

Report of the Global Programme Managers' Meeting on Leprosy Control Strategy

New Delhi, India, 20-22 April 2009

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Acronyms and abbreviations

AFRO	WHO Regional Office for Africa	MB	multibacillary
CBR	community-based rehabilitation	MDG	Millennium Development Goals
EMRO	WHO Regional Office for the Eastern Mediterranean	MDT	multidrug therapy
G2D	grade-2 disabilities	NGO	nongovernmental organization
HIV	human immunodeficiency virus	NPM	National Programme Manager
IDEA	International Association for Integration, Dignity and Economic Advancement	PB	paucibacillary
IEC	information, education and communication	POD	prevention of disability
ILA	International Leprosy Association	SEARO	WHO Regional Office for South-East Asia
ILEP	International Federation of Anti-Leprosy Associations	TB	tuberculosis
ISF	impairment summary form	UNCRPD	United Nations Convention on the Rights of Persons with Disabilities
LEA	Leprosy Elimination Alliance	WHA	World Health Assembly
		WHO	World Health Organization
		WPRO	WHO Regional Office for the Western Pacific

Brief description of the disease

Leprosy is a chronic infectious disease caused by *Mycobacterium leprae*. It usually affects the skin and peripheral nerves, but has a wide range of clinical manifestations. The disease is classified as paucibacillary or multibacillary, depending on the bacillary load. Paucibacillary leprosy is a milder disease characterized by few (up to five) hypopigmented, anaesthetic skin lesions (pale or reddish). Multibacillary leprosy is associated with multiple (more than five) skin lesions, nodules, plaques, thickened dermis or skin infiltration, and in some instances, involvement of the nasal mucosa, resulting in nasal congestion and epistaxis. Involvement of certain peripheral nerves may also be noted, sometimes resulting in the characteristic patterns of disabilities. In most cases of both paucibacillary and multibacillary disease, the diagnosis is straightforward, but in a small proportion of cases, suspects without anaesthetic patches require examination by a specialist to look for other cardinal signs of the disease, including nerve involvement and a positive laboratory test (the slit skin smear).

Among communicable diseases, leprosy is a leading cause of permanent physical disabilities. Timely diagnosis and treatment of cases, before nerve damage has occurred, is the most effective way of preventing disabilities due to leprosy; effective management of leprosy complications, including reactions and neuritis, can prevent or minimize the development of further disabilities. The disease and its associated deformities are responsible for social stigma and discrimination against patients and their families in many societies.

The mode of transmission of the leprosy bacillus remains uncertain, but most investigators believe that *M. leprae* is spread from person to person, primarily as a nasal droplet infection. The incubation period is unusually long for a bacterial disease, generally 5-7 years. The peak age of onset is young adulthood, usually 20-30 years of age; disease is rarely seen in children less than five years old. While humans are considered to be the major host and reservoir of *M. leprae*, other animal sources, including the armadillo, have been incriminated as reservoirs of infection. The epidemiological significance of these findings is unknown, but is likely to be very limited, except perhaps in North America. Unlike tuberculosis, there is no evidence to suggest that an association exists between HIV infection and leprosy. BCG vaccination is known to have some protective effect against the disease.

Background



one



The goal of elimination of leprosy as a public health problem was set out in 1991 by the Forty-fourth World Health Assembly (Resolution WHA44.9)¹. This goal-of attaining a level of prevalence of less than one case per 10 000 population-was reached at the global level in the year 2000. The enormous success in global leprosy control is due to a combination of three elements: a clear objective, availability of an effective technology and an explicit implementation strategy. The *Strategic Plan for Leprosy Elimination 2000-2005*² encouraged major commitment among leprosy-endemic countries, and support to ensure that leprosy services would be available and accessible to all persons affected by leprosy at their nearest health facility. The *Global Strategy for Further Reducing Leprosy Burden and Sustaining Leprosy Control Activities 2006 – 2010*³ aimed to improve programme sustainability by promoting integration within the general

1 Available online at www.who.int, "Governance"

2 World Health Organization. The final push towards elimination of leprosy: strategic plan 2000–2005. Geneva, WHO, 2000 (WHO/CDS/CPE/CEE/2000.1).

3 World Health Organization. Global strategy for further reducing the leprosy burden and sustaining leprosy control activities: plan period 2006–2010. Geneva, WHO, 2005 (WHO/CDS/CPE/CEE/2005.53).

health system. This ensured a renewed focus on quality of services, reaching underserved communities and building effective partnerships for further reducing the disease burden due to leprosy.

However, despite the enormous reduction in the number of patients registered for treatment, new cases of leprosy will continue to appear for many more years. Therefore, health services must sustain the provision of quality services at all levels in the foreseeable future. The *Enhanced Global Strategy for Further Reducing Disease Burden Due to Leprosy: 2011–2015* has been formulated as a natural extension of the World Health Organization's (WHO) earlier strategies. It offers opportunities to enhance efforts towards addressing the remaining challenges in reducing the disease burden due to leprosy through careful implementation of evidence-based strategies and optimized use of every available opportunity to expand the vision of a world without leprosy. The strategy will continue to be based on the principles of morbidity control, i.e., timely detection of new cases and their cure with effective chemotherapy. However, additional elements will be needed to accelerate further reduction in the disease burden and sustain political and professional commitment to leprosy control.

The *Enhanced Global Strategy* has been developed in consultation with Member States, WHO regions and partners, including persons affected by leprosy. It will help to sustain the gains made so far and further reduce the disease burden in all endemic countries. The leprosy control agenda could be further reinforced by

- investing in targeted research to find more powerful antileprosy drugs;
- new therapies for the prevention and management of neuritis and reactions;

**Updated
operational
guidelines
for the
implementation
of the
Enhanced
Global Strategy
have also been
developed**

- innovative interventions to prevent and limit disabilities due to leprosy;
- new diagnostics and prevention tools; and,
- operational research to increase the access to and impact of disease control measures.

The principles of integration, quality, equity and sustainability have been accorded primacy in the formulation of this *Strategy*. Updated operational guidelines for the implementation of the *Enhanced Global Strategy* have also been developed.

To discuss collaboratively and endorse the *Enhanced Global Strategy and Operational Guidelines* by all concerned and revise it if needed, the World Health Organization's Regional Office for South-East Asia (WHO SEARO) organized a three-day meeting on 20 - 22 April 2009 in New Delhi, India. The meeting was attended by national programme managers (NPMs) from 44 leprosy-endemic countries, partners, donors, national and international experts and people affected by leprosy.



Objectives



two



The main objective of the meeting was to discuss with national programme managers responsible for leprosy, representatives of national and international partners, and public health and leprosy experts, the draft version of:

- *Enhanced Global Strategy for Further Reducing the Disease Burden Due to Leprosy: 2011–2015*, and
- *Operational guidelines (updated): 2011–2015*, in order to obtain consensus and endorsement from all stakeholders.

Inaugural session



three



Dr V. Pannikar, Team Leader, WHO Global Leprosy Programme, welcomed the delegates and thanked them for their help with the new *Global Strategy*.

Dr Samlee Plianbangchang, Regional Director, WHO South-East Asia Region, thanked participants for sparing their time to attend this important meeting. The meeting aimed to review the *Enhanced Global Strategy* to ensure that it increased the effectiveness of leprosy control programmes and helped solve the remaining unresolved issues.

Leprosy is one of the few communicable diseases wherein the situation is well under control. The number of newly detected cases has decreased and free availability of multidrug therapy (MDT) worldwide has helped cure 15 million people and prevented disability in another two to three million people. Leprosy control activities have been integrated with the general health services, thus helping to improve service coverage and ensure sustainability.

As the disease burden declines further, additional challenges are likely to emerge. The most important challenge is to maintain the gains achieved so far. To do this, we must reaffirm global and national commitment and not allow complacency to set in. Partnerships must be strengthened, and special attention paid to bolstering national health programmes in the milieu of the present socioeconomic crisis, as resources to tackle the problem will be limited. Careful prioritization of resources is needed. Referral systems must be in place, especially now that the disease burden is declining, so that patients get care. Efficiency and effectiveness must be the hallmark of all leprosy control efforts.

Effective treatment of leprosy must continue, for which drugs are necessary. However, the potential for developing drug resistance must be kept in mind, and the lessons learnt from the human immunodeficiency virus (HIV), malaria and tuberculosis (TB) programmes must be applied to effectively address drug resistance. In the longer term, primary prevention must be thought of, and balanced consideration given to the factors of agent, host and environment. Effective strategies are needed for capacity building in national programmes and ensuring that the necessary expertise is available in the country. Country capacity strengthening is the key issue in leprosy control programmes.

Efficiency and effectiveness must be the hallmark of all leprosy control efforts



The Global Leprosy Programme has prepared a draft version of the *Enhanced Global Strategy*, which presents an overview of the concepts, ethics and guiding principles of the strategy. The *Strategy* document is accompanied by the updated *Operational Guidelines*, which describe practical suggestions for implementing leprosy control activities based on current evidence and best practices. The meeting aims to develop the *Enhanced Global Strategy* and its *Operational Guidelines* for use over the next five to six years.

To tackle the remaining problem of leprosy in the years to come will be a challenge. Dr Samlee urged participants to face the challenge with determination and commitment, and wished them success in their deliberations.

Remarks by partners

Dr Yo Yuasa, Medical Consultant, Nippon Foundation/Sasakawa Memorial Health Foundation, Tokyo, Japan, explained how the Foundation had initiated its financial commitment to the cause of leprosy control. Financial contribution from the Sasakawa Memorial Health Foundation for leprosy has continued since 1975. The Foundation works closely with WHO as it is the body that supports health activities in countries worldwide.

He said it is hoped that all countries will give accord commensurate importance to further reducing the leprosy burden globally and allocate resources for leprosy accordingly. The scope of this meeting, he said, is not merely what to do and how to do it but to see how to secure political commitment in each country, and ensure the availability of financial and other resources.





Dr S.K. Noordeen, President, Leprosy Elimination Alliance (LEA), Chennai, expressed concern at how countries had seemingly reduced their political commitment towards leprosy control and accorded it increasingly less priority. However, he appreciated the fact that the programme had mustered “excellent” partners. The Nippon Foundation provides funding to WHO. Drugs are being provided free of cost to all Member countries by WHO through donations from Novartis Foundation for Sustainable Development, and earlier by The Nippon Foundation. Without these contributions, the achievements made till date would not have been possible, he opined.

Mr Rene Staehli, President, International Federation of Anti-Leprosy Associations (ILEP), London, said the fight against leprosy over the past 25 years has been very successful. However, solving the problems that remain is a challenge. This includes sustaining the quality of leprosy control services, and ensuring equity and social justice for people suffering from leprosy.

Some innovative inputs are needed in the strategy, he added. "A world without leprosy" requires specific goals, one of which is to avoid nerve damage. MDT, provided free by Novartis Foundation for Sustainable Development, is a tool for leprosy control. A strategy is needed for those suffering from the consequences of leprosy. Strategies are also needed to keep leprosy on the agenda of national governments and ensure that people are not afraid or reluctant to seek treatment. New ideas, indicators and targets are needed to achieve these in the present environment of decreasing numbers of patients and thereby lesser priority accorded to leprosy.

**The fight
against leprosy
over the past
25 years has
been very
successful**





Since ancient times, the care of leprosy patients has been in the hands of what we understand to be nongovernmental organizations (NGOs). They continue to play a crucial part in leprosy control. NGOs do not have to respond to political pressure and are close to the people and their problems. Thus, they are important partners and key observers who are able to identify deficiencies and problems.

Mr Staehli added that ILEP members would be happy to share their expertise with their partners to secure a world without leprosy.

Dr York Lunau, representative of the Novartis Foundation for Sustainable Development in Basel, Switzerland, emphasized that while drug donation was important, it was meaningless without the other components of the leprosy programme. He said that the Novartis Foundation was proud and happy to be a part of the fight against leprosy. He quoted the CEO of Novartis Pharma, as saying that they “will continue efforts to reach out and help those afflicted with this disease until leprosy is finally eradicated.”

Dr Lunau reiterated Novartis Foundation’s commitment to providing MDT free of charge for as long as there is leprosy in the world.

Dr P.K. Gopal, President, International Association for Integration, Dignity and Economic Advancement (IDEA), India, explained that IDEA was a forum started and managed by people affected by leprosy. In recent years, IDEA has been collaborating with WHO. IDEA India has been networking with members of the 700 colonies for people affected by leprosy in India. Each state of India now has leprosy-affected people who lead programmes and initiatives for the development of persons affected by leprosy in their respective states.

Dr Gopal expressed happiness over the fact that the *Enhanced Strategy* lays more emphasis on the social aspects of leprosy control, taking into account the needs of the people affected by leprosy, such as gender issues, equity, social justice and human rights. These issues have been included as major challenges in the draft.

He thanked partners and donors for their help and looked forward to working together and taking partnerships to the field level.

Dr Marcos Virmond, President, International Leprosy Association (ILA), Bauru, Brazil, said the *Enhanced Strategy* will be a turning point in the control of leprosy. ILA is one of the oldest international scientific organizations devoted to congregating researchers and health personnel, and aimed to shed new light on unanswered questions. Today, drug resistance is one of the most challenging issues. ILA is very active in stimulating the production and dissemination of knowledge on leprosy, and has recently renewed its liaison as an NGO with WHO. ILA is fully committed to providing technical and political support, and assisting the global leprosy programme in every way to achieve a world without leprosy at the earliest, he reiterated.





Technical session



four

Case detection together with treatment with MDT formed the basis for leprosy control

Dr Samlee proposed the names of the office-bearers, which were seconded by the participants. Dr S.K. Noordeen was selected as the chairperson, Professor WCS Smith and Dr Maria Leide W. Oliveira as co-chairpersons, and Dr Francesca Gajete and Dr P. Krishnamurthy as rapporteurs.

4.1 Problem areas in case detection

Dr S.K. Noordeen made a presentation on the problem areas in case detection. Case detection together with treatment with MDT formed the basis for leprosy control. Case detection is a good proxy for incidence when operational factors are minimized and is the best indicator to measure progress towards reduction in disease burden. The number of cases detected should come down if antileprosy activities are implemented with sufficient coverage and sufficient intensity for a sufficiently long period. Maximal coverage of patients even with limited services is more important than inadequate coverage with excellent services.

Leprosy has a very uneven distribution. This is both a challenge and an opportunity. Progress towards reduction in disease burden is best measured through trends in case detection, but this has also been very uneven due to both epidemiological and operational factors.

4.2 Global target and indicators for monitoring and evaluation

Professor WCS Smith explained why targets and indicators for monitoring and evaluation are necessary. A good target would give a sense of direction in achieving something worthwhile.

The WHO Technical Advisory Group in its ninth report⁴ expressed the importance of the sustainability of leprosy control services at all levels. This was a key element of the *Global Strategy 2006 - 2010*. However, wide and sudden fluctuations were seen at the national and subnational levels in new case detection. Sustaining the capacity of and retaining trained staff is becoming difficult, as is access to quality care for patients.

⁴ WHO. *Report of the ninth meeting of the Technical Advisory Group on Leprosy Control*. Cairo, Egypt, 6-7 March, 2008 (SEA-GLP-2008.3).





The draft *Enhanced Global Strategy 2011 - 2015* has a number of indicators, such as those for monitoring progress, case detection, patient management and a target. Targets should have epidemiological and operational considerations. Targets provide accountability and enable programme planning. They are important for political commitment and securing resources. However, there is a potential for misuse as data may be manipulated. Thus, a target should be robust, and there should be means in place to check the validity of the target.

A key feature of a target is that it must have been obtained by consensus, and be owned by the community and populations concerned. In addition, a target should evidence-based, realistic, attainable, reasonable, measurable and valid, and linked to implementation. Targets are tools for influencing policy. Among the various options for choosing a target for leprosy, the target of reducing new cases with grade-2 disabilities (G2D) per 100 000 population is challenging. The rationale for choosing this target is as follows:

- It promotes early case detection. This reduces delay in diagnosis, and thus has an impact on disability and transmission.
- It addresses concerns about underdetection.
- It reduces stigma and discrimination.
- It reduces service and patient costs of disability care and rehabilitation.
- It promotes prevention of disability (POD) activities.
- It promotes collaboration.
- It is robust to measure.
- It is acceptable to partners and to those affected by leprosy.

Thus, it has been proposed to have not just a target but also a timescale (2011 - 2015), which will coincide with the timeframe of the UN Millennium Development Goals (MDGs). Programmes can make adjustments and pay more attention to early case detection and POD activities.

For leprosy, the vision, goal, target and indicators could be synopsized as follows:

Vision: A world without leprosy

Goal: Dramatically reduce the global burden of leprosy by 2015 in line with MDG 6.

Target: Linked to the MDGs and endorsed by NPMs, WHO, ILEP, The Nippon Foundation, ILA, Novartis Foundation for Sustainable Development and IDEA.

To reduce rate of new cases with grade-2 disabilities by at least 35% by 2015

Indicators:

- New case detection: the number of new cases, proportion G2D, proportion children, proportion multibacillary (MB), proportion female.
- Quality of patient management: treatment completion, proportion correct diagnosis, proportion treatment defaulters, number of relapses, proportion new disability.

4.3 Strategies for sustaining leprosy expertise in endemic countries

Dr P. Krishnamurthy made a presentation on behalf of Dr E. Declercq, who was unable to attend, and highlighted certain issues to complete the picture.

Maintaining expertise levels on leprosy in low-endemic countries is a challenge for several reasons. The majority of general health staff in low-endemic areas rarely come across cases of leprosy, which limits the expertise available. With the urban population growing exponentially, patients with leprosy increasingly consult dermatologists who may be outside the purview of the leprosy control programme. Thus, training in a reference centre could be provided to dermatologists in low-endemic countries. For the general health staff, knowledge of when and how to suspect leprosy and its primary management should be provided in the training curriculum.

On-the-job training should be provided to peripheral staff during supervision. Usually, supervision is done by programme staff with managerial duties, but opportunities should also be provided to clinical staff to supervise peripheral health workers as well improve their skills in certain areas. Training should be in accordance with the operational guidelines of national programmes, and should be adapted and limited to the tasks expected from each type of health worker. Various levels of reference facilities should also be maintained. These should be used to confirm diagnosis, manage complications and prevent disabilities among cases referred by the peripheral health units.



4.4 Stigma and discrimination: A challenge to disease control

Mr Jose Ramirez Jr. spoke about the continuing stigma and discrimination faced by people affected by leprosy. He offered some suggestions which could assist in lessening the degree of stigma.

Improving the quality of services: The use of “first responders” was suggested to assist affected persons overcome their emotional trauma and act as mentors. Such persons could be volunteers from both the genders who receive a certain level and type of training to serve as first responders. First responders could also impart the necessary clinical knowledge. Such an empowered group of service-providers can have a positive impact, leading to quality services.

Equity, social justice and human rights: Religious influence, institutional mindset, labels of self-stigma and lack of effective partnerships are four factors that must be addressed as they contribute to the resurrection and continuance of stigma and are a challenge to disease control.

An institutional mindset is the manner in which a person suffering from leprosy retains a “patient” label throughout the course of life, and even after complete treatment and total cure. This needs to change. A change in mindset is also needed among persons researching the stigma associated with leprosy. Researchers must avoid the label of “self-stigma” when dealing with the findings of their research.

Role of persons affected by leprosy: This involves the inclusion of persons affected by leprosy in partnerships with anti-leprosy organizations. They should be actively involved in formulating strategies and policy decisions on anti-leprosy activities.



A change in mindset is also needed among persons researching the stigma associated with leprosy.

4.5 Global drug resistance surveillance network: Current status and next steps

Dr M. Matsuoka presented an overview of the chemotherapy of leprosy and the development of resistance to various drugs over time.

There is a need to monitor the level of drug resistance since chemotherapy is currently the main tool for leprosy control. The development of drug resistance threatens the current control strategy. Though cases of resistance have been reported from several countries, data on the prevalence of resistance in the MDT era are not available or are too sparse to interpret the current magnitude of drug resistance in leprosy.

The WHO Global Leprosy Programme has launched sentinel surveillance to monitor the level of drug resistance in relapse cases. Brazil, China, Colombia, India, Myanmar, Philippines and Viet Nam have joined the network and sites from Africa have been requested to join.

Drug resistance to dapsone, rifampicin and the quinolones is being identified by looking at mutations in the binding sites of these drugs. Clofazimine and minocycline resistance has not yet been reported. Previously, the mouse footpad method was used to detect drug resistance, but it is time-consuming and tedious. The molecular biological method is preferred for the examination of drug resistance for a large number of samples.

4.6 Need for developing new drugs for leprosy chemotherapy

Professor Baohong Ji explained the need for developing new MDT regimens for MB leprosy. The present duration of treatment is still too long, but it is highly unlikely to be further shortened significantly without dramatically modifying the composition of the regimen. The current regimen for MB leprosy is not rifampicin resistance-proof. A safe and effective alternative regimen should be developed for patients with rifampicin resistance or those who cannot tolerate it.

The key decisive factor in determining the duration of chemotherapy is the sterilizing activity of treatment measured by the relapse rate after completion of treatment. New MDT regimens could be of two types: one, to simplify treatment and facilitate supervision of drug administration for rifampicin-susceptible patients; and the other to treat patients with rifampicin-resistant leprosy or those who cannot tolerate rifampicin.

Table 1: List of newer drugs with bactericidal activities against *M. leprae*

Drug	Class	Bactericidal activity in mice*	Bactericidal activity in human*	Unit cost
Pefloxacin	Fluroquinoione	++	++	Moderate
Ofloxacin		++	++	Moderate
Moxifloxacin		+++	+++	High
Clarithromycin	Macrolide	++	++	Moderate
Minocycline	Tetracycline	++	++	Moderate
Rifapentine	Rifamycin	+++	Not done	High
R207910	Diaryiquinolone	+++	Not done	Not commercially available
Linezolid	Oxazolidinone	+	Not done	High

* Based on the activity of (+) for dapsone and (+++) for rifampicin

Administering these newer drugs on a daily basis would be prohibitively expensive, but the costs are manageable if they are administered once monthly. Only five of the eight compounds listed in Table 1 have been tested in short-term human trials, mostly as monotherapy. Therefore, their sterilizing activity is not known, i.e. their ability to kill the few, slowly metabolizing organisms that survive the initial killing, which is the decisive factor for determining the duration of treatment. Newer regimens must consist of three components that act by different mechanisms to avoid the potential for unknown resistance to one of the ingredients.

Ideally, a fully supervised, once-monthly regimen is the best possible one that will not overburden health workers. To be a component of such a regimen, a compound must display definite bactericidal activity against *M. leprae* with a single dose of monotherapy and be reasonably well tolerated by patients.

A fully supervised, monthly regimen for rifampicin-susceptible MB patients could include rifapentin 900 mg (or rifampicin 600 mg), moxifloxacin 400 mg, and clarithromycin 1000 mg (or minocycline 200 mg) for 12 months. For rifampicin-resistant patients, the intensive phase could include moxifloxacin 400 mg, clofazimine 50 mg, clarithromycin 500 mg, and minocycline 100 mg daily supervised for six months. The continuation phase could comprise moxifloxacin 400 mg, clarithromycin 1000 mg, and minocycline 200 mg once monthly, supervised for an additional 18 months.

However, the efficacy and safety of these suggested regimens should be established through long-term, well-designed and controlled clinical trials.

There is an urgent need to accelerate the development of new MDT regimens by screening new compounds with powerful bactericidal activity against *M. leprae*, measuring the bactericidal activity against *M. leprae* in an animal model or in human, and identifying a reliable surrogate marker for measuring the sterilizing activity of treatment against *M. leprae*. To do this, research capacity needs to be strengthened as the expertise in major leprosy institutes is rapidly deteriorating. Without such expertise, chemotherapy research would be very difficult to revive.

4.7 Chemoprophylaxis with a single dose of rifampicin for household contacts

Dr J.H. Richardus commenced with the rationale for chemoprophylaxis. Chemoprophylaxis could help in reducing the incidence of leprosy as no primary prevention in the form of a specific vaccine is available as yet for leprosy. Chemoprophylaxis also helps to treat subclinical leprosy.

The risk groups for leprosy include contacts of leprosy patients, categorized as household, neighbours and other social contacts. In a control programme, high-risk groups for leprosy are potential targets for chemoprophylaxis.

The evidence for chemoprophylaxis with single-dose rifampicin comes from the *Chemoprophylaxis in the Prevention of Leprosy (COLEP)* study in Bangladesh (2001–2007). This study enrolled >21 000 patients who were contacts of 1037 paucibacillary (PB) and MB patients. Single-dose rifampicin was given at a dose of 300 - 600 mg to the contact after the second MDT dose to the index patient (six weeks). The study found an overall reduction of leprosy of 57% (overall number needed to treat was 265) at the end of two years. There was no further reduction in the incidence of leprosy after four years.

Further research is needed to develop: (i) practical diagnostic tools for detecting subclinical leprosy to guide chemoprophylactic treatment in (very) high-risk contacts; (ii) prophylactic treatment regimens needed for (very) high-risk contacts; and (iii) epidemiological tools (e.g. mathematical modelling) to evaluate the potential effect of chemoprophylactic interventions at the population level. Operational/health systems research is also needed for successful implementation of chemoprophylaxis at the individual and population levels under routine leprosy control programme conditions.





4.8 Sustaining the quality of clinical leprosy services

Dr Paul Saunderson discussed issues related to the quality of clinical leprosy services as mentioned in the *Enhanced Global Strategy* under the section "Improving the quality of leprosy services". Quality can be applied to every aspect of leprosy control. Indicators for assessing the quality of leprosy services are:

- Proportion of new cases verified as correctly diagnosed.
- Proportion of treatment defaulters.
- Number of relapses.
- Proportion of patients who develop new/additional disability during MDT.

Of these, the first and fourth are the most important.

Section 1.5 of the *Operational Guidelines* describes what constitutes quality services and what these depend on. Quality services are accessible, patient-centred and competent in each aspect of patient management. Such services depend on appropriate training, regular supervision, monitoring of key indicators and motivated staff.

Indicators have two main functions:

- To indicate progress towards objectives (important for advocacy).
- To indicate problems which may prevent the achievement of objectives (forms the basis for improving the programme).

Indicators of quality are of three types:

- *Proxy indicators* – single-item measurements that give clues about overall quality, e.g. treatment completion rate.
- *Process indicators* – measure activities that promote quality, e.g. indicators of training and supervision activities.
- *Direct indicators of quality* - e.g. asking patients about their experience.

Proxy indicators mentioned in the *Global Strategy*:

- Treatment completion rate.
- Proportion of disability among new cases.
- Proportion of new cases correctly diagnosed.

Process indicators include:

- The proportion of training sessions that took place among those initially planned.
- The proportion of supervision visits that took place among those initially planned.
- The existence of a checklist (plus a schedule) for supervision.

A problem with using training as an indicator is that it is highly variable and on-the-job training is hard to measure.

Direct indicators of quality

- Proportion of patients who develop new/additional disability during MDT.
- Proportion of patients whose disability status improves during MDT.

The problem with these is that data on impairment and disability are not reliable or complete. Assessing patient contentment by various means could be another way of measuring the quality of services.



4.9 Investing in prevention of disabilities and rehabilitation

Dr Hugh Cross explained the importance of POD and rehabilitation for the *Enhanced Global Strategy*. Improving the quality of leprosy services stimulates confidence in leprosy control. However, it is of greater importance to relieve persons suffering from leprosy of the burden of stigma and discrimination due to disabilities, as this is the key issue for patients.

While discussing the objectives of the *Enhanced Global Strategy*, the current situation and the ability to implement the following are suggested:

- *Early recognition and correct management of leprosy:* This is universally recognized as the basis of good leprosy control and, by default, POD. However, MDT per se does not prevent disability.
- *Early recognition and intervention to prevent impairments due to leprosy reactions:* Treatment of reactions during MDT is widely accepted as a component of the general treatment regimen, but this is not so for people who have completed MDT.
- *Continuous, comprehensive interventions to prevent deterioration of existing impairments, including self-care, protective aids and reconstructive surgery:* Very few countries are able to address this issue.
- *Mobilization of communities, civil society, government and private sectors to promote inclusion and integration of those with disabilities:*

Leprosy control programmes may not be able to manage interventions for POD beyond those required through the active phase of the disease, or implement community-based rehabilitation (CBR) approaches.

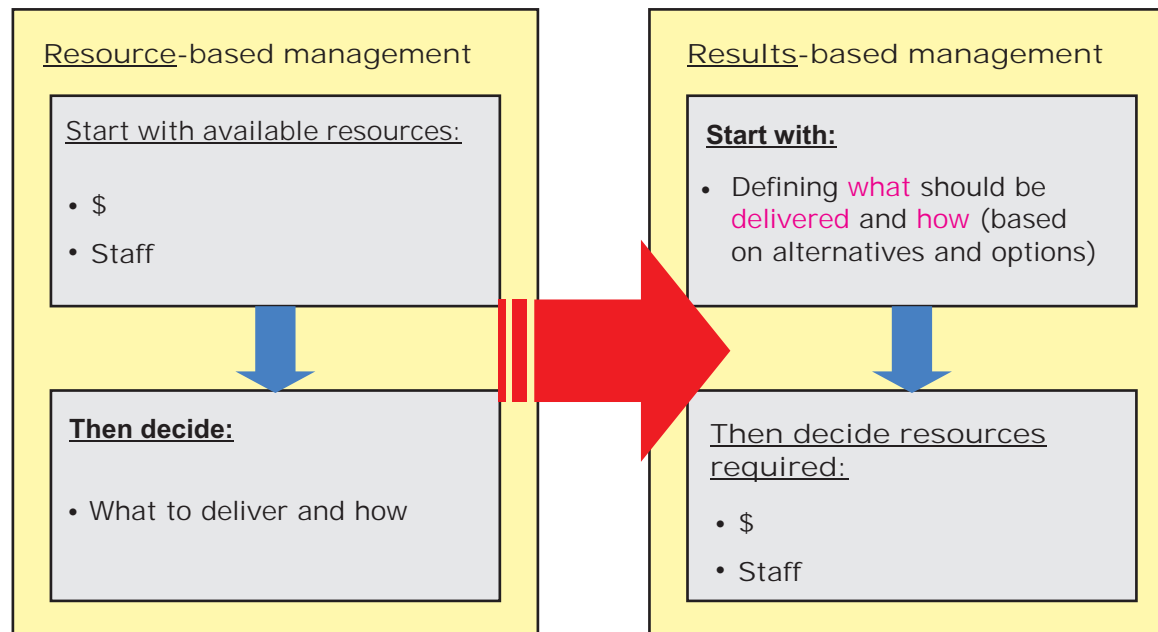


Another reason why we should engage in POD is the United Nations Convention on the Rights of Persons with Disabilities (UNCRPD), which has been signed by 33 of the 44 countries represented in this meeting.

4.10 Results-based management framework

A presentation was made by Dr Mark Brooks, Programme Planning and Coordination, WHO/SEARO on a results-based management framework versus a resources-based management framework.

Figure 1: Results-based versus resource-based management



A results-based framework is a management process with three components:

- Programme formulation that revolves around a set of predefined *objectives* and *expected results*;
- Expected results that form the basis of *resource requirement* and justify resource allocation;
- Actual achievements that are measured by *performance indicators*. This involves using indicators to support programme management by (i) establishing the *baseline* (to determine the situation at the beginning of planning period); (ii) setting a *target* (commitment); and (iii) measuring *achievement* (actual result).

These indicators can be used for monitoring as well as evaluation. The chosen indicator(s) should be:

- Simple: consensus on meaning; easy to interpret, assess and use
- Practical: timely data collection, can be collected at reasonable cost
- Useful: for decision-making and learning for better planning and implementation.





Review of the drafts



five

5.1 Discussion on the draft *Enhanced Global Strategy for Further Reducing the Disease Burden Due to Leprosy: 2011-2015*

Dr WCS Smith was invited to chair this session. The chairperson invited general comments on the *Enhanced Global Strategy*. This was followed by a discussion on the new elements in the *Strategy*. Participants were invited to focus on the two new elements in the Executive Summary:

- Using new cases with G2D as the key indicator to monitor progress, in addition to the current list of indicators.
- Exploring the use of chemoprophylaxis in situations where there is a high proportion of new cases among contacts.

The Chair invited all NPMs to present their views individually. All the NPMs unanimously agreed with the proposal to set a target, which is based on reducing the rate of new cases with G2D per 100 000 population by one third compared with the baseline at the end of 2010. The discussion centred around the extent by percentage to which this is achievable in a country. The majority of NPMs felt that a target of one-third reduction (35%) would be realistic, but those countries that could aspire for 50% reduction should do so.

The remaining issues in the Executive Summary were taken up for discussion one by one. Some additions/refinements were suggested by the participants. The *Enhanced Global Strategy* was unanimously accepted by all participants after the suggested revisions were incorporated.

The *Enhanced Global Strategy for Further Reducing the Disease Burden Due to Leprosy: 2011 – 2015* seeks to enhance the following elements:

- Sustaining political commitment at the national and local government levels in all endemic countries.
- Strengthening routine and referral services within the integrated health systems in all endemic countries.

- Using as a target the rate of new cases with G2D per 100 000 population as the key target and indicator to monitor progress, in addition to the current list of indicators.
- Implementing innovative approaches to case-finding in order to reduce delay in diagnosis and occurrence of G2D among new cases, including special efforts to improve control activities for populations living in difficult-to-access and suburban areas.
- Improving the quality of clinical services for the diagnosis and management of acute and chronic complications, including POD/impairments and provision of rehabilitation services through a well-organized referral system.
- Supporting all initiatives to promote CBR with special attention to activities aimed at reducing stigma and discrimination against persons affected by leprosy and their families.
- Ensuring the supply of drugs for MDT free of cost through effective distribution systems in all endemic countries.
- Establishing and maintaining a surveillance system to prevent and limit the development and transmission of resistance to antileprosy drugs.
- Promoting the development of more effective drugs/regimens to treat leprosy and its complications.
- Developing sustainable training strategies at global and national levels to ensure availability of leprosy expertise in all endemic countries.
- Fostering supportive working arrangements with partners at all levels including the involvement of people affected by leprosy in leprosy control activities.

5.2 Discussion on the draft: *Updated Operational Guidelines: 2011-2015*

The new sections were discussed and a few changes suggested, which would be carried out by the drafting group. The *Updated Operational Guidelines* were unanimously approved in principle by all participants.



Closing session



six

Chair: Dr Poonam Khetrpal Singh, Deputy Regional Director, WHO/SEARO

Mr Yohei Sasakawa, Chairman, The Nippon Foundation and WHO Goodwill Ambassador for Leprosy, greeted the participants and appreciated their work in achieving expert consensus on the new strategy. He said that the common vision of all those present was a world without leprosy.

Countries have different public health priorities and considerable efforts are needed to ensure their commitment to tackling leprosy, including the stigma attached to it and the social discrimination it breeds. Patients with leprosy have had to endure numerous human rights violations and discrimination over the centuries.

With the advent of MDT, leprosy is now curable and isolation of leprosy patients is a thing of the past. However, lingering social prejudice still discriminates against people affected by leprosy. This prejudice is manifest in many cultures. People diagnosed with leprosy and their families still find it difficult to secure education and employment of their choice or commensurate their ability, and to get married. Therefore, WHO deserves commendation for incorporating social issues in a large measure in its new strategy, and for taking the views of people affected by leprosy into account.

Mr Sasakawa likened leprosy to a motorcycle. He said that the front wheel represents the fight against leprosy and the back wheel the fight against discrimination. Both wheels must be of the same size and properly balanced for the motorcycle to run smoothly. Only when both medical and social issues are addressed together can we move towards a leprosy-free world, he said.



As the WHO Goodwill Ambassador, he envisaged twin roles for himself. The first is to spread three messages: that leprosy is curable, that treatment is available free of cost worldwide, and that social discrimination has no place in the fight against leprosy. The other role is to urge political leaders to take leprosy seriously. He urged participants to keep the motorcycle moving in the right direction till the vision of a leprosy-free world is realized.

Responses from WHO regions

The meeting invited representatives from among the NPMs of five WHO regions (AFRO, AMRO, EMRO, SEARO and WPRO) to make statements and endorse the *Enhanced Global Strategy*.

African Region: Dr Charles Nsom Mba (Cameroon)

For the African Region, maintaining political interest at the desired levels is an onerous task, despite the many successes. National Programme Managers of AFRO extended their support to the *Enhanced Global Strategy* and the *Operational Guidelines*, and emphasized that they were committed to implementing these. They welcomed the addition of new indicators. They would like to maintain a national training centre and hold a regional-level meeting with the widest possible representation once every year.

With the limited resources available in their countries, AFRO recognized the role played by NGOs and other partners. They would also involve people affected by leprosy in their planning. They requested WHO and partners to continue support, especially for capacity building, monitoring and evaluation, and implementation.





American Region: Dr Renato Gusmao (Regional Adviser Leprosy)

Leprosy in the Americas is going through an enormous change. Now people affected by leprosy are integrated into society, but this has been a long and arduous process. Progress has been steady in the Region and new ideas are being gradually incorporated into country workplans.

The Region would implement the revised document and resolutions adopted at the meeting, and will push towards further reducing the disease burden in all the Member countries.

Eastern Mediterranean Region: Dr (Ms) Mahshid Nasehi (Iran)

EMRO felt that while it would do its best to implement the *Enhanced Global Strategy*, they would need some help as leprosy was not a priority for their governments and political and financial support as well as human resources were inadequate. Considerable effort has to be put in to involve health staff, most of whom have little idea about leprosy.

Several countries of the Region are in the midst of conflict, and they would need much greater attention.

South-East Asia Region: Dr P.L. Joshi (India)

Though there has been a drastic reduction in the number of leprosy cases, a significant number of cases are still being reported. It is a challenge to place leprosy high on the health agenda of most Member countries as there has been a gradual decline in the interest evinced by decision-makers and politicians. Advocacy would be necessary for allocation of adequate funds.

The meeting has helped to revisit existing interventions and indicators, as well as added some more. This would lend further impetus to the programme. Country-specific strategies could now be initiated. Annual meetings of NPMs and stakeholders in SEA Region countries would help to update Member States on the work being carried out in the Region and share experiences.

Western Pacific Region: Professor Zhang Guocheng (China)

The goal of a leprosy-free world is some distance away but it is possible to see the day when cases with G2D will reduce by 35% to 50%. Countries would adapt the *Enhanced Global Strategy* to their own situation. Investing in research to develop better tools for chemoprophylaxis and immunoprophylaxis would greatly help in preventing people at high risk from contracting the disease.

For NPMs the aim is to bring maximum good to the people, and they have unanimously endorsed the Strategy. In their own countries NPMs would adapt the Strategy to their own situations and strive to reduce the disease burden further.

Dr Poonam Khetrpal Singh, Deputy Regional Director, WHO/SEARO, thanked all participants and NPMs for building consensus on the *Strategy* for the next five years. She also thanked all partners (Nippon Foundation, Sasakawa Memorial Health Foundation, Novartis, IDEA, ILEP, ILA), NPMs and the WHO Leprosy Programme for their active participation. She expressed happiness over the fact that WHO was moving towards reducing the burden of disability in leprosy.

The problems of drug resistance, need for advocacy and rehabilitation, the importance of quality of services and sustainability are issues that remain to be addressed, she said. There is a need to consider not just medical but also psychosocial issues. It is encouraging to note that all partners and participating NPMs have unanimously endorsed the *Strategy*, which will be an important tool in countries where leprosy is still endemic. This *Strategy* will help to sustain the efforts being made and renew the commitment to reduce the physical, medical and social consequences of leprosy.



Collaboration between national programmes, national and international partners, and WHO was renewed at this meeting, she said. She emphasized that despite the tremendous reduction in the burden of leprosy, we cannot afford to be complacent. In the coming years, all partners should work together to strengthen efforts to implement this *Enhanced Strategy*.

Dr V Pannikar, Team Leader, Global Leprosy Programme, quoted the Serenity Prayer by Reinhold Niebuhr:

“God grant me the serenity
to accept the things I cannot change;
courage to change the things I can;
and wisdom to know the difference.”

Dr Pannikar thanked all participants for taking the time to discuss and endorse the *Strategy*. He also thanked members of his team for their tireless efforts towards making the meeting a success.

APPENDIX-1

Programme

Monday, 20 April 2009

09:00 – 10:00	Opening session
10:00 – 10:30	Chairperson: Dr S.K. Noordeen Co-chairpersons: Professor WCS Smith and Professor Maria Leide W. Oliveira Rapporteurs: Dr P. Krishnamurthy and Dr Francesca Gajete
10:30 – 11:00	Problem areas in case detection (<i>Dr S.K. Noordeen</i>) <i>Discussion</i>
11:00 – 11:30	Global target and indicators for monitoring and evaluation (Professor WCS Smith) <i>Discussion</i>
11:30 – 12:00	Strategies for sustaining leprosy expertise in endemic countries: What should be done? (<i>Dr E. Declercq & Dr P. Krishnamurthy</i>) <i>Discussion</i>
12:00 – 12:30	Stigma and discrimination: A challenge to disease control (<i>Mr Jose Ramirez Jr</i>)
14:00 – 14:30	Global drug resistance surveillance network: Current status and next steps (<i>Dr M. Matsuoka</i>) <i>Discussion</i>
14:30 – 15:00	Need for developing new drugs for leprosy chemotherapy (Professor Baohong Ji) <i>Discussion</i>

15:00 – 15:30	Chemoprophylaxis with single dose rifampicin for household contacts: Pros and cons <i>(Dr J.H. Richardus)</i> <i>Discussion</i>
16:00 – 16:30	Sustaining high quality of leprosy services <i>(Dr P. Saunderson)</i> <i>Discussion</i>
16:30 – 17:00	Investing in prevention of disabilities and rehabilitation <i>(Dr Hugh Cross)</i> <i>Discussion</i>
17:00 – 17:30	Briefing on the next day's plan of work <i>(Dr Myo Thet Htoon)</i>

Tuesday, 21 April 2009

Review of the draft “*Enhanced Global Strategy for Further Reducing the Disease Burden Due to Leprosy: 2011–2015*”

Chairperson: Dr S.K. Noordeen
Co-chairperson: Professor WCS Smith and Dr Maria Leide W. Oliveira
Rapporteurs: Dr P. Krishnamurthy and Dr Francesca Gajete

09:00–10:30	Session 1: <i>Chapters 1, 2 and 3</i>
11:00–12:30	Session 2: <i>Chapter 4</i>
14:00–15:30	Session 3: <i>Chapter 5</i>
16:00–17:30	Session 4: <i>Chapter 6</i>

Wednesday 22 April 2009

Review of the draft "*Updated Operational Guidelines: 2011 – 2015*"

Chairperson: Dr S.K. Noordeen

Co-chairperson: Professor WCS Smith and Dr Maria Leide W. Oliveira

Rapporteurs: Dr P. Krishnamurthy and Dr Francesca Gajete

09:00–10:30	Session 1: <i>Chapters 1, 2 and 3</i>
10:30–11:30	Session 2: <i>Chapters 4–5</i>
11:30–12:30	Session 3: <i>Chapters 6–7</i>
14:00–14:45	Session 4: <i>Chapter 8</i>
14:45–15:30	Session 5: <i>Chapter 9</i>
16:00–16:30	Conclusion and recommendations
16:30–17:00	Closing session

APPENDIX-2

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The Global Programme Managers' Meeting on Leprosy Control was held in the South-East Asia Regional Office of the World Health Organization on 20-22 April 2009. The objective of the meeting was “to develop the Enhanced Global Strategy for 2011-2015 and the updated Operational Guidelines”. The meeting was attended by 120 participants including national programme managers from 45 countries representing all Regions of WHO (except Europe), experts from various fields such as social scientists, rehabilitation officials and persons affected by leprosy, and representatives from major partners such as The Nippon Foundation (TNF), Sasakawa Memorial Health Foundation (SMHF), Novartis Foundation for Sustainable Development, International Federation of Anti-Leprosy Association (ILEP), International Leprosy Association (ILA) and the International Association for Integration, Dignity and Economic Advancement (IDEA).

The highlights of the Enhanced Strategy are to: strengthen integration to sustain leprosy control activities as the disease burden declines further; improve quality of services which includes prevention of disabilities, rehabilitation and reducing stigma and discrimination; strengthen referral services in an integrated approach to support the primary health care system; monitor progress of the programme globally by using new cases with grade-2 disabilities rate per 100000 population as a target, and to reduce it by 35% in 2015 from the baseline of 2010; improve capacity building at the international, national and peripheral level so as to enhance expertise level, in countries dealing with leprosy; closely monitor the leprosy situation in countries to ensure that the burden of the disease continues to decline further; carry out drug resistance surveillance to monitor the situation, and promote research with the aim to develop new drugs and explore the use of chemoprophylaxis.

The Enhanced Global Strategy 2011-2015 and the Updated Operational Guidelines were endorsed by all participants.



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