PATIENT BE RE-STARTED WITH MDT WHEN TREATING FOR REACTIONS AFTER SUCCESSFULLY COMPLETING A FULL COURSE OF MDT?

If the diagnosis of leprosy reaction is correct and relapse is ruled out, then there is no need to re-start antileprosy therapy while treating leprosy reaction in a patient who has completed a full course of MDT. In case the anti-reaction management is prolonged (more than 6 months), then it is important to reassess patient's clinical status and skin smear examination periodically to ensure that the disease has not relapsed.. This is particularly relevant if the patient is undergoing prolonged treatment with immune-suppressive drugs such as steroids.

Q 79: IS THE STANDARD COURSE OF STEROIDS FOR 12 WEEKS SUFFICIENT TO CONTROL ALL LEPROSY REACTIONS?

The standard 12-week steroid regimen is sufficient for management of mild to moderate reactions. Several studies have demonstrated better results when steroids were administered for longer than 12 weeks, particularly while treating neuritis.

Q 80: IS THERE ANY BENEFIT OF USING STEROIDS AS A PROPHYLACTIC AGAINST NEURITIS?

Trials of prophylactic steroid use have demonstrated only a short-term effect on preventing nerve function impairment. Several studies have indicated that nerve function impairment improves without steroids when the patient is under treatment with MDT.

Q 81: ARE THERE ANY NEW ANTI-REACTION DRUGS?

Cyclosporin has been used to treat ENL reactions with mixed results. Azathioprine and methotrexate have been used for ENL reaction in combination with steroids. Pentoxifylline has shown no significant benefit. Several other potent antimetabolites showed little or no effect in either type of reactions. Similarly, TNF-alpha, IL-2, and other cytokines showed minimal beneficial effects on reactions.

Q 82: HOW USEFUL IS THALIDOMIDE IN THE TREATMENT OF LEPROSY REACTIONS?

Several studies have shown the usefulness of thalidomide in the treatment of acute ENL reaction. However, its use is restricted due to its teratogenic effects and due to ethical and legal considerations. In addition, thalidomide availability is limited due to restrictions on its import and supply in many endemic countries. Therefore, WHO recommends its use only under strict medical supervision in specialized referral facilities.

Q 83: HOW IS RELAPSE DISTINGUISHED FROM A LEPROSY REACTION?

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

Criteria	Relapse	Reaction
Time since completion	More than three years	Less than three years
Progression	Slow	Rapid
Skin lesions	New lesions	Old and new inflamed lesions
Pain, tenderness	No	Yes-nerves, skin
Nerve damage	Slow	Rapid
General condition	Not affected	Affected
Steroid test	No change	Rapid improvement

OPERATIONAL ISSUES

COMPLIANCE/DEFAULTERS

Q 84: IS IT IMPORTANT THAT SIX DOSES OF PB-MDT ARE TAKEN WITHIN 9 MONTHS AND 12 DOSES OF MB-MDT ARE TAKEN IN 18 MONTHS?

It is desirable that a patient takes all the MDT doses as regularly as possible. It has been shown that the first dose of MDT kills most of the bacilli and renders the patient non-infectious to others. Occasional irregularity does not affect the efficacy of MDT. Wider use of flexible treatment options, supported by proper information to the patient and his or her family, will play an important role in better compliance with the treatment and early cure (accompanied MDT).

Q 85: WHAT IS MEANT BY FLEXIBLE TREATMENT DELIVERY?

The delivery of treatment should be adapted to the needs of patients so that every patient is encouraged to complete the treatment course in time. This is particularly important

for those patients who live in difficult-to-access areas, have nomadic lifestyle, unable to attend the health facility regularly due to social, cultural or economic reasons. It will be helpful if arrangements can be made for such patients to receive several MDT blister-packs at once so that the visits to the clinics are made less frequent. Counselling and information about the importance of regularity of drug intake is essential along with advice to report to the clinic in case of any problem. In some cases it may be useful to involve a close friend, family member or community volunteer to help the patient to continue treatment properly from home (accompanied MDT).

Q 86: WHAT SHOULD BE DONE IF A PATIENT DOES NOT REGULARLY ATTEND CLINIC FOR TREATMENT?

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

- poor accessibility of the clinic because of distance, travel cost or inconvenient timings;
- difficulty in taking time off from work, studies or nomadic lifestyle;
- lack of understanding about the disease and the importance of regular treatment;
- social pressure because of stigma and need to hide the diagnosis;
- a poor relationship with health worker;
- frequent shortage of MDT stocks in the clinic.

Every effort must be made to educate the newly diagnosed patient at the time of registration about the importance of regular treatment. If there is likely to be any difficulty, ways must be found in which it can be made easier for the patient to receive a regular supply of MDT blister-packs through alternative methods.

Q 87: WHO IS A DEFAULTER AND WHAT SHOULD BE DONE IF A DEFAULTER COMES BACK FOR TREATMENT?

A defaulter is a patient who has failed to complete treatment within the maximally allowed time frame, inspite

of repeated attempts to trace and persuade the patient to come to the centre for assessment and to collect treatment. Thus, whenever a PB patient missed more than three months treatment or an MB patient more than six months treatment it is not possible for them to complete treatment in the maximum time allowed and they should be declared as defaulters. Any patient who has been categorized as a defaulter should be removed from the register.

A defaulter who returns to the health centre for treatment should be re-examined and re-classified into MB or PB category, depending on the current status of the disease and given a new course of appropriate MDT. For registration purposes, returning defaulters are not considered as newly detected cases.

COUNSELLING

Q 88: WHAT IS THE IMPORTANCE OF COUNSELLING IN LEPROSY?

Leprosy is one of the diseases that leaves a strong social and psychological impact on the persons affected and their families. Counselling will be needed for empowering the affected persons and their family members to address the daily challenges of stigma, discrimination and unsympathetic attitudes of society. At the same time, counselling will be required for the members of society in order to remove misunderstanding and myths regarding the disease and to accept persons affected by leprosy without any prejudice.

Q 89: WHAT ARE CONSIDERED TO BE GOOD PRACTICES IN THE CONTEXT OF LEPROSY?

Good practices are:

- being friendly, reassuring and encouraging;
- being well informed and giving correct information about the disease;
- answering questions and relieving doubts;

- maintaining confidentiality;
- keeping up-to-date records;
- providing patients with choices about when and where to return for check-up;
- using “Accompanied MDT” where appropriate;
- providing leprosy services free of charge;
- avoiding unnecessary investigations.

MONITORING, RECORDING AND REPORTING

Q 90: WHY IS IT IMPORTANT TO KEEP TREATMENT REGISTERS UP TO DATE?

Treatment registers provide the basic information for calculating prevalence rates and estimating the overall disease burden in the community, as well as for quantifying the MDT requirements. Removing cured and/or unaccounted-for patients from registers is good standard practice within programmes, but is often neglected. Keeping cured patients on a registry is not only unethical but also promotes social stigma and places unnecessary demands on the national programme. Moreover, an inflated caseload confounds any situational analysis and makes it impossible to quantify the MDT required or to establish a rational and cost-effective drug delivery system.

Q 91: WHEN SHOULD PATIENTS BE CONSIDERED AS CURED AND REMOVED FROM TREATMENT REGISTERS?

Every MB patient who has completed 12 months of MB-MDT and every PB patient who has completed 6 months of PB-MDT are cured and should be removed from the treatment register. Once the person has completed a full course of treatment, he or she should not be further referred by any term which may directly or indirectly refer to the person having been affected by leprosy in the past. He or she must be addressed as any other member of the community.

Q 92: IS ACTIVE SURVEILLANCE OF PATIENTS AFTER COMPLETION OF TREATMENT ESSENTIAL?

No. Because the risk of relapses after completion of the WHO-recommended MDT regimens has been negligible, it is not necessary to continue active post-MDT surveillance. Instead, patients who complete treatment should be informed about how to recognize early signs of possible relapse or reactions and the importance of reporting promptly to the nearest health centre.

Q 93: WHAT ARE THE MAIN INDICATORS FOR MONITORING AND EVALUATION OF LEPROSY CONTROL EFFORTS?

The indicators for monitoring and evaluating the leprosy control efforts can be divided into three groups.

1. Indicators for monitoring progress including:
 - (a) the number and rate of new cases detected per 100 000 population per year;
 - (b) rate of new cases with grade-2 disabilities per 100 000 population per year;
 - (c) treatment completion/cure rate.
2. Indicators for evaluating case detection including:
 - (a) proportion of new cases presenting with grade-2 disabilities;
 - (b) proportion of child cases among new cases;
 - (c) proportion of female cases among new cases;
 - (d) proportion of multibacillary cases among new cases.
3. Indicators for assessing the quality of services including:
 - (a) proportion of new cases verified as correctly diagnosed;
 - (b) proportion of treatment defaulters;
 - (c) number of relapses;
 - (d) proportion of patients who develop new/additional disability during multidrug therapy.

INDEPENDENT EVALUATION OF THE PROGRAMME

Q 94: WHAT IS THE IMPORTANCE OF INDEPENDENT EVALUATION OF THE LEPROSY CONTROL PROGRAMMES?

National leprosy control programmes need periodic independent evaluation of the structure, process and outcomes of the programme so that an objective assessment can be made that would enable corrections and adjustments to be made in the strategies and activities particularly at the local level. The exercise can be carried out by trained independent evaluators from within the country or from outside or can be made by a team consisting of both internal and external evaluators. It is important to include representatives from NGOs and representatives of people affected by leprosy in all such initiatives.

RESEARCH PRIORITIES

Q 95: WHAT ARE THE CURRENT RESEARCH PRIORITIES?

In the past decade, leprosy research has benefitted from the availability of the genome sequences of several strains of *M. leprae* and its human host. Several reviews of research priorities have been undertaken by WHO and other international agencies. The following are the key areas that have been highlighted:

- Molecular tools should be used to understand the basis of transmission and monitor the success of the control programme. The use of molecular tools could also provide insight into possible non-human sources of infection, such as the role of armadillos in transmitting leprosy in the Americas.
- It is important to develop diagnostic tests to identify individuals with disease or those who are at high risk of developing leprosy.

- Much progress has been made in developing new drugs for other mycobacterial diseases. The efficacy of these drugs in combination against *M. leprae* should be established in the laboratory and clinical trials. New immunomodulatory agents may also find application in the management of leprosy reactions and could represent an alternative to the current therapies.
- More research is needed in the area of prevention and management of nerve function impairment and the underlying reactions in order to improve the treatment of neurological conditions and prevent disabilities.
- Development of chemoprophylactic and immunoprophylactic tools for prevention of leprosy is required.
- It is important to perform operational, epidemiological and implementation research to improve sustainability and quality of leprosy services.

ROLE OF WHO

Q 96: WHAT IS THE ROLE OF WHO?

WHO is working on all fronts to sustain leprosy control services and to reduce the disease burden further. Its role includes the following elements:

- Technical – to further simplify and standardize the existing technology as well as to provide technical support at the country level.
- To assist country programmes to adapt the global leprosy control strategy to the national leprosy control policies as relevant to the local conditions.
- Logistical – to forecast annual MDT requirements, provide and distribute MDT treatment free of charge for all in need, including in those areas that are difficult to reach.
- Operational – to plan, guide and monitor implementation of the focused strategy.
- Societal and cultural – to change the negative image of leprosy.

- Political – to mobilize the necessary political commitment at all levels, as well as the necessary resources.
- Partnership – to ensure productive collaboration between partners at the global and country levels.

Q 97: CAN ANY COUNTRY REQUEST FREE SUPPLIES OF MDT THROUGH WHO?

Yes. WHO manages the procurement and free supply of MDT from Novartis for all countries through both health ministries and NGOs authorized by their national health authorities. In exceptional circumstances, such as in war-affected areas or those areas where the coverage of the national programme is limited or non-existent, WHO supplies free MDT directly to NGOs. The NGOs then deliver the drugs to patients, using cross-border operations from neighbouring countries where necessary.

Q 98: WHAT IS WHO'S ROLE IN PREVENTING/CARING FOR LEPROSY-RELATED DISABILITIES?

WHO focuses its efforts on the prevention of future disabilities through early detection and cure. The Organization also believes that, at the community level, the problems facing disabled people need to be considered in their entirety, whatever the primary cause of the disability. Thus, access to all existing programmes that provide for the social and economic welfare of the disabled, including community-based rehabilitation, should also be available to leprosy-affected persons.

The current global strategy for control and elimination of leprosy as a public health problem is a continuation of WHO's earlier strategies evolving with time and current epidemiology of the disease. During the 1950s, with the introduction of dapsone, the institutional treatment approach changed to domiciliary treatment of patients. With the introduction of multidrug therapy (MDT) in the 1980s, and its widespread implementation in the 1990s, a more ambitious concept of eliminating leprosy as a public health problem was introduced. The elimination strategy aimed at reducing the prevalence of cases registered for treatment to less than 1 case per 10 000 population at the global level. The goal was reached at the global level in 2000, and at the national level in most of the endemic countries in 2005.

The current strategy - the “Enhanced Global Strategy for Further Reducing the Disease Burden Due to Leprosy 2011-2015”, focuses on reducing the disease burden in terms of reducing the occurrence of new cases and occurrence of grade-2 impairments and disabilities. The strategy also addresses issues such as gender equity, human rights and initiatives to reduce stigma and discrimination faced by persons affected by leprosy and their families.

It is important to explain to all the stakeholders the changes in WHO's strategies, technical improvements in the case management and new concepts currently being applied to reducing the disease burden due to leprosy. This Questions and Answers booklet is an attempt to provide clarifications and justification for decisions taken for introducing changes. It is hoped that the booklet will be of interest to a wide range of decision-makers, health professionals as well as members of the community. The booklet answers questions on the strategy for leprosy control, epidemiology of the disease, case management, including management of complications and many other questions that are frequently asked.



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