The Final Push Strategy
to Eliminate Leprosy as a
Public Health Problem

Questions and Answers

Second Edition

World Health Organization
Geneva

© World Health Organization 2003
All rights reserved.

The designations employed and the presentation of the material in this publication do not imply
the expression of any opinion whatsoever on the part of the World Health Organization
concerning the legal status of any country, territory, city or area or of its authorities, or
concerning the delimitation of its frontiers or boundaries. Dotted lines on maps represent
approximate border lines for which there may not yet be full agreement.

The mention of specific companies or of certain manufacturers' products does not imply that
they are endorsed or recommended by the World Health Organization in preference to others of
a similar nature that are not mentioned. Errors and omissions excepted, the names of
proprietary products are distinguished by initial capital letters.

The World Health Organization does not warrant that the information contained in this
publication is complete and correct and shall not be liable for any damages incurred as a result of
its use.
## CONTENTS

**FOREWORD**

**STRATEGIC ISSUES – THE ELIMINATION OF LEPROSY AS A PUBLIC HEALTH PROBLEM**

1. Why is the elimination of leprosy as a public health problem feasible?  
2. What does eliminating leprosy as a public health problem mean?  
3. What has been the impact of the elimination strategy?  
4. What are the main problems facing the elimination effort?  
5. Does the high rate of new case detection indicate a failure of the elimination strategy?  
6. Why has the prevalence rate been selected as the yardstick for elimination?  
7. Why not aim for the eradication of leprosy rather than elimination?  
8. What is the difference between leprosy control and leprosy elimination?

**GLOBAL ALLIANCE FOR ELIMINATION OF LEPROSY AND THE FINAL PUSH STRATEGY**

9. Why was the Global Alliance created and the "Final Push" to Eliminate Leprosy launched?  
10. What are the key elements of the Final Push strategy?  
11. What has been achieved at country level since the creation of the Global Alliance?  
12. What possible problems could arise in the future that might prevent the goal of elimination being attained in the remaining highly endemic countries?  
13. Is support for leprosy diminishing because of the success of the elimination effort?  
14. Will new cases of leprosy continue to occur beyond the year 2005? If so, how can they be explained?

**INTEGRATION WITHIN THE GENERAL HEALTH SERVICES**

15. Why is it crucial to integrate leprosy within the general health services?  
16. What are the basic requirements for integration in the field?  
17. What is meant by easy access to MDT services and why is it important?  
18. What type of training should be provided to general health workers?  
19. How can MDT be provided in a patient-friendly and flexible manner?  
20. What is Accompanied MDT (A-MDT) and why was it introduced?

**COMMUNICATIONS STRATEGY**

21. Why do we need to change the image of leprosy?  
22. What are the most important messages about leprosy for the community?  
23. What are the key channels for an effective communications campaign?  
24. When should the communications campaign be launched?  
25. Why should communities be actively involved in leprosy elimination efforts?
SPECIAL CAMPAIGNS TO ELIMINATE LEPROSY

26. What are Special Campaigns?
27. What activities are carried out during the actual campaign?
28. Where are Special Campaigns particularly needed? What population groups should be targeted?
29. Why not simply conduct house-to-house surveys to detect all cases? Why wait for people with possible symptoms to self-report?
30. What are the main challenges encountered when conducting a Special Campaign?
31. How will the Special Campaigns be evaluated?

TECHNICAL ISSUES

Multidrug therapy (MDT)

32. What was the guiding principle in the development of MDT?
33. What are the recommended standard treatment regimens for leprosy?
34. What is the evidence that MDT is effective in MB and PB leprosy?
35. Is there any evidence that the drugs included in MDT can antagonize each other's antibacterial activity?
36. Does MDT help in reducing the frequency and severity of lepra reactions?
37. Why is rifampicin given only once a month?
38. Why is clofazimine given once a month in addition to the daily dose?
39. Can MDT prevent the development of resistance of M. leprae to antileprosy drugs?
40. Can MDT eliminate persisting M. leprae?
41. Is MDT contraindicated in patients suffering from tuberculosis?
42. Is MDT contraindicated in patients suffering from human immunodeficiency virus (HIV) infection?
43. Is MDT safe during pregnancy and lactation?
44. How long does it take for skin discoloration caused by clofazimine to disappear?
45. Why is MDT considered to be one of the most effective and cost-effective interventions in public health?

Alternative antileprosy drugs

46. Are there other antileprosy drugs besides those used in MDT?
47. What treatment can be given to patients who do not tolerate MDT due to adverse reactions or contraindications?

Discontinuation of skin smears for diagnosis

48. Why have skin smear examinations been discontinued?

Shorter duration of MDT treatment for MB patients

49. Why was the duration of MDT for MB patients shortened to 12 months?
50. Is any problem foreseen in using the 13-month MDT regimen to treat MB patients with a high bacteriological index?
51. Will shortening the duration of MDT treatment for MB leprosy increase the risk of M. leprae developing resistance to rifampicin?
Vaccines/Chemoprophylaxis
52. Is there an effective vaccine against leprosy? 29
53. Are there any drugs that provide protection against leprosy? 29

OPERATIONAL ISSUES
Compliance/Defaulters
54. 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? 29
55. What should be done if a patient does not take treatment regularly? 29
56. What is a defaulter? What should be done if a defaulter comes back for treatment? 30

Relapse vs reactions
57. After patients have stopped treatment, how is relapse recognized? How can relapse be distinguished from the various types of reactions? 30
58. Should individuals previously cured with dapsone monotherapy be re-treated with MDT? 30

Management of reactions
59. How should lepra reactions be managed? 31
60. How should severe ENL reactions be managed? 31
61. Can WHO assist programmes to procure thalidomide for treating patients with lepra reaction? 33
62. What is WHO’s position on the use of Prednipacs™ for management of lepra reactions in the field? 33

Registers
63. Why is it important to keep treatment registers up to date? 34
64. When should patients be considered as cured and removed from treatment registers? 34
65. Is active surveillance of patients after completion of treatment essential? 34

Good practice
66. What are considered to be good practices in the context of leprosy management? 34

ROLE OF WHO
67. What is the role of WHO in ensuring progress towards elimination? 35
68. Can any country request free supplies of MDT through WHO? 35
69. What is WHO’s role in preventing/caring for leprosy/related disabilities? 35

TERMS FREQUENTLY USED IN LEPROSY PROGRAMMES 36
For centuries, often with the best possible intentions for their welfare as well as that of the wider community, leprosy patients were turned out of their homes and isolated in “leprosaria”. Children were often forcibly separated from their parents for long periods of time. Today, throughout the world, all persons diagnosed with leprosy can be treated and cured while leading a completely normal life. Now the challenge is one of logistics and infrastructure, of determination and dedication, of joining hands and not letting go until the goal of ensuring that no further lives are devastated by this disease is achieved.

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 leprosy, and multidrug therapy (MDT) must be made available in all primary health centres to enable patients to be treated as close as possible to their homes. While we are striving to make treatment readily available, a simultaneous priority must be to create a positive environment in which leprosy is seen in the same light as any other curable disease. Our role is to help decision-makers, health providers and communities to understand that the challenge of eliminating leprosy from their homes, schools and villages is no longer insurmountable. We must provide them with simple information clearly communicating the message that there is no need to be afraid of leprosy, that it can be cured, and that the treatment is available free. All the techniques at our disposal must be deployed to make communities demand their right to live in a world without leprosy.

The decisive factor in this final push towards leprosy elimination, however, is the human element. We need people who show initiative and who are not afraid to come forward with new ideas; individuals who wish to be active partners in this global effort and who want safer and happier lives for themselves and their families. I sincerely hope that this booklet will help towards a better understanding of the strategy and the MDT technology behind it, and will contribute to the final push in eliminating leprosy. We look forward to receiving your comments and suggestions for improvement.

Dr David Heymann
Executive Director
Communicable Diseases
STRATEGIC ISSUES – THE ELIMINATION OF LEPROSY AS A PUBLIC HEALTH PROBLEM

1. Why is the elimination of leprosy as a public health problem feasible?

Leprosy is one of the few infectious diseases to meet the strict criteria for elimination:

- There is only one source of infection: untreated, infected human beings.
- Practical and simple diagnostic tools are available: leprosy can be diagnosed on clinical signs alone.
- The availability of an effective intervention to interrupt its transmission: multidrug therapy (MDT).
- Under natural conditions, “incident cases” (new cases in which the disease has recently developed) make up only a small fraction of the prevalence pool. Below a certain level of prevalence, any resurgence of the disease is very unlikely.
- Unlike tuberculosis, the leprosy situation does not appear to be adversely affected by HIV infection.

2. What does eliminating leprosy as a public health problem mean?

In 1991, the World Health Assembly passed a resolution to eliminate leprosy as a public health problem by the year 2000. Elimination was defined as a prevalence rate of less than 1 case per 10,000 inhabitants. Although this was achieved at the global level by the end of 2000, extra efforts are still needed to achieve the goal at the national level in some countries.

The elimination strategy is based on detecting and treating all cases with MDT and thereby reducing the disease burden to a very low level. At this low level, the transmission of Mycobacterium leprae is likely to be reduced to such an extent that the occurrence of new cases in the community would gradually decrease. The key will be to ensure that all new cases continue to have access to MDT services.

3. What has been the impact of the elimination strategy?

The leprosy elimination strategy enabled the mobilization of significant resources and political commitment. This resulted in the large-scale implementation of MDT, which has brought many backlog and new cases of leprosy under treatment, thus reducing the pool of infection within communities. More than 12 million patients have been detected and cured with MDT. In addition, some 4 million people have been protected from developing deformities. This tremendous impact alone is sufficient justification for the elimination programme.

Over the past 18 years, the global prevalence has been reduced by 90% globally. By the end of 2000, leprosy had been eliminated as a public health problem on a global level.
Now, early in 2003, 110 countries have reached the elimination target at the national level and leprosy remains a public health problem in only 12 countries.

The leprosy burden is now concentrated in the five most endemic countries (Brazil, India, Madagascar, Mozambique, and Nepal), which account for 83% of prevalence and 88% of detection worldwide. The combined prevalence rate in these countries is about 4 per 10,000 inhabitants.

Every year, about 600,000 new cases are detected as the coverage of leprosy services increases and the public are better informed about the cure and its availability free of charge at local health facilities.

4. **What are the main problems facing the elimination effort?**

The main problems involved in implementing the elimination strategy are operational in nature rather than technical.

A core element of the elimination strategy is to make MDT drugs available free of charge to all leprosy patients. However, the implementation of the strategy needs to be adapted to the field reality, particularly in areas that have not been covered so far. These areas generally have weaker health care infrastructures and are difficult to access from all perspectives - geographically, socially, economically, and culturally.

The fact that leprosy diagnosis and treatment remain highly centralized activities, often conducted only by specialized staff, is a major operational problem. In addition, the guidelines followed in some countries are very rigid and complex, with the result that patients in these countries have poor access to MDT drugs. This in part explains the substantial hidden caseload that still remains and serves as a reservoir of infection, spreading the disease in communities. Other reasons are poor geographical coverage of MDT services, limited community awareness about the availability of free and effective treatment, and prejudice - all of which often have tragic consequences such as late diagnosis, high disability rates, and low cure rates. Intense fear of leprosy still persists, leading to stigmatization of affected individuals and their families.

A simplified approach to diagnosis and treatment is needed, using the general health worker at the village level and making services "patient-friendly" and uncomplicated, so that patients are able to complete the course of treatment with minimum disruption to their daily lives.

5. **Does the high rate of new case detection indicate a failure of the elimination strategy?**

An integral element of the elimination strategy is the expansion of geographical coverage of leprosy services by integrating them into the general health services as well
as by conducting Leprosy Elimination Campaigns. In the short term, an increase in "new" cases is not only inevitable but also desirable, as large numbers of previously undetected cases are now coming forward for diagnosis and treatment. Experience clearly indicates that most of the newly detected cases have in fact been suffering from leprosy for many years. Only a small percentage are true "incident" cases, i.e. with disease onset within the past year.

A lack of appropriate tools makes it impossible to measure the true incidence of leprosy, which would be the best indicator for monitoring the impact of elimination efforts on leprosy transmission in the community. The next best indicator - new case detection rates - has severe limitations as it is directly related to the level of operational activities and thus not a reliable indicator for transmission.

From an epidemiological standpoint, an increase in new case detection is compatible with progress towards elimination. A number of countries have demonstrated that a significant decline in the annual new case detection rates can be achieved after wide-scale application of MDT for several years. The paradoxical trends with relatively stable detection rates reported in some major endemic countries (notably India, which contributes 78% of the global annual case detection) could be the result of several operational and administrative shortcomings, rather than epidemiological factors.

6. Why has the prevalence rate been selected as the yardstick for elimination?

Prevalence at the end of the year is a simple and easily understandable indicator, which gives the balance of the disease burden after counting how many new cases were detected and cured during the year.

The main thrust of the strategy to eliminate leprosy as a public health problem is to reduce the burden of the disease to very low levels. Today, as MDT services are expanding to reach previously uncovered or poorly covered areas, most of the new cases detected each year are those who acquired the disease several years earlier but who remained undetected for various reasons. The true "new" or "incident" cases, who developed the disease only within the past year, constitute only a very small proportion of the total cases detected. The long incubation period and the lack of tools to study transmission levels in the community make it impossible to measure incidence on a standard basis and use it as a yardstick for monitoring.

WHO is fully aware of the limitations of using registered prevalence as an indicator of progress towards elimination. However, in the absence of practicable alternatives, prevalence is probably the best indicator available. Moreover, WHO has made specific recommendations for improving the accuracy and validity of prevalence as an indicator. For example, WHO recommends periodic "updating" of leprosy registers: retaining cured patients on a register results in overestimates of the leprosy burden in the area. On the other hand, the disease burden is underestimated in areas where leprosy services are unavailable locally and people are therefore not encouraged to seek
treatment.

7. Why not aim for the eradication of leprosy rather than elimination?

Eradication would mean the complete absence of the disease and the organism that causes it throughout the world. At present, we lack the tools both to protect people from developing leprosy and to diagnose and treat the disease in its subclinical form. Significant resources would be required to develop and deploy the necessary tools, and would be impossible to justify when set against the needs of other diseases, such as malaria and tuberculosis, which have high mortality rates.

8. What is the difference between leprosy control and leprosy elimination?

Leprosy control is a more limited concept than elimination, based on detecting and treating leprosy patients without necessarily attempting to achieve complete geographical coverage with MDT. Leprosy control services are usually provided by specialized staff rather than by general health workers. In contrast, the concept of leprosy elimination takes advantage of:

- the free availability of MDT in local health clinics;
- the willingness of the general health services to work towards a defined goal within a specified time frame; and
- the active participation of communities through intensified information campaigns.

GLOBAL ALLIANCE FOR ELIMINATION OF LEPROSY AND THE FINAL PUSH STRATEGY

9. Why was the Global Alliance created and the "Final Push" to Eliminate Leprosy launched?

Despite the tremendous achievements to date, a number of challenges remain. The acceptance and implementation of MDT in many highly endemic countries has been slow, and the geographical coverage of MDT services remains poor in some countries. The combined prevalence rate in the five most endemic countries is still almost four times the elimination target.

The key challenge is to increase the coverage of MDT services rapidly and to get local health services and communities to take on the responsibility for eliminating leprosy. WHO believes that this can best be achieved through partnership and collaboration.

At the initiative of WHO, the Global Alliance for Elimination of Leprosy (GAEL) was established in November 1999 to ensure that a common strategy, based on past
experiences of leprosy elimination efforts, was adopted, intensively implemented and effectively monitored. GAEL takes the World Health Assembly mandate to its logical next step: after eliminating leprosy at a global level, the next challenge is to eliminate the disease at the national level from every country in the world by the year 2005. It is expected that about 2.5–2.8 million people will be detected and cured during the period 2000-2005.

GAEL brings together all the key players - governments of leprosy-endemic countries, WHO, the Nippon Foundation/Sasakawa Memorial Health Foundation, and the Novartis/Novartis Foundation for Sustainable Development. It works closely with patients, communities and all agencies interested in leprosy, such as the Danish International Development Assistance (DANIDA), Movimento de Reintegração de Pessoas Atingidas pela Hanseníase (MORHAN) and Pastoral da Criança in Brazil, Handicap International, and the World Bank. This has already led to more effective and coordinated field-level collaboration among partners.

10. What are the key elements of the Final Push strategy?

The key elements of the final push strategy are:

- Integration of leprosy services into the general health services to improve access to treatment.
- Capacity building to enable general health care staff to diagnose and treat leprosy.
- Improve logistics to ensure adequate stocks of MDT at health centres.
- Change society's perception of leprosy and motivate people to seek timely treatment.
- Ensure high cure rates through flexible and patient-friendly drug delivery systems.
- Simplify monitoring to keep track of progress towards elimination.

11. What has been achieved at country level since the creation of the Global Alliance?

Activities in the first three years of GAEL have focused on assessing the situation in the most endemic countries, better understanding the field realities, and adapting strategies to address local circumstances. The task is made more difficult by the paucity of information on the leprosy situation in some areas due to lack of health infrastructure, political tensions, armed conflicts, or inaccessibility.

The key organizational changes taking place in the priority countries are:

- Highly vertical programmes with very poor coverage of MDT services (in many countries, less than 10% of general health facilities provide MDT services) are now being integrated into the general health care services to improve MDT coverage.
- The highly centralized management of leprosy elimination activities is giving way to decentralization, thereby giving "ownership" of leprosy elimination to the state or provincial health authorities.
- General health care workers are being reoriented and retrained so that they are now responsible for elimination.
- The role of staff of vertical programmes is being revised to support the general health workers or the staff are being retrained or reassigned to other disease control programmes.
- Community awareness and involvement in leprosy elimination activities are being improved.
- Cure rates, especially in difficult areas with poor access to MDT services, are being improved by simplification of guidelines for treating patients and by better management of the MDT drug supply.

12. What possible problems could arise in the future that might prevent the goal of elimination being attained in the remaining highly endemic countries?

We all need to be on our guard against such problems as:

- lack of commitment to integration of MDT services within the general health services in order to improve access and increase geographical coverage with MDT services;
- failure to redefine the role of the vertical programme after integration and to transfer staff to other functions;
- initial success breeding complacency, so that health services are unable to sustain high MDT coverage;
- failure to extend MDT services into difficult-to-access areas/populations with weak or non-existent health infrastructure;
- exceptional circumstances, such as the total breakdown of health services due to civil disturbances or other factors (e.g. natural disasters) in areas already covered by MDT.

13. Is support for leprosy diminishing because of the success of the elimination effort?

There is always a risk that the political commitment of politicians, administrators, and financial donors could decrease with time, especially if the number of leprosy cases decreases sharply as a result of the elimination programme. In addition, other health priorities, such as HIV/AIDS, malaria, and tuberculosis, can easily overshadow leprosy. There is no indication, however, that motivation among decision-makers has declined so far - rather the contrary, as there appears to be a growing self-reliance within national programmes, reflecting an increased confidence in the real progress that is being achieved.
14. Will new cases of leprosy continue to occur beyond the year 2005? If so, how can they be explained?

New cases will continue to occur in small numbers beyond the year 2005 because the disease will appear in individuals who acquired their infection several years earlier as a result of the long incubation period of the disease.

However, with integrated services and the extension of MDT to previously uncovered areas, together with improving community awareness, the number of new cases is expected to fall steadily.

INTEGRATION WITHIN THE GENERAL HEALTH SERVICES

15. 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);
− consolidate the substantial gains made in reducing the leprosy burden in communities.

16. What are the basic requirements for integration in the field?

WHO has made integration part of its Final Push strategy to achieve and sustain the goal of elimination in all countries. The basic five-step principles advocated by WHO are simple:

− Every health facility in an endemic area should provide MDT services\(^1\) 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.

\(^1\) MDT services include diagnosis, treatment with MDT, patient and family counselling, community education, and referral for complications.
- Information, Education and Communication (IEC) materials should be available for patient, family, and community education and counselling.
- 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.

17. 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;
- are not too expensive (considering all “costs” - bus fares, travelling time, loss of wages, consultation costs, social costs, etc.);
- are open on every working day;
- are welcoming and can be approached without fear or prejudice;
- diagnosis, treatment and advice are all readily available.

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

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

Training of general health workers should enable them to:
- 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.

To facilitate the integration of leprosy diagnosis and treatment into general health services, a simple guide has been developed for general health staff, which is clear and easy to follow. The signs described in the guide cover about 70-80% of typical leprosy cases. If the general health worker routinely tests all skin lesions for sensory loss, an
increasing number of leprosy cases will be detected at an early stage of the disease. This will be a major improvement on the current situation, where patients lose many years before starting treatment, often because the health services are not in a position to recognize leprosy or are not encouraged to do so. Referral mechanisms will be needed to deal with more complex cases.

19. 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;
− it is very effective (almost no relapses);
− it is safe (almost no side-effects);
− it is standard for all patients and so rarely needs to be changed or modified;
− it is effective even if taken irregularly;
− it does not create drug resistance;
− patients can easily understand which drugs they need to take and when;
− it is easy to store and take at home.

20. What is Accompanied MDT (A-MDT) and why was it introduced?

Accompanied MDT ensures that patients receive a full course of treatment. It was designed to address a frequent problem in field programmes: Patients often have to interrupt their treatment because of a shortage of drugs at the health centre, poor access to health services or simply because no one is at the health centre when they come to collect their treatment.

With Accompanied MDT, a patient receives:

− a full course of MDT at the time of diagnosis;
− information (advice and printed materials\(^1\)) about the disease, its treatment, and when and where to come for follow-up or in the event of complications.

The term "Accompanied MDT" has been adopted because someone close to or important to the patient assumes the responsibility for helping him or her to complete a full course of treatment.

Accompanied MDT does not prevent patients from having regular contact with health staff, and - because less energy and fewer resources are needed for routine drug delivery and distribution - it can often leave those staff with more time for patient counselling and disability prevention. Patient compliance with treatment is likely to be

\(^1\) WHO has produced patient information leaflets in English, French, Hindi, and Portuguese.
increased, with fewer defaulters, as patients are no longer forced to travel long distances on a monthly basis (often with attendant loss of income).

COMMUNICATIONS STRATEGY

21. Why do we need to change the image of leprosy?

Significant numbers of undetected leprosy cases still remain in communities. These cases are not coming forward for variety of reasons, including poor awareness of the availability of free and effective treatment, fear of leprosy, and deep social stigma. It is expensive and time-consuming to detect them through active case-finding - which may anyway yield large numbers of "new" cases through wrong diagnosis.

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 patches. 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 attractive 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;
- **decision-makers** - to give their support for elimination and to make leprosy services readily accessible.

22. What are the most important messages about leprosy for the community?

The communication approach must be positive and attractive 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.

23. 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 leprosy elimination among all those involved. 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.

24. When should the communications campaign be launched?

The communications 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 for ever.

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.

25. Why should communities be actively involved in leprosy elimination efforts?

It is important that local communities accept leprosy elimination 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.

SPECIAL CAMPAIGNS TO ELIMINATE LEPROSY

26. What are Special Campaigns?

Special Campaigns are usually carried out in areas (or among population groups) presumed to have a high hidden caseload. In these circumstances, the coverage of MDT services is typically still poor, awareness about the disease is low, and the negative images traditionally associated with leprosy persist. These factors have prevented patients from coming early for diagnosis and treatment, thus increasing the risk of their becoming disabled and transmitting the disease to others. Special Campaigns are needed to focus attention and change this situation as quickly as possible.

Special Campaigns combine three objectives:

- capacity-building of general health workers to provide MDT services to the communities they serve;
- raising community awareness and encouraging participation, to promote self-reporting and remove negative perceptions about the disease;
- ensuring that all cases of leprosy are diagnosed and that patients receive a full course of treatment.

27. What activities are carried out during the actual campaign?

The Special Campaign itself is usually of short duration, and its success will depend to a great extent on how well the preparatory activities have been carried out. The campaigns concentrate on:

- case-finding through creating community awareness (self-reporting by patients) and providing clear information on where to go for diagnosis;
- starting treatment with the first dose of MDT and providing clear information on how to continue taking the treatment;
- providing enough treatment or information about where to go for continuation of treatment;
- removing negative perceptions about the disease through intense IEC activities, using various communication methods specially adapted to local situations.

28. Where are Special Campaigns particularly needed? What population groups should be targeted?

Special Campaigns are needed in the following areas and for the following target groups:

- **Rural areas** - where MDT services are not operating effectively and there are indications that large numbers of undetected (hidden) cases exist (e.g. migrant labourers).
- **Difficult to access/border areas** - where MDT services are not available or easily accessible for certain population groups living under difficult conditions (e.g. minority groups, tribal groups, nomads, displaced people, refugees).
- **Urban/peri-urban/urban slum areas** - in these areas stigma is generally high, awareness about the disease is relatively low, and MDT service coverage is poor due to the inadequate involvement of both the general health care system and the private sector.

It is also clear that, in many programmes, there is a significant "gender gap" in accessibility to MDT services for women. Every effort must be made to ensure that this gap is narrowed.

29. Why not simply conduct house-to-house surveys to detect all cases? Why wait for people with possible symptoms to self-report?

In the ideal situation, the community would be so well informed about leprosy that anyone who developed a suspicious skin lesion would come forward for timely diagnosis and treatment. This requires both an effective communications strategy, adapted to local culture and customs, and readily available and accessible leprosy services.

By contrast, house-to-house surveys are very time-consuming and require considerable financial and human resources. Such surveys also expose new patients and their family members to unnecessarily stressful situations, and may often result in rejection of the diagnosis and patients defaulting from treatment. Active search campaigns have also had a high rate of misdiagnosis of doubtful lesions.

30. What are the main challenges encountered when conducting a Special Campaign?
The problems commonly encountered in carrying out Special Campaigns are:

- **Poor coverage** - activities may cover only a small portion of the population in the target areas.
- **Inadequate community awareness** - information provided to the community may not be appropriate and the communication methods used may be unattractive or ineffective.
- **Limited involvement of the general health services** - the general health services may not be fully involved during and after the Campaigns, which will create problems in sustaining MDT services.
- **Emphasis on detection** - overenthusiasm on the part of health workers and volunteers in detecting cases may result not only in a significant proportion being wrongly diagnosed but also in the reregistration of previously treated cases as new cases (recycling).
- **Inadequate preparation** - poor planning leads to the existing health infrastructure being unable to cope with the increased demand for MDT services, which in turn results in drug shortages, and in patients getting irregular or no treatment.

### 31. How will the Special Campaigns be evaluated?

National programmes must ensure that every Campaign is evaluated: future activities can be improved on the basis of the lessons learned. The following indicators may be used in evaluation:

- Increase in the number of new health facilities providing MDT services on a daily basis after the Campaigns.
- Correctness of diagnosis, classification, and recording of new cases (paucibacillary, multibacillary, women, children, and grade 2 disabilities) detected during the campaign.
- Level of community participation and feedback on the Campaign.
- Number and categories of general health workers competent in, and routinely providing, MDT services.
- Coverage of awareness activities and impact, particularly in terms of the proportion of new cases self-reporting to the nearest health centre.

### TECHNICAL ISSUES

**Multidrug therapy (MDT)**

**32. 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.

33. 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 adult and children.

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
- **Duration**: 12 months.

The standard adult treatment regimen for PB leprosy is:
- **Rifampicin**: 600 mg once a month
- **Dapsone**: 100 mg daily
- **Duration**: 6 months.

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
- **Duration**: 12 months.

The standard child treatment regimen for PB leprosy is:
- **Rifampicin**: 450 mg once a month
- **Dapsone**: 50 mg daily
- **Duration**: 6 months.

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

34. 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.
35. 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.

36. Does MDT help in reducing the frequency and severity of lepra reactions?

The available evidence shows that there is a significant 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 probable anti-inflammatory effect of clofazimine, particularly in MB patients.

37. 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 possible 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.

38. 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.

39. 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, very few patients have relapsed after treatment with MDT and re-treatment with the same MDT regimen has been effective in all cases of relapse.

40. 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 evidence to date indicates that persisters do not play an important role in the occurrence of relapse among leprosy patients treated with MDT.

41. 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.

42. 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 lepra 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.

43. 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 discoloration of the infant’s skin caused by clofazimine.

44. How long does it take for skin discoloration caused by clofazimine to disappear?
The discoloration 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 discoloration starts to diminish noticeably in 6 months; it is completely reversible, and the skin returns to its normal colour within a year.

45. 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 is no reported 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 4 weeks' treatment.
- The drugs can be stored under ordinary storage conditions.

Alternative antileprosy drugs

46. Are there other antileprosy drugs besides those used in MDT?

Drugs from the minocycline (tetracycline) group, ofloxacin/moxifloxacin (quinolone) group, clarithromycin (macrolide) group, and newer derivatives of rifampicin have potential for use in the treatment of leprosy. However, none of these is superior to the combination of drugs used in the standard MDT. The most important use of these drugs is for the small number of patients who for various reasons (e.g. side-effects, contraindications, resistance to MDT drugs) cannot take the standard MDT regimens.

47. What treatment can be given to patients who do not tolerate MDT due to adverse reactions or contraindications?

Such cases are very rare. However, it is very important to establish conclusively that the adverse reactions seen are caused by the antileprosy drugs. Only then should other antileprosy drugs be tried.

In place of rifampicin, it is possible to use ofloxacin 400 mg daily and minocycline 100 mg daily, given along with the daily 50-mg dose of clofazimine for the first 6 months.
This should be followed by daily administration of clofazimine 50 mg with ofloxacin 400 mg or minocycline 100 mg for the next 18 months. This regimen should be administered under direct supervision in a referral centre.

Patients who cannot take clofazimine can be treated with a combination of 600 mg rifampicin, 400 mg ofloxacin, and 100 mg minocycline, given once a month for 24 months.

If the toxic effects of dapsone are severe in PB patients, this drug may be replaced by clofazimine in the same dosage as that used for MB patients but given for 6 months only. In MB patients, dapsone should be stopped and treatment continued with rifampicin and clofazimine in the standard dosage for 12 months.

Discontinuation of skin smears for diagnosis

48. Why have skin smear examinations been discontinued?

Since the introduction of MDT, many procedures have been simplified so that leprosy patients can be efficiently managed by general health workers in the field. Experience from many endemic countries convincingly demonstrates that, after appropriate training, health workers at peripheral levels are able to diagnose and treat leprosy.

Taking into account the actual situation in the field, the diagnosis of leprosy is based on clinical signs and symptoms. In the pre-MDT era, skin smears were routinely used for classifying a case of leprosy as PB or MB. However, the quality of skin smears and of microscopy was the weakest link in most leprosy elimination programmes: fewer than 15% of newly diagnosed cases show positive results in this investigation, and diagnosis is rarely based on skin smear results under field conditions. Moreover, in many countries where leprosy remains endemic, all skin-piercing procedures carry the potential risk of transmitting HIV and hepatitis infections.

WHO has made it clear that skin smears are not a prerequisite for managing leprosy elimination programmes, and there is no need to maintain or establish skin-smear services exclusively for leprosy. The clinical system of classification for the purpose of treatment includes the use of numbers of skin lesions as the basis for grouping the leprosy patients into MB and PB. If in doubt, the patient should be treated with the MB regimen.

In summary:

- There is no need to take skin smears for diagnosis or classification or in order to monitor progress with treatment.
- Leprosy can be easily diagnosed and classified on the basis of clinical findings.
- MDT treatment regimens are standardized and usually do not require mid-course changes based on results of smear examinations.
- Cure of leprosy is based on completion of a full course of standard MDT regimen.
- Skin smears from most leprosy patients will yield negative results.
- Unnecessary skin-piercing procedures are unethical: they are painful and carry the risk of serious infection (particularly HIV and hepatitis).
- Use of skin smears should be limited to referral centres, particularly for special investigations (suspicion of resistance, complex relapse cases) and research purposes.

**Shorter duration of MDT treatment for MB patients**

49. *Why was the duration of MDT for MB patients shortened to 12 months?*

The most important component of the MDT regimen is rifampicin. Most rifampicin-susceptible *M. leprae* are killed by a few monthly doses of rifampicin. It has been shown that the daily combination of dapsone and clofazimine is also highly bactericidal, and is capable of eliminating any rifampicin-resistant mutants in an untreated MB leprosy patient in about 3–6 months. Several studies have demonstrated that MB leprosy patients given only a few monthly doses of MDT responded as favourably as those who received 24 or more doses. At its seventh meeting, the WHO Expert Committee on Leprosy concluded that the duration of treatment of MB leprosy could be reduced to 12 months without compromising the efficacy of the MDT regimen.¹

50. *Is any problem foreseen in using the 12-month MDT regimen to treat MB patients with a high bacteriological index?*

Patients with a high bacteriological index (BI) at the time of diagnosis may be at greater risk of developing reactions and nerve damage than those with a low BI at diagnosis. High-BI patients are also likely to show slower clearance of skin lesions and to have a significant BI at the end of 12 months compared with patients with lower BI. Most high-BI patients will continue to improve after completing 12 doses of MDT. In the rare event of a patient showing evidence of deterioration, he/she can be re-treated with an additional 12 months of MDT for MB leprosy.

51. *Will shortening the duration of MDT treatment for MB leprosy increase the risk of *M. leprae* developing resistance to rifampicin?*

No. If the patient takes all the drugs prescribed in the MDT, there is no risk. Several studies have shown that even a few doses of rifampicin kill all organisms susceptible to the drug. Naturally occurring rifampicin-resistant mutants are killed by the clofazimine/dapsone combination within a few months. Therefore, the chances of any live bacilli being found after 12 doses of MDT are almost zero.

Vaccines/Chemoprophylaxis

52. Is there an effective vaccine against leprosy?

There is no specific and effective vaccine against leprosy. Several candidate vaccines have been tested (BCG, M. leprae, M. w, ICRC bacillus, M. habana, M. vaccae, etc). However, none of the candidates or combinations provides a level of efficacy that can be considered a cost-effective intervention for a public health programme. Studies to date have indicated that, in some populations, the vaccine provides limited protection against leprosy as well as against TB.

53. Are there any drugs that provide protection against leprosy?

No. Several studies using one or more antileprosy drugs (mainly dapsone, long-acting injectable dapsone-acedapsone, rifampicin) as chemoprophylaxis against leprosy failed to demonstrate any significant protective effect. At present, therefore, the only practical method of prevention is early detection and treatment of all leprosy patients with MDT.

OPERATIONAL ISSUES

Compliance/Defaulters

54. 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?

Although it is not essential, 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 Accompanied MDT, 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.

55. What should be done if a patient does not take treatment regularly?

Irregularity in taking treatment should be the exception in a good programme that provides MDT services with minimum inconvenience to the patient and informs the patient of the importance of taking the drugs regularly. It is important that a PB patient takes 6 doses of PB-MDT and a MB patient takes 12 doses of MB-MDT.
However, the efficacy of MDT regimens is not affected by occasional irregularity in taking the drugs. In most cases, if the patient is properly advised at the time of diagnosis, it should be possible to provide the full course of Accompanied MDT and allow the patient take full responsibility for his or her treatment.

56. What is a defaulter? What should be done if a defaulter comes back for treatment?

A defaulter is a patient who has not collected treatment for 12 consecutive months, in spite of repeated attempts to trace and persuade the patient to come to the centre for assessment and to collect treatment. 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 given a new course of MDT when he or she shows one or more of the following signs:

- reddish and/or raised skin lesions;
- appearance of new skin lesions since the previous examination;
- new nerve involvement (e.g. changes in skin sensation) since the previous examination;
- lepromatous nodules;
- signs of reversal reaction or ENL.

For registration purposes, returning defaulters are not considered as newly detected cases.

Relapse vs reactions

57. After patients have stopped treatment, how is relapse recognized? How can relapse be distinguished from the various types of reactions?

Relapse in MB leprosy is defined as the multiplication of *M. leprae*, suggested by the marked increase (at least 2+ above the previous value) in the BI at any single site, usually with evidence of clinical deterioration (new skin patches or nodules and/or new nerve damage). This can be confirmed in most cases by clinical findings and by the growth of *M. leprae* in the mouse footpad system.

Recognition of relapse in PB leprosy, which is difficult to distinguish from a lepra reaction, is somewhat problematic. In theory, a therapeutic test with corticosteroids may be able to distinguish between the two phenomena: definite improvement during 4 weeks of corticosteroid therapy denotes a lepra reaction, and non-response to corticosteroids over the same period favours the diagnosis of clinical relapse. Definite evidence of clinical deterioration (new skin patches and/or new nerve damage) is sufficient to identify a relapse in a PB case.
58. **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.

**Management of reactions**

59. **How should lepra reactions be managed?**

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 2 weeks. Maximum dosage of prednisolone is 1 mg/kg of body weight.

60. **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 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.

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 does not support the use of thalidomide for the management of ENL in leprosy.

61. Can WHO assist programmes to procure thalidomide for treating patients with lepra reaction?

No. WHO does not assist or support the use of thalidomide by programmes because of the well known teratogenic side-effects of the drug. In addition, the importation of this drug is banned by many countries where leprosy is endemic. In the rare instance that a referral centre decides to import thalidomide for its patients, this must be arranged directly with the manufacturers, with careful national/international ethical, legal, and scientific justification. Most importantly, patients who require thalidomide for complicated ENL-type reactions are very rare: in practice, most patients with lepra reactions can be successfully managed by the proper use of other available anti-reaction drugs.

62. What is WHO’s position on the use of Prednipacs™ for management of lepra reactions in the field?

WHO does not promote the uncontrolled use of Prednipacs™ (prednisolone) for lepra reactions in the field for the following reasons:

- Most patients under treatment with MDT (more than 90%) do not develop lepra reactions.
- Most lepra reactions can be controlled by non-steroidal drugs.
- As fewer than 2% of patients who start MDT develop lepra reactions that require treatment with steroids, ensuring the correct distribution of the drugs and securing prompt access for needy patients would present logistic challenges.
- There are numerous contraindications to the use of prednisolone, and the drug has serious side-effects, particularly when used for long periods.
- Strict compliance with a prescribed prednisolone course and regular monitoring of a patient’s condition are crucial for the successful outcome of this therapy.
- Prednisolone is an important drug for many serious and life-threatening conditions and it would therefore be unethical to restrict or deny its use for non-leprosy patients.
- Most health centres acquire MDT as part of the essential drugs they receive, but they may not receive adequate stocks of prednisolone.
- WHO does not support the use of prednisolone as a prophylactic against lepra reactions and/or neuritis in the field.
Finally, it should be stressed that early diagnosis of the disease and treatment with MDT constitute the most cost-effective way of preventing leprosy-related disabilities.

Registers

63. **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.

64. **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 is cured and should be removed from the treatment register.

65. **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.

Good practice

66. **What are considered to be good practices in the context of leprosy management?**

Good practices are:

- being friendly, reassuring and encouraging;
- being well informed and give 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.

ROLE OF WHO

67. What is the role of WHO in ensuring progress towards elimination?

WHO is working on all fronts to make leprosy elimination a reality. 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.
- **Logistic** - 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.

68. 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 nongovernmental organizations (NGOs) authorized by their national health authorities. A few international NGOs, however, continue to purchase MDT from other sources, which is a waste of resources.

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.

69. 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.

TERMS FREQUENTLY USED IN LEPROSY PROGRAMMES

leprosy patient
A person who has a skin patch or patches with a definite loss of sensation, and who has
not yet completed a full course of treatment with multidrug therapy. Cured persons
with residual disabilities are not considered to be leprosy
patients.

newly diagnosed case
A person who has been diagnosed as a leprosy case and who has not taken MDT in
the past.

misdiagnosed case
A person who has been wrongly diagnosed as suffering from leprosy. (Other
terms used are “overdiagnosed” and “wrongly diagnosed”.)

recycled case
A person (usually with residual signs of leprosy) who has completed a full or
partial course of MDT but who has now been reregistered as a newly diagnosed
case and has restarted treatment with MDT.

defaulter case
A person who was diagnosed as a case of leprosy and started on treatment with
MDT, but
– who has not completed the full course, and
– who has not collected MDT during the past 12 consecutive months.