

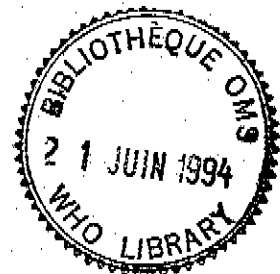
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# GLOBAL STRATEGY FOR THE ELIMINATION OF LEPROSY AS A PUBLIC HEALTH PROBLEM

*Document prepared by the Leprosy Unit, World Health Organization, Geneva  
1994*



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## EXECUTIVE SUMMARY

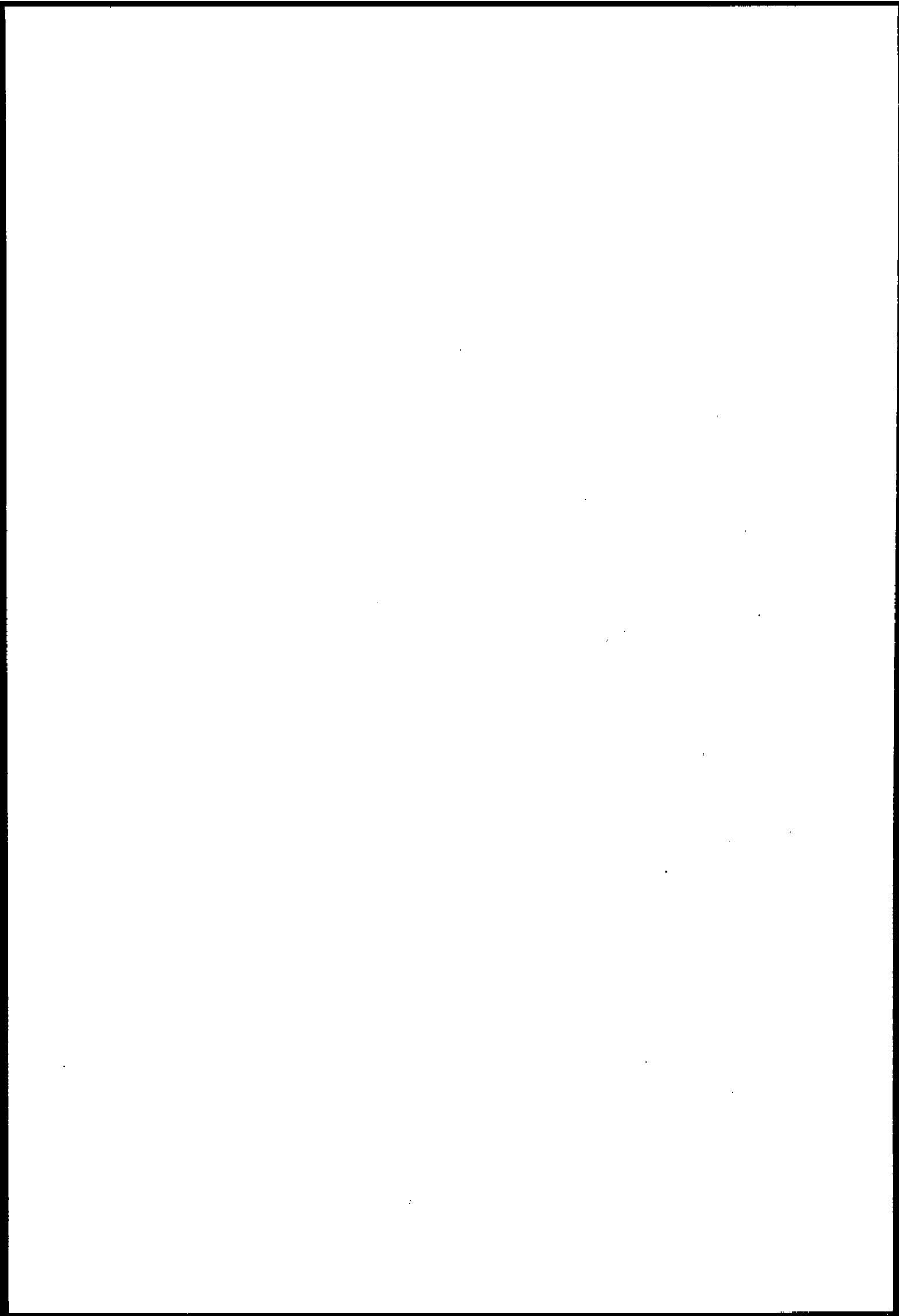
### Global Strategy for the Elimination of Leprosy as a Public Health Problem

Leprosy is still a dreaded disease even in countries where it has long ceased to be endemic. There are some 2.4 million (1994) sufferers and 79 countries with significant numbers of cases. Besides the permanent progressive disability it causes, the grim social consequences that infection has for its victims make it a unique public health problem. Until the early 1980s, efforts to control the disease by treating patients with dapsone proved ineffective because treatment had to continue for a long period and because of the occurrence of drug resistance. This frustrating situation dramatically changed following the introduction of the WHO-recommended standard multidrug therapy (MDT).

MDT has shown itself effective in combating the disease. Experiences based on many thousands of patients treated with MDT over the past decade indicate extremely low relapse rates (cumulative relapse rates around 1%). By the end of 1993, some 5.6 million patients had been cured, and the global cumulative MDT coverage of registered patients had reached 89%. The number of registered cases has fallen from 5.4 million in 1985 to 1.7 million in 1994. The significant progress made in leprosy control enabled the World Health Assembly in 1991 to set the goal of eliminating leprosy as a public health problem by the year 2000. Provided leprosy control through MDT is further intensified in the coming years, there is every reason to believe that this goal - specifically, reducing the prevalence to less than one case per 10 000 population in endemic areas - can be reached.

This proposed global strategy calls for increased resource allocation and priority setting at global, regional and country levels, while underlining that public awareness at the community level will be vital to ensure early detection of cases. One important epidemiological factor is that this is a very unevenly distributed disease; 65% of the problem is confined to only five countries and 92% concerns just 25 countries. The elimination strategy aims to stratify the situation at different levels, identify priority areas for action, set intermediate targets, and monitor them. The size and intensity of the problem and the accessibility of leprosy control services, including MDT, will determine the level of each stratum. Political commitment as well as mobilization and coordination of resources, including those from donor NGOs, will be essential prerequisites for the elimination strategy. The core activities will continue to focus on implementing MDT, together with intensive case-detection. Programme monitoring and evaluation and epidemiological surveillance will also be important elements of the strategy. The WHO Working Group on Leprosy Control will continue to monitor the progress towards global elimination of the disease.

The elimination strategy envisages identifying and treating with MDT a total of about 5 million cases from 1994 to the year 2000. The cost of dealing with these cases has been estimated at US\$ 420 million, including US\$ 150 million for the drugs. It will be possible to mobilize these resources over the next five to seven years, provided the need for eliminating leprosy as a public health problem is fully recognized, and provided all interested agencies actively work together in a spirit of partnership. For the goal of elimination to be attained, it is essential for everyone to recognize and seize this opportunity to rid humanity of a disease that has plagued it for millennia.

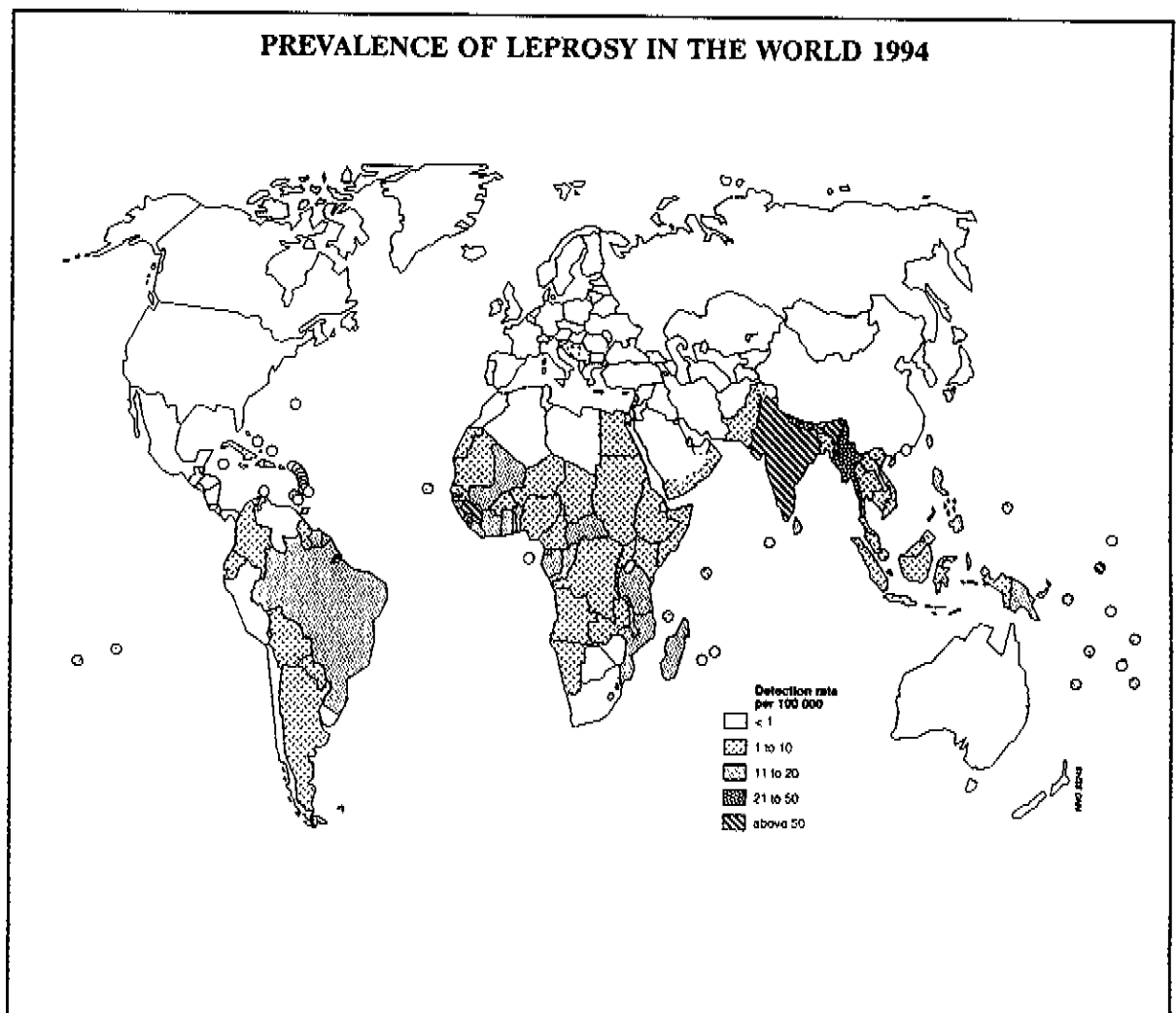


## 1. INTRODUCTION

### 1.1 The global burden of leprosy

Leprosy has struck fear into human beings for thousands of years, and was well recognized in the oldest civilizations of China, Egypt and India. A cumulative total for the number of human beings who, over the millennia, have suffered its 20- or 30-year course of incurable disfigurement and physical disability can never be calculated. But for the estimated global total of 2.4 million sufferers living today, relief is in sight and 1.7 million of them are registered for treatment, of whom half receive the highly successful multidrug therapy (MDT).

The intense social stigma attached to leprosy sufferers and the social discrimination against them should logically begin to weaken as the total elimination of the disease becomes ever more feasible. Nevertheless there is a long way to go. There are 79 countries in the world with significant numbers of cases and 600 000 new ones are detected annually. Around 2400 million people live in countries where the prevalence of leprosy is more than one in 10 000. In addition, between two and three million people are visibly and irreversibly disabled; their problems will persist long after the bacteria within their bodies have been killed.



## 1.2 Failure and success

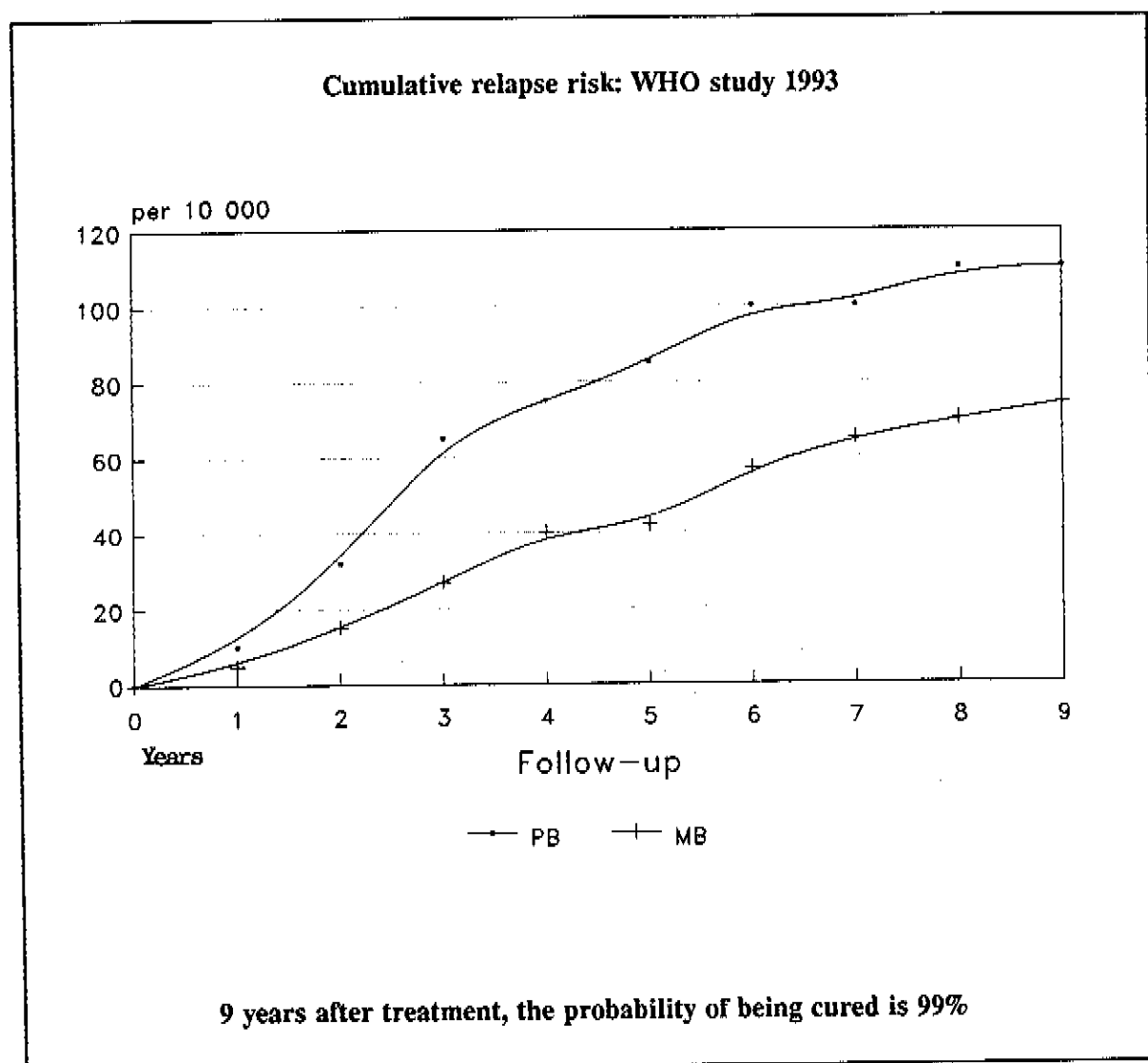
Throughout most of recorded history, the only way society found to deal with leprosy was by separating the sufferer from the rest of his fellow men. This enforced isolation of the leprosy patient added to the dreadful reputation of the disease. As a method it was understandable but, for a variety of reasons, not very effective. Nevertheless, since the efforts in the 1870s of the Norwegian scientist G.H.A. Hansen, who identified the bacterium which caused leprosy and named it *Mycobacterium leprae*, considerable clinical and scientific knowledge about the disease has been amassed.

The era of chemotherapy of leprosy started in the 1950s when the drug dapsona was found to be effective against the bacterium in the human body. The routine treatment of patients in their homes became possible and this encouraged many countries sufficiently to embark on organized programmes of case-detection and health education.

Resistance to the drug arose, however, and leprosy became yet another example of Darwinian principles of natural selection at work. In any population of millions of bacteria, only a very few might be naturally resistant but - when the rest were killed off by dapsona - a competitive advantage was conferred on them and they were able to proliferate. Eventually, leprosy bacteria that were resistant to dapsona became widespread and treatment became less and less successful. There was poor patient response to the length and discipline of treatment, and control of the disease became generally ineffective.

This period of failure and frustration came to an end with the introduction in 1981 of treatment by combinations of drugs given at the same time, known as multidrug therapy (MDT). In such a situation the likelihood of a bacterium in a population being resistant to all three drugs is exceedingly small, perhaps one in a trillion. This theoretical prediction has been borne out in practice.

The leprosy patient can be assured that the annual risk of relapse is less than one in a thousand after nine years.



The first recommendations of standard regimens of MDT made by the WHO Study Group on Chemotherapy in 1981 thus inaugurated an era of optimism. The recommendations received enthusiastic support from leprosy-endemic countries, international and nongovernmental organizations (NGOs), WHO regional committees, donor agencies and professional bodies alike.

### 1.3 A unique opportunity in human history

We have never come so close to seeing leprosy dispelled from the planet. This ancient disease which still afflicts millions of people physically and socially can now be vanquished. In 1991, the Member States of WHO, through a resolution in the World Health Assembly, declared their intention to eliminate leprosy as a public health problem, in view of the very encouraging results of 10 years of intensive use of MDT. That same year, a WHO Working Group on Leprosy Control (LWG) outlined the strategy for elimination of the disease. In 1991 and 1992, the most affected countries and the WHO Regional Offices discussed the practicalities of this strategy and prepared national and regional plans. In July 1993, the LWG and the main NGOs, especially members of the International Federation of Anti-Leprosy Associations (ILEP), met to assess the progress that had been made, adopt a global strategy and bring the requisite resources into play.

But how can this be brought about? Is it really possible to do away with a disease that has afflicted humanity since time immemorial? It is no simple matter, since leprosy is an insidious, slowly-developing disease whose transmission path is not well known and which flourishes mainly in the 'poverty belt' of the globe. It once affected every continent and it has etched a terrifying image in history and human memory - of mutilation, rejection and exclusion from society. Leprosy has always and everywhere been regarded as a special disease. How, then, can this silent and crippling enemy be destroyed?

What seemed impossible 10 years ago became a reality with the appearance and wide distribution of a simple and relatively inexpensive course of treatment - MDT; it is well tolerated and accepted by patients, and it is highly effective. It rapidly cures patients, interrupts transmission of the disease and therefore makes its elimination a possibility. And yet, for this to be achieved, the vast majority of existing patients must be diagnosed and treated, and new cases appearing must be given immediate treatment. Furthermore, since the disease has a relatively long incubation period, this strategy must be kept up for a number of years; we have to keep up a "multidrug pressure" on the reservoir of bacilli if we are to have a chance of destroying it.

It is because of this opportunity that leprosy must be given high priority in a world that faces many intractable problems. All the work and resources put into this effort will bear fruit in the short and long term. Over and above the satisfaction of seeing leprosy disappear, communities will no longer need to look after people who are handicapped, usually for life. The cost of the leprosy elimination programme will quickly be offset by the number of handicaps forestalled, and by the saving of many people from moral and social ostracism.

## 2. PROGRESS TOWARDS ELIMINATION

The leprosy situation has improved considerably since the resolution adopted in May 1991 by the World Health Assembly (WHA44.9) on elimination of leprosy as a public health problem - that is, reducing the prevalence to less than one case per 10 000 population. This improvement is a result of increased multidrug therapy (MDT) coverage in most of the endemic countries, better data reporting, and more realistic estimates.

The introduction and expansion of MDT has dramatically changed the leprosy profile in all endemic countries. Table 1 shows the number of cases, the prevalence rate and the proportion of patients being treated with MDT in each of WHO's six Regions in 1994. The global total of cases registered for treatment stands at 1.7 million patients.

### 2.1 Progress with MDT coverage

The proportion of registered cases treated with MDT at the time of the current report is over 54%, and the cumulative MDT coverage since this strategy was introduced has reached 89%. Some 5.6 million cases have been cured since 1985. Although it is becoming more difficult to increase, or even to maintain, the coverage in some countries, these figures show that an increasing number of patients have access to diagnosis and are able to receive effective treatment for leprosy.

### 2.2 Situation in the 25 most endemic countries

Leprosy remains a public health problem in 79 countries or areas, but 25 countries contribute nearly 92% of the leprosy cases in the world. For planning purposes, the ranking of countries is based on the absolute number of estimated cases. The ranking for registered cases or prevalence rate may vary for some countries. Table 2 shows the number of registered cases

for the top 25 countries, and their achievements with MDT, based on registered and estimated number of cases.

**Table 1** Prevalence of registered cases and coverage with Multidrug Therapy by WHO region

WHO REGION (Number of endemic countries)	Registered Cases	Prevalence per 10 000 <sup>(a)</sup>	MDT Coverage %	Completed MDT	Cumulative MDT Coverage %
Africa (34)	155 536	2.96	65.02	257 757	86.84
Americas (16)	276 498	3.71	38.13	55 251	48.44
Eastern Mediteranean (3)	22 594	0.55	91.88	29 907	96.51
South-East Asia (9)	1 173 630	8.57	53.89	5 123 958	91.41
Western Pacific (17)	57 972	0.37	89.72	132 332	96.87
Europe (0)	4 927	0.06	47.49	2 134	63.36
<b>Total (79)</b>	<b>1 691 157</b>	<b>3.10</b>	<b>54.06</b>	<b>5 601 339</b>	<b>89.35</b>

**Table 2** Magnitude of the leprosy problem in the top 25 endemic countries

Countries and Areas	Registered Cases	Prevalence per 10 000 <sup>(a)</sup>	Patients on MDT	MDT Coverage %	Completed MDT	Cumulative MDT Coverage %
India	995 285	11.34	516 413	51.20	4 557 126	91.16
Brazil	223 539	14.30	72 694	32.52	23 008	38.82
Bangladesh <sup>(b)</sup>	19 932	1.63	13 007	65.26	35 618	87.53
Indonesia	70 961	3.71	45 831	64.59	77 933	83.12
Myanmar	56 410	12.98	31 646	56.10	101 998	84.37
Nigeria	36 907	4.17	22 473	60.89	2 251	63.14
Philippines	15 317	2.34	14 751	96.30	28 491	98.71
Iran <sup>(b)</sup>	2 627	0.46	2 627	100.00		
Nepal	21 702	10.81	16 426	75.69	25 137	88.74
Sudan <sup>(b)</sup>	4 579	1.71	4 579	100.00	2 478	
Zaire	8 190	2.16	5 460	66.67	41 957	94.56
Ethiopia	15 673	3.00	12 059	76.94	50 578	94.54
Mozambique	12 838	7.77	5 413	42.16	533	44.47
Guinea	6 942	11.36	6 942	100.00	18 366	100.00
Colombia	15 930	4.65	7 449	46.76	1 668	51.81
Côte d'Ivoire	3 762	2.90	3 602	95.75	16 163	99.20
Vict Nam	9 449	1.36	7 423	78.56	23 284	93.81
Mali	8 000	8.15	4 800	60.00	3 279	71.63
Madagascar <sup>(b)</sup>	5 369	4.19	5 369	100.00	9 118	100.00
Chad	6 952	11.64	761	10.95	2 472	34.31
Mexico	8 938	0.97	6 187	69.22	4 417	79.40
Cambodia	1 627	1.88	1 627	100.00	3 152	100.00
Niger	6 563	7.96	1 690	25.75	1 662	40.75
Thailand	6 819	1.19	6 667	97.77	36 054	99.65
Egypt	3 338	0.61	3 338	100.00	16 024	100.00
<b>Total</b>	<b>1 567 649</b>	<b>7.33</b>	<b>819 234</b>	<b>52.26</b>	<b>5 348 737</b>	<b>89.18</b>

<sup>(a)</sup> using the 1993 mid-year population data from Demographic Data for Health Situation Assessment and Projections (WHO/HIS/GSP/93.2)

<sup>(b)</sup> incomplete information based on partial review of registered cases

### 3. STRATEGY FOR GLOBAL ELIMINATION AND ACTIVITIES AT COUNTRY LEVEL

Elimination aims at reducing prevalence below one case per 10 000 population. Thus a major focus, at least in the early years, is to reach all prevalent cases with MDT and to cure them. By continuously reducing the source of infection, it is expected that transmission of the disease will be significantly reduced over a period of time. It should be emphasized, however, that - even when this elimination goal is attained - there will still be significant numbers of cases of leprosy, and people with severe psychological, economic and social problems caused by leprosy who will need continued assistance.

#### WHA Resolution on the Elimination of Leprosy

WHO declares its commitment to continuing to promote the use of all control measures including multidrug therapy together with case-finding in order to attain the global elimination of leprosy as a public health problem by the year 2000. Elimination is defined as the reduction of prevalence to a level below one case per 10 000 population.

A global strategy is essential if the envisaged goal is to be achieved. Its time-limited nature warrants constant review of the progress being made and the application of flexible approaches, particularly in areas where special problems are faced.

Leprosy is a disease with a very uneven distribution among and within countries. The development of health services and their capacity to implement disease control vary widely in the different leprosy-endemic countries. The elimination strategy will have to take into account such variations and must be capable of adaptation to suit specific needs.

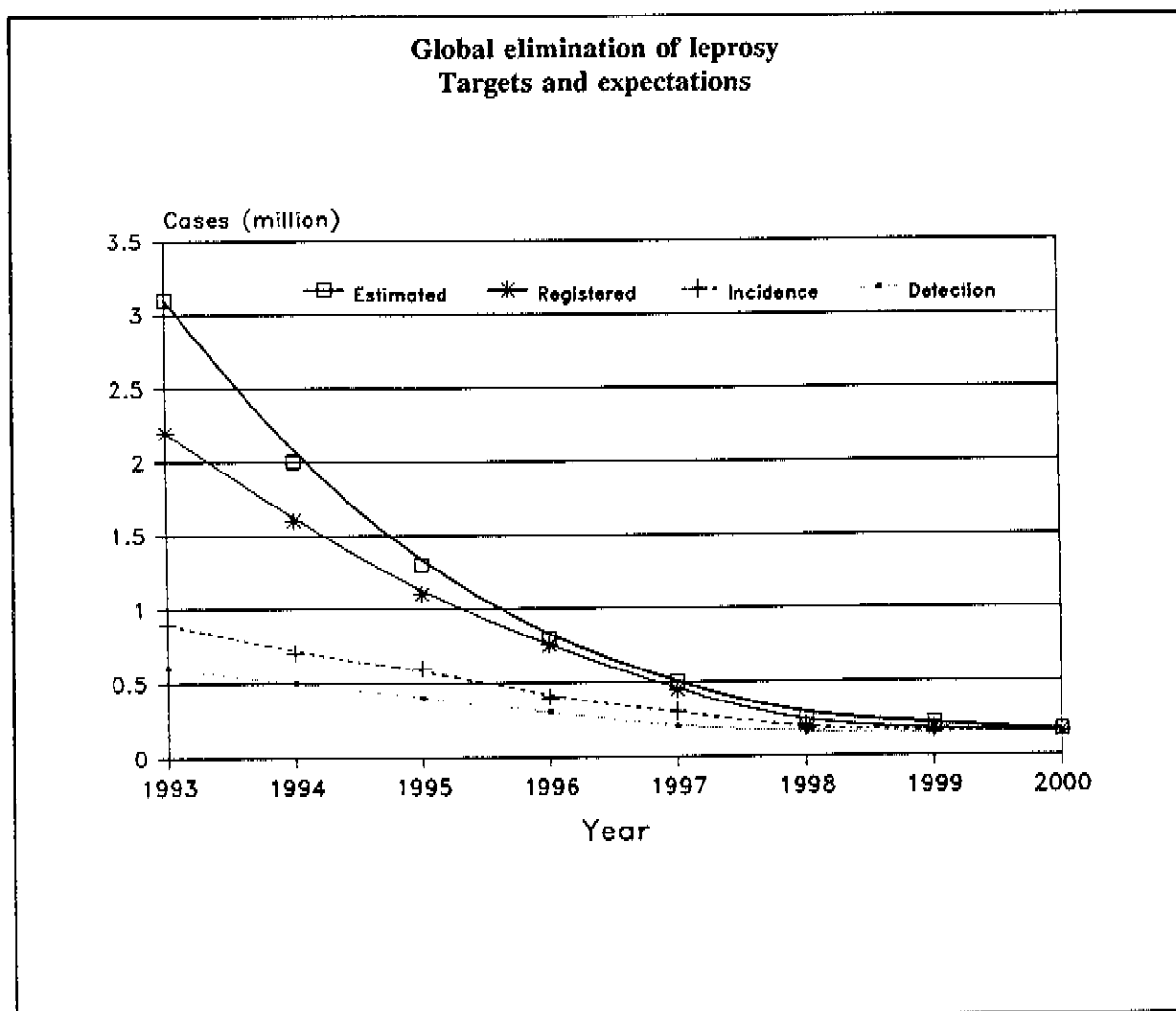
In countries with large populations, such as China, the elimination goal has already been reached (0.2 per 10 000 in 1992), but pockets of high prevalence remain. For instance, in some counties of Wenshan Prefecture, Yunnan Province, with populations of more than 350 000, prevalence has decreased to 2 per 10 000 (1992) after six years' control with MDT, but the detection rate remains at 3.2 - 12.7 per 100 000, with high deformity rate.

The uneven distribution of leprosy among countries is very striking. Based on 1994 data, one can see that just one country, India, contributes 59% of all registered cases; six countries, namely Bangladesh, Brazil, India, Indonesia, Myanmar and Nigeria, together contribute 82%; and 92% of all registered cases in the world are accounted for by the top 25 leprosy-endemic countries.

Delivery of leprosy control services also varies considerably, both in quality and in organizational set-up. A small number of high endemic countries and some dependent upon external support have special programmes, while in a large majority, leprosy control is delivered through integrated health services, although most of them have specialized supervisory and referral services.

The approaches essential for achieving elimination are the detection of patients and their treatment with MDT. Disability prevention and rehabilitation are also important, although not directly related to the elimination goal. The elimination strategy calls for the setting of intermediate targets and constant monitoring of the progress made towards them. Short-term target-setting will relate mainly to reducing cases through the cure of patients with MDT and the consequent reduction in prevalence. While prevalence reduction is directly proportional to the number of patients treated, incidence reduction will depend upon early treatment of all patients, and maintenance of a high coverage with MDT.

If the intensification of leprosy control activities through MDT continues as anticipated, the expectations are that the figures for estimated prevalence, registered prevalence, estimated incidence and case-detection will approximate each other in or around the year 2000.



### 3.1 Prerequisites for achieving elimination

For the elimination strategy to be effective it must be simple enough to be widely implemented and flexible enough to adapt to the rapidly changing needs of the disease and of disease control.

The strategy calls for firm political commitment and effective mechanisms to ensure collaboration between national governments, WHO, international NGOs and other donor agencies, particularly in relation to the coordination of financial and technical resources. Multilateral arrangements involving governments and participating agencies, including the NGOs and WHO, have already proved valuable in facilitating this process.

### 3.2 Preparatory activities

- A. Plan of action: It is essential to prepare long- and medium-range plans of action, or modify existing ones in order to achieve the elimination goal. These plans should guide the formulation of the yearly activities.

- B. **Mobilization of resources:** The elimination strategy demands an intensification of activities. This calls for the mobilization of additional resources, particularly for drugs, which may be acquired from bilateral or multilateral international agencies as well as international NGOs. Long-term commitment from external agencies is particularly important so that such support is available for the full period covered by the plan.
- C. **Organization of health services:** Leprosy control activities should preferably be implemented through whatever health services exist or are planned in the country/area. In general, totally vertical programmes or combinations of two vertical programmes are no longer justified, except under special circumstances. The general health services should be able to deal with most situations provided they have specialized elements at intermediate and central level for supervision, referral, training and evaluation.

#### Example of phased planning at district level

PHASING OF ACTIVITIES IN RELATION TO ELIMINATION			
Intensification phase (duration one year)	Expansion phase (duration 2-3 years)	Maintenance phase (duration 4-5 years)	Post-elimination phase
<ul style="list-style-type: none"> <li>■ Re-assess the magnitude of the problem</li> <li>■ Increase MDT coverage up to 75% by using standardized procedures</li> </ul>	<ul style="list-style-type: none"> <li>■ Extend MDT in a systematic way to reach the optimal geographic coverage</li> <li>■ Increase MDT coverage up to 100%</li> <li>■ Combine various approaches to reach all estimated existing cases</li> </ul>	<ul style="list-style-type: none"> <li>■ Treat all incident cases with MDT</li> <li>■ Decentralize diagnosis and treatment activities</li> <li>■ Implement flexible approaches to suit needs of patients</li> </ul>	<ul style="list-style-type: none"> <li>■ Increase diagnostic specificity</li> <li>■ Strengthen epidemiological surveillance</li> <li>■ Plan for eradication</li> </ul>

### 3.3 Core activities

- A. **Updating of registers:** Information on registered cases in countries with high prevalence rates and low MDT coverage will need to be checked for accuracy to find out whether or not the cases actually exist, and whether or not the patients have active disease requiring MDT.
- B. **MDT implementation:** The implementation of MDT is central to the elimination strategy. The aim is to bring all registered cases and new cases under MDT. There may be a need to initially focus on certain geographic areas, as a result of operational and resource limitations. All previously dapsone-treated MB patients should receive MDT wherever resources permit. Although laboratory confirmation of diagnosis through skin-smear is

important, it should not be prerequisite to the introduction of MDT. Sufficient and uninterrupted drug supply as well as a system for ensuring drug quality should be established.

- C. **Treatment compliance and completion of treatment:** Treatment compliance, both for supervised doses as well as self-administered doses of MDT, is essential if MDT is to be successful. Adequate health education should ensure that all patients who start MDT will complete their treatment.
- D. **Case-detection:** The most cost-effective approach for case detection is the promotion of self-reporting of suspect lesions through increased community awareness about the disease and its curability. In addition, all household contacts of newly detected patients should be examined at the time of diagnosis. Special efforts may be needed to identify cases in high endemic pockets. Peripheral health service staff should be adequately trained to recognize early signs of leprosy. Where the incidence is becoming very low, it may be necessary to have the diagnosis confirmed by specialized health workers. Assessment of disabilities among new cases at the time of diagnosis provides an indirect indicator for delay in diagnosis.
- E. **Disability assessment, prevention and management:** Early cure is the most effective way to prevent disabilities. Disability assessment, prevention and management, using simple cost-effective approaches, should be incorporated into routine leprosy programmes, not only for the benefit of the patients but also for the credibility of the programme. Increased credibility will result in earlier self-reporting and improved compliance with MDT, and consequently will contribute to bringing about the goal of elimination.

#### 3.4 Supportive activities

In addition to the core activities, the following supportive activities will contribute significantly towards achieving the goal of elimination:

- Patient and family counselling
- Community education
- Adequate referral systems
- Promotion of social and economic integration.

#### 3.5 Evaluating activities

- A. **Programme monitoring and evaluation:** These are essential activities for measuring the progress towards specific targets as well as identifying problems and possible solutions. While problem-solving through previous experience will be possible in many instances, in others, a systematic approach through health systems research (HSR) will be necessary to find solutions for specific local problems.
- B. **Epidemiological surveillance:** This should be done through information collected routinely. Under low endemic conditions, epidemiological surveillance may require special methods of investigation. Surveillance through sentinel centres is likely to be a useful method for predicting future trends.

## 4. WORKPLAN

### 4.1 Priorities in countries

The target of less than one leprosy case per 10 000 population by the year 2000, which is a very specific target, needs to be considered at various population levels - global, national, district and community, but also at the level of risk groups. From the operational point of view, it is clear that the elimination strategy starts from the community where transmission of the disease is still active. From the public health point of view and for planning purposes, it is important to first define high priority zones and then to zoom in to them in order to select priorities and take appropriate action. Therefore the elimination strategy as proposed by WHO aims to act locally and to plan globally.

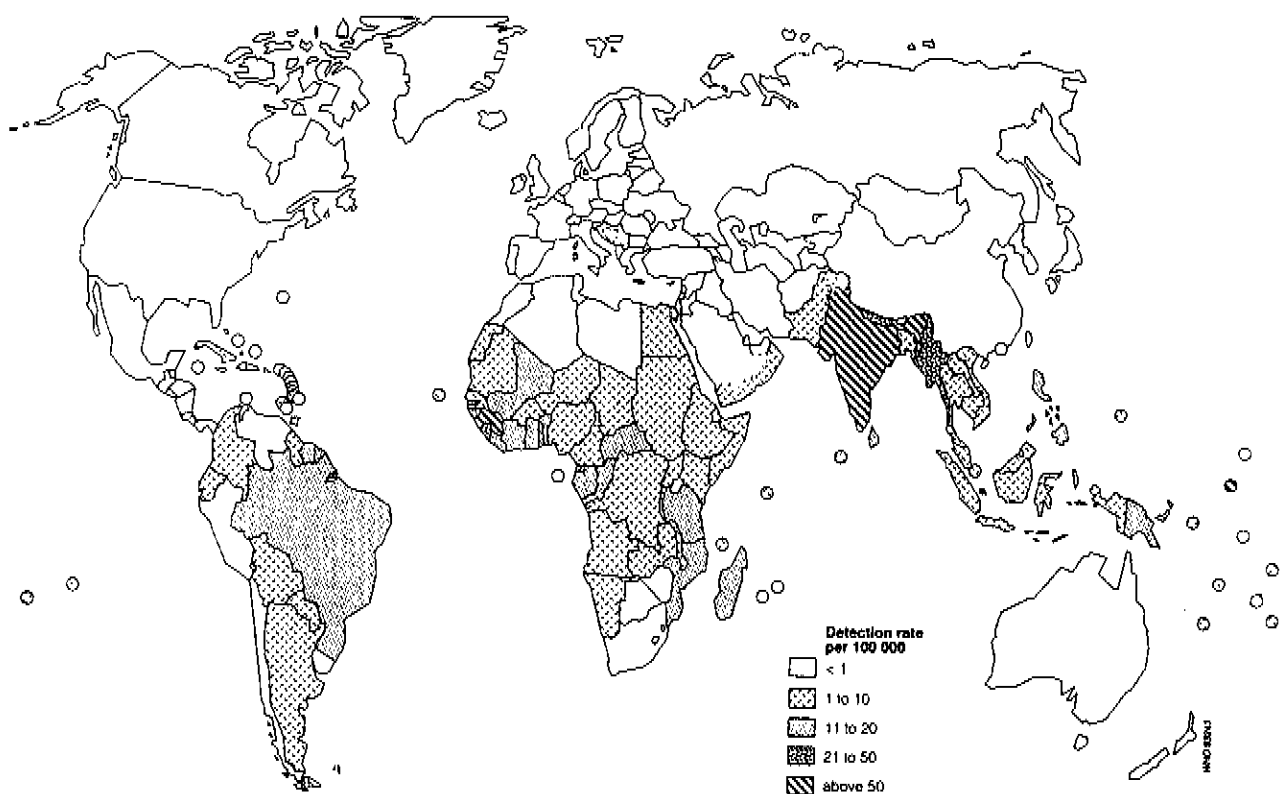
The first step is to decrease the current global leprosy prevalence from 4.5 per 10 000 (1994 estimates) to 1 per 10 000, and to focus simultaneously on regions, countries, districts and communities having high endemicity.

Different WHO regions are expected to reach elimination levels at different times. Meanwhile, each endemic country should identify districts where leprosy is still endemic and give priority to them. In concrete terms, it is proposed to use the country as a focal point and to identify, for each priority country, the critical activities to be implemented. Again, the same approach could be used within a given country to identify priority districts.

#### 4.1.1 Grouping of affected countries

The criteria for grouping of the leprosy-endemic countries are based on epidemiological and operational information. The epidemiological information includes absolute numbers and prevalence rates of estimated as well as registered cases; in some situations it should also be possible to utilize information on case-detection rates. The operational information taken into consideration is mainly the progress being made with MDT coverage.

**Detection of leprosy in the world. 1993**



### Methods for estimates

While sample surveys are the methods of choice for estimating prevalence of diseases affecting more than 10% of the population, they are not appropriate for leprosy. For the sample investigation to yield results with acceptable precision, the size of the sample must be very large, and the non-sampling errors minimal. Achieving these can be very expensive and time-consuming. Some indirect procedures are therefore used for practical purposes of estimating case-loads. These procedures are based on knowledge of the completeness of routine reporting and on certain epidemiological patterns. Possible methods for three different situations are given below:

#### ■ Before MDT implementation

- Use the prevalence/detection ratio to assess the dynamic of the control programme
- Extrapolate from registered cases, generally after reviewing registers and re-examining registered cases (cleaning of register)
- Extrapolate from child prevalence
- Rapid village surveys

Example - Nigeria (1992 figure): 62 080 registered cases versus 63 000 estimated cases.  
Correction factor 1.02

#### ■ During MDT implementation (1-4 years)

- Monitor operational efficiency
- Monitor detection trend and age-specific incidence
- Assess the programme coverage and self-reporting

Example - Guinea: 6 900 registered cases versus 15 000 estimated cases. Correction factor 2.2

#### ■ MDT maintenance phase (after 4 years of good operation)

- Accept registered cases and a small percentage of unknown cases
- Use Delphi approach if necessary to get expert consensus opinion on the correction factor

Example - Thailand: 6 820 registered cases versus 10 000 estimated cases. Correction factor 1.5

By applying these methods to various regions of a given country, one could reasonably estimate the workload at a given time. Since the situation is evolving rapidly with MDT implementation, it is clear that estimates have to be revised annually.

Based on 1994 estimates, the world can be divided into six groups, the first three of which require intensive intervention:

- group 1: country with more than one million cases: one country, India
- group 2: countries with a prevalence of more than 1 per 10 000 and the number of cases from 30 000 to 300 000: 7 countries
- group 3: countries with a prevalence above 1 per 10 000 and the number of cases from 10 000 to 30 000: 17 countries
- group 4: countries where leprosy is a public health problem needing moderate incremental action: prevalence above 1 per 10 000 and the number of cases from 5 000 to 10 000: 14 countries
- group 5: countries expected to reach the target provided present levels of activity are maintained: 40 countries
- group 6: countries where leprosy is no longer a public health problem at a national level: 118 countries (NB: China, Pakistan and USA could be considered as exceptions because they have still more than 5 000 cases).

**Group I - 1 country**

India

**Group II - 7 countries**

Bangladesh, Brazil, Indonesia, Iran, Myanmar, Nigeria, Philippines

**Group III - 17 countries**

Cambodia, Chad, Colombia, Côte d'Ivoire, Egypt, Ethiopia, Guinea, Madagascar, Mali, Mexico, Mozambique, Nepal, Niger, Sudan, Thailand, Viet Nam, Zaire

**Group IV - 14 countries**

Angola, Argentina, Burkina Faso, Cameroon, Central African Republic, Congo, Laos, Liberia, Malaysia, Senegal, Sri Lanka, Tanzania, Uganda, Venezuela

**Group V - 55 countries**

American Samoa, Antigua and Barbuda, Bahamas, Bahrain, Benin, Bhutan, Bolivia, Botswana, Cape Verde, Comoros, Cook Islands, Costa Rica, Cuba, Cyprus, Djibouti, Dominican Republic, Ecuador, Equatorial Guinea, Fiji, French Guiana, Gabon, Gambia, Ghana, Grenada, Guadeloupe, Guam, Guinea-Bissau, Guyana, Haiti, Kiribati, Lesotho, Libya, Malawi, Maldives, Marshall Islands, Martinique, Mauritania, Micronesia Fed. Stat, New Caledonia, Papua New Guinea, Paraguay, Reunion, Seychelles, Sierra Leone, Singapore, Solomon Islands, Somalia, St. Lucia, Suriname, Togo, Turks & Caicos Islands, Vanuatu, Western Samoa, Yemen, Zambia

**Group VI - 126 countries**

Rest of the world

#### 4.2 Priorities for action

The first priority action for eliminating leprosy is to treat all registered cases with MDT, and then to improve the case-finding in terms of coverage and early detection. Further, it is very important that high MDT coverage should be sustained for a period of at least four to five years if it is to have an impact on the transmission of the disease. Attainment of the goal of elimination calls for urgent action in terms of the following:

- a) Political commitment and plans of action aimed at elimination
- b) Mobilization of resources to implement plans of action
- c) Updating of existing information
  - Systematic identification of registered cases in need of MDT
  - Cleaning registers of patients not requiring treatment
  - Analysis of existing information to update the estimated number of cases
- d) Treating all existing cases with MDT. This activity must not be delayed. Sufficient supply, distribution and accessibility of drugs must be ensured.
- e) Improving case-detection and sustaining high MDT coverage. Promotion of public awareness will also have an impact on early case-detection.
- f) Training is considered an important component, but it should not delay the implementation of key activities.
- g) Monitoring the progress of the elimination plan.

**Priority activities according to the leprosy situation and time-frame**

Activities	Groups	Time frame	Action to be taken
Political commitment	2	1994	National and regional meetings
Mobilizing/ Re-allocating resources	2	by 1994	Donors' meeting
Updating information	2	by 1994	Special assessment teams
Treating all registered cases with MDT	1 & 2	by 1994	Provision of drugs/stock control
Preparing/revising national plans of action	2	by 1994	Technical assistance from WHO staff; meetings; guidelines
Better case-finding, detection, reporting	2	1993-2000	HSR; integration into general health services; promoting self-reporting
Training and HSR	1 & 2	1994-2000	Task Force; national network
Monitoring implementation	1 & 2	1993-2000	Comprehensive annual programme review
Evaluating elimination	1, 2 & 3	1998-2000	Double-checking of registers

#### 4.3 Additional resources needed

Extensive and continuous leprosy control based on MDT offers an opportunity to eliminate leprosy as a public health problem. In a number of endemic countries, leprosy competes with many other diseases and is given a low priority. However, the feasibility of eliminating leprosy should be given earnest consideration. The cost of such a strategy should be analysed in terms of additional resources needed and, above all, in terms of cost-effectiveness. Leprosy control based on MDT has demonstrated that the prevalence of the disease can be dramatically reduced in a short period of time (2-3 years). Prevalence being reduced, one might expect a sharp decrease in the cost of leprosy control and therefore the re-allocation of resources to other priorities. On the other hand, the cost of the maintenance phase, which is essential in order to eliminate leprosy in a given area, should not be underestimated.

WHO Region	Cases to be cured	Additional costs (Million US \$)
Africa	340 000	34
Americas	383 000	37
Eastern Mediterranean	80 000	12
South-East Asia	4 060 000	321
Western Pacific	130 000	20
Europe	7 000	1
<b>World</b>	<b>5 000 000</b>	<b>425</b>

- Five to six million cases to be cured by the year 2000.
- Additional cost: US\$ 400 to 500 million, including US\$ 120 to 150 million for drugs alone and US\$ 280 to 350 for delivering services

More detailed information on additional resources needed can be obtained from the Leprosy Unit on request

#### 4.4 Essential indicators for monitoring progress

##### **I Prevalence rate : Registered cases**

The point prevalence rate is defined as the number of cases registered for chemotherapy at the end of the year divided by the population in which the cases have occurred. This indicator reflects the magnitude of the problem and helps in planning and evaluating control measures. It is useful to express the prevalence using absolute numbers and rate per 10 000.

##### **II Detection rate : Newly detected cases**

This rate is defined as the number of new cases detected during a year divided by the population in which the cases have occurred. This indicator is the most appropriate for estimating the true incidence of the disease in a given population when analysed in conjunction with the proportion of disabled patients (grade 2) among newly detected cases. It should always be related to the prevalence, and should be expressed using absolute numbers and rate per 10 000.

##### **III Proportion of patients with grade 2 disabilities among new cases**

This is defined as the proportion of newly detected cases with grade 2 disability among the total number of newly detected cases during the year. This indicator is supposed to reflect the effectiveness of the programme in terms of early case-finding and the level of community awareness of the disease.

##### **IV MDT coverage**

###### **- Current MDT coverage :**

This is defined as the proportion of cases receiving MDT at any time during the year among the total number of cases appearing on the register during the year. This indicator reflects the programme performance in achieving full MDT coverage and helps to set targets.

###### **- Cumulative MDT coverage :**

The cumulative MDT coverage is a composite indicator defined as the proportion of leprosy patients who are, or have been, treated with MDT since the programme based on MDT started among all patients registered during the same period of time.

##### **V Cure rate**

This rate is defined as the proportion of registered cases cured of leprosy. This indicator is extremely useful in monitoring MDT at global level. It can be calculated using cohort reporting, the cohort being defined as a group of patients starting their treatment at the same given time (or over the same period of time).

##### **VI Relapse rate/ Relapse risk**

This rate is defined as the number of individuals who were cured of leprosy (Expert Committee definition) and then show new signs of the disease. The relapse rate has to be expressed in person/years of follow-up and the relapse risk as an annual likelihood for each cured patient to relapse. This type of follow-up is not practicable as a routine measure and, for this reason, absolute and cumulative numbers of relapses may be used.

### Operational definitions for control programmes

The Sixth Expert Committee clearly defined the operational classification, with or without bacteriological examination, for newly detected cases and for cases who have already been treated.

A "case of leprosy" is a person showing clinical signs of leprosy, with or without bacteriological confirmation of the diagnosis, and requiring chemotherapy. It is recommended that this definition be adopted by all countries so that information on prevalence can be meaningfully interpreted.

- (1) Paucibacillary leprosy will include only smear-negative indeterminate (I), polar tuberculoid (TT) and borderline tuberculoid (BT) cases in the Ridley-Jopling classification, or indeterminate (I) and tuberculoid (T) cases in the Madrid classification. Any case belonging to these types but showing smear positivity will be classified as multibacillary for purposes of multidrug therapy programmes.
- (2) Multibacillary leprosy will include all mid-borderline (BB), borderline lepromatous (BL) and polar lepromatous (LL) cases in the Ridley-Jopling classification, or borderline (B) and lepromatous (L) in the Madrid classification, as well as any other smear-positive types.

For the purposes of multidrug therapy, patients who have already been treated should be classified as follows:

- (1) Those who would have been in the multibacillary group at the time of diagnosis of their disease should be classified as such, irrespective of their current bacterial index.
- (2) Patients who would initially have been in the paucibacillary group should be classified according to their current clinical and bacteriological status.

## 5. IMPROVING MANAGEMENT

### 5.1 Training

In many endemic countries, shortcomings in the planning, implementation and evaluation of well-structured leprosy control programmes contribute to the continuation of leprosy as a major public health problem. Many leprosy patients in those countries do not benefit from appropriate treatment using MDT.

To help address this problem, a set of five training modules was produced by the Leprosy Unit of WHO, with financial support from the Netherlands' Ministry of Development Cooperation and with the technical collaboration of the Royal Tropical Institute (KIT), Amsterdam. The aim of this training package is to strengthen managerial capabilities of health workers who are responsible for planning leprosy programmes. All training should be simple, cost-effective, regularly revised and repeated as necessary; its impact should be regularly monitored.

Similar packages to train all those involved in leprosy control need to be developed. Special training programmes for health workers seeing patients in integrated health care systems may be necessary to take into account the much smaller numbers of cases being seen, which may result in declining skills in detecting and managing such cases.

## 5.2 Health Systems Research (HSR)

For the purpose of improving leprosy control, HSR is defined as the approach towards systematic problem-solving in the field. HSR in leprosy should, as far as possible, be suitable for evaluating all aspects of the control programme. Its methodologies should be relatively simple and cost-effective to apply, and it should identify priority, site-specific problems on the basis of their need to be solved.

The programmes carrying out HSR in leprosy should be subjected to both short-term and long-term evaluations, so that the benefits from HSR are measured not only in immediate terms of solving specific problems but, in the long term, in relation to improved disease control as well as building research and managerial capability.

In order to support HSR in leprosy and following the recommendation made by the Working Group on Leprosy Control during its first meeting in July 1991, a Task Force on HSR in leprosy was created. The objectives of the Task Force are (1) to promote HSR as a management tool to improve leprosy control; (2) to review HSR proposals submitted for WHO funding; and (3) to promote collaboration with agencies having similar interests.

## 6. CURRENT RESEARCH NEEDS AND DEVELOPMENTS

### 6.1 Need for improved treatment

Standard WHO-recommended MDT has been very successful and the immediate need is to encourage national programmes to implement it as quickly as possible.

However, only three anti-leprosy drugs - rifampicin, dapsone and clofazimine - can be safely applied in the field. If an MB patient does not accept clofazimine because of skin coloration, he or she has no access to an easily applicable, alternate MDT regimen. Alternative regimens are also required for individual patients unable to receive rifampicin, whether because of intolerance, rifampicin resistance arising from improper use of the drug or intercurrent disease (such as chronic active hepatitis). Leprosy control programmes and patients may in some instances require alternative regimens according to the needs of the programme and/or of individual patients.

There is also a need to develop new drug regimens for future application for the following reasons:

It would help enormously if the total duration could be substantially shortened to less than two years, even though some patients may still require further care for late complications, including reactions and consequences of nerve damage.

It is important for future schemes of therapy to be as simple as possible for application within the general health services, with the further proviso that they depend mainly upon supervised administration of drugs. Monthly outpatient contact for drug administration is in general very acceptable, helpful for the rapid diagnosis of reactions and other complications, and much cheaper than inpatient treatment.

### 6.2 Progress with research

Three new drugs, namely, ofloxacin (a fluoroquinolone), clarithromycin (a macrolide), and minocycline (a tetracycline), all acting by different mechanisms, have recently shown very promising anti-leprosy activity in experimental models and short-term clinical trials. These drugs

offer the potential for increasing the effectiveness and shortening the duration of anti-leprosy chemotherapy. In addition, new drugs may prove useful against *Mycobacterium leprae* strains that are resistant to the drugs currently in use, especially those resistant to rifampicin.

MULTICENTRE FIELD TRIAL OF OFLOXACIN-CONTAINING REGIMENS IN LEPROSY			
Country	No. of centres	No. of patients	
		MB	PB
Brazil	2	450	600
India	5	300	200
Kenya	1		100
Mali	1	100	200
Myanmar	1	300	300
Pakistan	3		200
Philippines	1	400	200
Vietnam	1	200	200
<b>Total</b>	<b>15</b>	<b>1 750</b>	<b>2 000</b>

### 6.3 Future directions

We now have a number of new drugs available, and the development of regimens to fully utilize the potential of these drugs will continue to be important. This will entail continuing to evaluate the efficacy, acceptability and operational feasibility of ofloxacin-containing multidrug regimens in a field trial now underway in 15 centres in eight leprosy endemic countries. Development of fully supervised intermittent regimens using combinations of rifampicin, ofloxacin, clarithromycin and minocycline is also important.

Since a variety of new anti-leprosy drugs are available, a high priority should now be accorded to the development of anti-reaction drugs to diminish the occurrence of disabilities. Those currently available, such as corticosteroids and thalidomide, have a number of serious side-effects which limit their application under field conditions.

In addition, studies are clearly needed to monitor post-treatment relapses, to counter the development of resistance to existing and new drugs, and also - through HSR - to improve drug delivery systems and patient compliance.

Other priorities for research in leprosy include the development of new diagnostics for the detection of infection, early cases, drug resistance and the viability of *M. leprae*. Support should also be continued to complete the evaluation of vaccines currently on trial.

## 7. NEED FOR A PARTNERSHIP APPROACH

Eliminating leprosy as a public health problem calls for coordinated efforts by all interested parties, keeping in mind the specific mandates of the various agencies interested in leprosy control, the amount and nature of the resources available to them, their relative advantages and their special interests. Ongoing coordination efforts should be further strengthened so that the resources available are utilized to the maximum.

Leprosy programmes which lack resources are being supported by the international community, and particularly by international NGOs in leprosy, notably the Sasakawa Foundation, the International Federation of Anti-Leprosy Associations (ILEP), and the World Bank. At the international level, WHO has been monitoring the leprosy situation closely, developing cost-effective and easily applicable interventions, building national capabilities to carry out leprosy control, and supporting and facilitating the implementation of leprosy control through MDT. WHO has also been investing in research to develop improved interventions such as more effective drug combinations for treatment.

#### WHAT HAVE BEEN THE CONTRIBUTIONS FROM ILEP?

The financial contributions of ILEP have been very substantial, over US\$ 619 million in the past 25 years. It is surely significant that contributions to Africa and Asia are almost equal (Africa US\$ 273 million, Asia US\$ 274 million), with relatively small amounts going to the Americas (US\$ 28 million), Europe and Oceania (US\$ 44 million). ILEP member agencies have, however, provided much more than money. The 900 leprosy treatment projects which member agencies have organized, supported and run have demonstrated on a substantial scale that leprosy is curable, for these projects have been able to declare over 1.5 million cases cured. These include large numbers of patients for whom disability has been prevented and premature death as a result of the indirect effects of leprosy almost eliminated. Agencies have also provided training for thousands of workers, including workers for national programmes, and have undertaken significant research in non-endemic as well as endemic countries. By involvement in national programmes, member agencies have also stimulated governments to catch a vision of the possibility of eliminating leprosy as a public health problem, and it is true to say that, in some instances, leprosy control could not have been possible without such support from these agencies. Members of ILEP, in support of programmes, go well beyond the immediate target of MDT for all, taking action in all aspects of patient care, including prevention of disabilities, rehabilitation and social reintegration.

Many partners contribute to the task of combating leprosy, ranging from large government health services to voluntary organizations, from religious and charitable foundations to individual scientists, doctors and field health workers.

The world's first examples of charitable citizens' organizations, which today are NGOs, were founded to combat leprosy. Some of them with missionary connections were founded in the last century. Those which are members of the International Federation of Anti-Leprosy Associations (ILEP) are spending in 1993 more than US\$ 74 million, of which some US\$ 67 million is being spent in the field and US\$ 5.5 million on research. They address the welfare of over 20 per cent of the world's registered patients and have as their objective "MDT for all leprosy patients" by the year 2000.

Others concerned with complementing field activities are the International Leprosy Association (ILA), which specializes in scientific issues, and the International Leprosy Union (ILU), which links NGOs in developing countries and concerns itself with creating awareness, developing people's participation and networking with other NGOs and governments for effective MDT programmes. The Sasakawa Foundation of Japan supports the activities of WHO at headquarters and in its regional offices, and strengthens national capabilities in leprosy control. A considerable degree of international and intersectoral cooperation is thus already a feature of the battle to eliminate leprosy and to alleviate the suffering of existing victims.

The elimination strategy depends crucially on both mobilizing new resources and deploying existing resources in even more effective ways. Leprosy programmes which lack resources are being supported by the international community, including donor governments. At the international level, WHO has been working hard to develop cost-effective and easily applicable interventions, and has invested in research on more effective drug combinations in treatment.

The target of eliminating leprosy as a public health problem by the year 2000 calls for the joint effort among partners to be intensified. What they have already achieved shows that success is now in sight.

Partnership is based on mutual trust, understanding and respect. It is a process of working closely together to reach a common goal by utilizing the differing strengths and functions of governments, WHO, intergovernmental and nongovernmental organizations.

While the common objective envisaged by the WHO Resolution of May 1991 is "elimination of leprosy as a public health problem by the year 2000," there is a need to look beyond elimination. A number of countries which are achieving this goal are asking how they can cope with new issues that are emerging in the post-elimination period. The WHO Resolution indicates the direction of work in the future by emphasizing the need "to strengthen case-finding activities through various approaches, including health education, community participation and training of health workers; to integrate leprosy control within general health services and provide appropriate social and economic rehabilitation measures as soon as possible in accordance with local realities; and to coordinate the technical and financial resources made available for leprosy control by international and nongovernmental organizations so that they are utilized in the best way."

At the operational level, this partnership can take many forms, such as improved exchanges of information, commonality in advocacy roles and flexibility in cooperative action at all levels. At the regional and global levels, mechanisms to coordinate technical support in specific areas of training, research and advocacy should be developed. At the country level, it is important to develop a tripartite relationship where governments will play a key role and work with WHO and nongovernmental organizations to plan, implement and evaluate leprosy programmes. Involving the community in this partnership network is a must without which the process of normalization of patients will not be complete.

This process of partnership will not only avoid duplication but will encourage coordination and increase the effectiveness of the programme. The need for effective partnership is greater today than ever before because of the magnitude and nature of the common goal.

## 8. CONCLUSIONS

Given the available and anticipated technologies and strategies for leprosy control, given the political will that has been generated in recent years, and given the opportunities to raise resources through various mechanisms, the elimination of leprosy as a public health problem by the year 2000 is now a real possibility. It is essential for the major leprosy endemic countries to further intensify and maintain their leprosy control activities, including MDT coverage, in order to reach the elimination target. While large reductions in prevalence can be achieved in the next few years, major reductions in incidence are expected to require a span of several years because of the long incubation period of the disease as well as the need to ensure full coverage with MDT.

The attainment of the goal will not come easily, and it calls for the unrelenting and coordinated efforts of all concerned. It can be attained provided that substantial and intensified efforts are made during the next few years, in terms of both action and mobilization of adequate resources. For the leprosy-endemic countries, this is an important opportunity to solve once and for all a major public health problem, and it is an opportunity that must not be missed.

\* \* \* \* \*

## DEFINITIONS

### **Case-detection or Case-finding**

A systematic method of finding new leprosy patients in the earliest possible stage of the disease.

There are two approaches:

- active case-detection, e.g. population survey, school survey, systematic examination of household contacts;
- passive case-detection, e.g. voluntary (self) reporting by patients.

### **Case-holding**

The methods used to make sure that leprosy patients take the prescribed treatment in the correct schedule for the necessary period of time.

### **Classification of leprosy patients**

An accepted system of categorization of the various manifestations of leprosy in the patient into certain defined types or groups.

The Madrid classification is used mainly for clinical purposes. More detailed classification is possible through the Ridley and Jopling classification which is based on the immunological, histological, bacteriological and clinical findings. For programmes applying multidrug therapy (MDT), patients are classified into paucibacillary (PB) and multibacillary (MB).

### **Compliance**

The acceptance or willingness to fulfill formal requirements or guidelines. Compliance with treatment is the willingness of a patient to follow the prescribed treatment. It includes regularity of clinic attendance as well as drug intake.

### **Coverage (Health coverage)**

A concept indicating the extent of the provision of a given amount of health services to a specified population.

### **Criteria**

Criteria are standards against which something is judged and by which decisions are made and actions are measured.

## **Defaulter**

A patient who does not turn up for treatment (= supervised drug intake + collection of drugs for self-administration at home) within a defined period after the date of appointment. Depending on local standards, this period will vary. Defaulters should be traced by the staff (messages, home visits etc.)

## **Detection rate**

The number of new cases diagnosed (detected) by a specified health service in a specified population during a specified period of time (e.g. a year) in relation to the average population over that period.

## **Disability grading**

A method of defining the extent of disability in a number of grades according to certain criteria. The WHO Expert Committee on Leprosy (1988) suggested a simple, three-grade (0, 1 and 2) system of classification, primarily for collection of general data regarding disabilities and/or impairments.

It will often be necessary to provide information on overall disability grading for the patient. In that case, the highest leprosy disability grade for any part of the body will be taken as the overall disability grading of the patient.

## **Disability prevention**

This component of leprosy control aims at the prevention of disability, e.g. early recognition of nerve function impairment and complications, provision of health education to the patient, provision of protective footwear, etc.

## **Disability rate**

Proportion of patients with a defined disability grade amongst a defined group of patients (e.g. proportion of disabled grade 2 among newly detected patients).

## **District**

The most peripheral geographical and administrative area of government which has full powers and responsibilities for the major ministries concerned with local affairs, e.g. health, agriculture, education. A typical district has a population of between 100 000 and 300 000 people and an area of between 5 000 and 50 000 sq. kms. Different terms are used in various countries for such an area.

## **Integrated health care**

A pattern of health care in which all types of care (curative, preventive, health promoting) for all kinds of health problem are given at the same place. The level of care is dependent on the knowledge and skills of the staff involved and other resources available. It may be achieved in a coordinated way either by different staff members working at the same time or by the same staff members providing different types of care. An adequate referral system is part of integrated health care.

## **Integrated health services**

The services necessary for the health protection of a given area and organized either under a single administration or under several agencies, with proper provision for the coordination of their services. An integrated health system is a system which is organized as a whole, i.e. one in which the various elements are disposed, organized and coordinated with reference to a common objective: the acceptance of responsibility for the health of a population.

## **MDT**

Multidrug therapy, a term used for a leprosy treatment with two or more chemotherapeutic drugs.

## **Multibacillary (MB) leprosy**

MB leprosy includes all mid-borderline (BB), borderline lepromatous (BL) and polar lepromatous (LL) cases in the Ridley-Jopling classification, or borderline (B) and lepromatous (L) cases in the Madrid classification, as well as any other smear-positive types.

## **Paucibacillary (PB) leprosy**

PB leprosy includes only indeterminate (I), polar tuberculoid (TT) and borderline tuberculoid (BT) cases in the Ridley-Jopling classification, or indeterminate (I) and tuberculoid (T) cases in the Madrid classification. Any case belonging to these types but showing smear positivity will be classified as MB for purposes of MDT programmes.

## **Regularity of treatment**

This definition is arbitrary. A reasonable definition of regularity of treatment for PB patients would be six doses of MDT taken in a period not exceeding a total of nine months. For MB patients, a reasonable definition would be 24 doses taken within a period of 36 months.

## **Relapse**

A leprosy patient who in the past was released from treatment as cured, but has now returned for treatment with active disease, has a relapse of his/her disease.

## **Trend**

Observations of the same type recorded over a period of time are designated time-series data. The smooth or regular movement of a series of such data is called a trend and is used for making forecasts under certain assumptions.

## **Acronyms and initials**

HIV	Human Immunodeficiency Virus
HSR	Health Systems Research
ILA	International Leprosy Association
ILU	International Leprosy Union
ILEP	International Federation of Anti-Leprosy Associations
LWG	Leprosy Working Group
MDT	Multidrug Therapy
NGO	Nongovernmental Organization
WHA	World Health Assembly
WHO	World Health Organization