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News and Notes

Progress towards leprosy elimination

The following is extracted from *Weekly Epidemiological Record*, 1997, **72**, 165–172:

Following the implementation of the global plan of action for eliminating leprosy as a public health problem, as elaborated in 1992, there is continuing evidence from endemic countries that multidrug therapy (MDT) is highly effective in curing patients and reducing disease prevalence. The process of implementing MDT has by itself contributed to a better understanding of the disease and its distribution. The fact that by 1996 almost all known patients were being treated with MDT is a tremendous achievement. The challenge now is to bring this effective technology to cases who have little or no access to MDT, and to implement it even where health facilities are minimal.

Information for monitoring the elimination of leprosy in endemic countries is now well standardized and is generated by national information systems. However, a major difficulty, particularly in the context of elimination, is to assess the proportion of the population covered by the programme. WHO, in collaboration with national programmes of the top endemic countries, is promoting new initiatives such as Leprosy Elimination Monitoring (LEM) and the use of the Geographical Information System with the objective of identifying difficult operational and/or epidemiological situations calling for special intensified efforts.

Although the performance of national elimination programmes is assessed by reductions in prevalence, MDT coverage and number of patients cured, increasing attention is now being given to the geographical coverage and quality of MDT services, timely detection of cases, and prevention of impairments or disabilities attributable to leprosy and its complications.

The prevalence of leprosy in the world continued to show a declining trend in 1997, and most of the countries endemic for leprosy have reported considerable progress against the disease. The number of countries showing prevalence rates above 1 per 10 000 population has been reduced from 122 in 1985 to 55 at the beginning of 1997. However, in some of the major endemic countries, epidemiological trends over the past few years indicate a slowing down of further reduction in prevalence. The present report records the progress that has been made towards the goal of elimination of leprosy as a public health problem, and updates figures published in June 1996.

Global and regional leprosy situation

COUNTRIES ENDEMIC FOR LEPROSY

In 1985, before large-scale implementation of MDT, 122 countries were showing prevalence rates above 1 case per 10 000 population. After more than 10 years of intensive activities, most of these countries have reviewed their leprosy registers and have treated patients in need of it with MDT. As a result, 67 countries have reduced the leprosy prevalence to below 1 per 10 000 population. Although it is too early to judge whether or not this situation is sustainable, one can be reasonably confident that leprosy as a public health problem has been eliminated in most of these countries. In some others, further investigation might be needed to make sure that remaining pockets of leprosy have not been missed and that detection rates continue to decline.

PREVALENCE

At the beginning of 1997, it is estimated that there are about 1 150 000 leprosy cases in the world, out of whom 888 340 are registered for treatment.

Distribution of estimated and registered prevalence by WHO Region is shown in Table 1. Only a modest reduction in the number of registered cases has been noted between 1996 and 1997. The global prevalence rate of registered cases, which was constantly decreasing over the last 10 years, is still about 1·6 per 10 000 population. More importantly, in the 16 major endemic countries which represent 91% of the global leprosy problem, the prevalence rate is still 4·3 per 10 000, indicating that additional efforts will be required to achieve elimination of leprosy as a public health problem. It is possible that some of these countries might need to continue and intensify activities beyond the year 2000 to reach their leprosy elimination targets.

Detection of leprosy cases

The number of cases detected in 1996, by WHO Region, is shown in Table 2. About 555 000 cases were detected during 1996 as notified by 79 countries. Some endemic countries (Cameroon, Papua New Guinea, Paraguay and Zaire) were not able to send information at the time of the preparation of this report. Assuming that these countries would have detected the same number of patients during 1996 as during 1995, the global detection can be estimated to be as high as 566 000 (9·8 per 100 00 population). About 535 000 cases (95%) were detected in the 16 major endemic countries, and 73% of the newly detected cases are living in India alone. Among newly detected cases more than 85 000 (16%) are children, about 170 000 (31%) are multibacillary (MB) cases and about 30 000 (5·5%) were showing severe disabilities at the time of diagnosis.

The increase in detection that is observed in many endemic countries reflects an increase in case-finding activities and geographical coverage of leprosy elimination programmes rather than changes in the incidence of the disease. Although the situation varies from one WHO Region to the other, and from one country to another within the same Region, the global detection trend remained stable over the last 12 years. However, analysis of disaggregate information is needed for a better understanding of the impact of the elimination strategy. The geographical distribution of leprosy as well as its clinical profile have changed dramatically, and the disease is now shrinking to a limited number of countries, or of districts within countries. Furthermore, it should be recognized that there is no direct relationship between detection trends and intensity of transmission of the disease, and therefore detection trends should be interpreted with great caution. This complex matter will be discussed in detail in the next issue of the *Weekly Epidemiological Record.*

Progress with MDT coverage

Almost all leprosy patients registered for treatment are now treated with MDT, even in countries facing difficult practical problems. During 1996, about 1·4 million patients were treated with MDT and more than 550 000 were cured. Table 3 gives details on notified and estimated MDT coverage for registered patients and the cumulative number of persons cured with this treatment, by WHO Region. This impressive progress made in MDT coverage is the direct result of the efficacy of MDT and of efforts made by governments, WHO, nongovernmental organizations and other agencies to ensure the free supply of drugs to all patients in need. During the last 2 years, WHO, through a contribution from the Nippon Foundation, has supplied MDT for more than 1·7 million patients living in 35 endemic countries.

While treating all registered patients with MDT is a considerable achievement in the fight against leprosy, it should be recognized that the geographical coverage of health facilities able to provide MDT services is far from satisfactory. This is mainly because leprosy has always been considered as a special

Table 1. Number of estimated and registered cases of leprosy, by WHO Region, and percentage change between 1996 and 1997

Tableau 1. Nombre estimé et enregistré de cas de lèpre, par Région OMS, et variation en pourcentage entre 1996 et 1997

WHO Region—Région OMS	Estimated number of cases (rate per 10 000) Nombre estimé de cas (taux pour 10 000)	Number of registered cases (rate per 10 000) Nombre de cas enregistrés (taux pour 10 000)		Percentage change Variation en pourcentage
	1997	1996	1997	
Africa—Afrique	140 000 (2·4)	95 901 (1·77)	82 758 (1·39)	(–) 14
Americas—Amériques	140 000 (1·7)	123 537 (1·64)	127 866 (1·63)	(+) 4
South-East Asia—Asie du Sud-Est	800 000 (5·7)	651 562 (4·72)	637 413 (4·50)	(–) 2
Eastern Mediterranean—Méditerranée orientale	30 000 (0·6)	23 005 (0·54)	13 038 (0·28)	(–) 43
Western Pacific—Pacifique accidental	40 000 (0·2)	32 254 (0·20)	26 533 (0·16)	(–) 18
Europe	Less than – Moins de 1 000	–	732 (0·01)	–
Total	1 150 000 (2)	926 259 (1·67)	888 340 (1·54)	(–) 4

Table 2. Detection of leprosy, by WHO Region, 1996[a]

Tableau 2. Détection de la lèpre, par Région OMS, 1996[a]

WHO Region—Région OMS	Number of new cases notified Nombre de nouveaux cas notifiés	Detection rate per 100 000 Taux de détection pour 100 000 habitants
Africa—Afrique	46 489	7·80
Americas—Amériques	43 783	5·59
South-East Asia—Asie du Sud-Est	457 921	32·36
Eastern Mediterranean—Méditerranée orientale	5 761	1·25
Western Pacific—Pacifique occidental	12 613	0·77
Europe	37	–
Total	566 604	9·84

[a] Or latest available information. – Ou dernières donnés disponibles.

disease requiring special systems for dealing with it. As a result, the procedures and norms for diagnosing and treating the disease were seen as beyond the capabilities of the majority of general health services.

With the large experience gained in using MDT, even under difficult conditions, WHO is now promoting simplified procedures aimed at making access to MDT easy for all patients. In so doing, it is estimated that programmes in endemic countries should detect and treat about 2 million cases over the next 4 years.

Most of the leprosy elimination programmes are now using cohort reporting systems to assess cure rates with MDT. Since 1996, independent monitors are collecting detailed information from some of the major endemic countries in order to validate the cure rates, and to analyse the quality of and coverage with MDT services. In general, compliance with MDT is high and cure rates are ranging from 75% to 95%. Flexibility in delivering MDT to patients and the use of blister calendar packs have helped to improve cure rates, especially for patients living in difficult-to-access areas. However, in some countries, cure rates are relatively low, notably for MB patients. This is observed either in programmes not following fixed-duration MDT and therefore keeping patients for too long in treatment registers, or among patients defaulting from treatment for various reasons. However, defaulting rates are relatively low in leprosy, ranging from 1% to 25% according to countries, with a global average of 11%.

Detailed situation in the top 16 endemic countries

Leprosy remains a public health problem in 55 countries or areas, but 16 countries account for 91% of the leprosy problem in the world. Table 4 shows the number of registered cases, the number of cases detected in 1996, and the achievements with MDT in the top 16 endemic countries.

Conclusion

Most of the purely technical problems hindering the process of eliminating leprosy as a public health problem have been solved over the past 15 years, but many operational issues are still to be overcome in order to reach remaining patients and to accelerate the progress. The main challenges for national programmes are (i) to reach geographical areas and populations which have not yet benefited from MDT services, (ii) to reduce the delay in detecting and diagnosing the disease, and (iii) to continue to provide patients with good quality services, including the supply of drugs free of cost. This can only be achieved

Table 3. Registered cases of leprosy and coverage with multidrug therapy (MDT), by WHO Region, 1997

Tableau 3. Cas de lèpre enregistrés et couverture par la polychimiothérapie (PCT), par Région OMS, 1997

WHO Region—Régions OMS	Registered cases Cas enregistrés	Cases on MDT Cas sous PCT	Reported MDT coverage (%) Couverture par la PCT Signalée (%)	Estimated[a] MDT coverage (%) Couverture par la PCT estimée[a] (%)	Cured with MDT (cumulative total) Guérisons par la PCT (total cumulé)
Africa—Afrique	82 758	81 764	98·8	58	507 123
Americas—Amérique	127 866	121 144	94·7	75	235 116
South-East Asia—Asie du Sud-Est	637 413	620 798	97·4	77	7 377 199
Eastern Mediterranean—Méditerranée orientale	13 038	12 166	93·3	45	58 455
Western Pacific—Pacifique occidental	26 533	26 400	99·5	71	236 483
Europe	732	726	99·2	–	1 945
Total	888 340	862 998	97·1	76	8 416 321

[a] Calculated according to the number of estimated cases requiring treatment.—Calculée selon le nombre estimé de cas nécessitant un traitement.

Table 4. Registered prevalence of leprosy, coverage with multidrug therapy (MDT) and detection rate in the top 16 endemic countries[a]

Tableau 4. Prévalence enregistrée de la lèpre, couverture par la polychimiothérapie (PCT) et taux de détection dans les 16 principaux pays d'endémie[a]

Country—Pays	Registered cases beginning of 1997 Cas enregistrés début 1997	Prevalence per 10 000 Prévalence pour 10 000 habitants	Cases on MDT Cas sous PCT	MDT coverage (%) Couverture par la PCT (%)	Cured with MDT (cumulative total) Guérisons par la PCT (total cumulé)	Cases detected in 1996 Cas détectés en 1996	Detection rate per 100 00 Taux de détection pour 100 000 habitants
India—Inde	553 793	5·9	537 180	97·0	6 862 000	415 302	44·0
Brazil—Brésil	105 744	6·6	101 000	95·5	181 763	39 792	24·7
Indonesia—Indonésie	33 739	1·7	33 739	100·0	175 104	15 071	7·5
Bangladesh	13 385	1·1	13 385	100·0	70 063	11 225	9·4
Myanmar	18 758	4·1	18 758	100·0	148 982	6 935	15·1
Nigeria—Nigéria	14 309	1·2	14 309	100·0	45 720	6 871	6·0
Nepal—Népal	12 828	5·8	12 828	100·0	42 362	6 602	30·0
Zaire[b]—Zaïre[b]	6 082	1·3	6 069	99·8	49 422	5 526	11·8
Mozambique	10 905	6·1	10 091	92·5	7 414	4 225	23·7
Ethiopia—Ethiopie	8 272	1·4	8 272	100·0	71 291	4 747	8·2
Madagascar	6 656	4·3	6 656	100·0	23 112	3 921	25·5
Sudan—Soudan	3 471	1·3	3 471	100·0	8 566	2 126	7·8
Philippines	8 663	1·3	8 663	100·0	70 967	4 051	5·9
Cambodia—Cambodge	2 960	2·9	2 960	100·0	7 792	2 404	23·4
United Republic of Tanzania—République-Unie de Tanzanie	3 077	1·0	3 077	100·0	47 192	2 747	8·9
Guinea—Guinée	3 732	5·0	3 732	100·0	28 127	3 326	44·2
Total	806 374	4·3	784 190	97·2	7 839 877	534 871	28·3

[a] The top 16 endemic countries included in the above table have the following characteristics: (i) they have a prevalence of more than 1 in 10 000 population, and (ii) the number of prevalent leprosy cases is more than 5 000, or the number of newly detected cases is more than 2 000. Ranking of countries is based on the number of estimated cases.—Les 16 principaux pays d'endémie figurant dans le tableau ci-dessus présentent les caractéristiques suivantes: i) la prévalence y dépasse 1 pour 10 000 habitants et ii) le nombre total de cas de lèpre est supérieur à 5 000 ou le nombre de cas de lèpre nouvellement détectés dépasse 2 000. Les pays sont classés d'après le nombre de cas estimés.

[b] 1995 data.—Données de 1995.

through increased community involvement, sustained political will and continuous support from the international community. The findings that MDT coverage is now reaching the highest possible level and that case detection continues to improve indicate that elimination of the disease is well under way. However, reaching patients in remote areas and hidden cases will continue to be a major challenge as these problems are interlinked with overall problems of poverty and underdevelopment. While the progress made so far in eliminating leprosy is very impressive, these remaining problems call for further intensification of efforts using focused yet flexible approaches.

Global case detection trend in leprosy

The following is extracted from *Weekly Epidemiological Record*, 1997, **72**, 173–180:

Background

Since the advent of chemotherapeutic drugs against *Mycobacterium leprae*, control of leprosy has been based on case-detection and treatment of patients, with the aim of reducing the infection pool and thereby the transmission of the disease. This strategy, based on detection and mass treatment with dapsone monotherapy, was reasonably effective for many years but failed subsequently with the emergence of resistance of *M. leprae* to dapsone. After the introduction of multidrug therapy (MDT) in the 1980s, achievements during the first 5 to 6 years of implementation were so impressive that the possibility of eliminating leprosy as a public health problem was envisaged. The level of prevalence to be reached was set at 1 case per 10 000 population, and it was decided to evaluate the success of the strategy by monitoring mainly the prevalence of the disease.

Although it was logical to consider monitoring of incidence as a more appropriate and theoretically more relevant measure for evaluating progress towards leprosy elimination, it was clear that this was not technically possible for reasons outlined below. The overall elimination strategy is based on (i) timely case-detection, (ii) cure of all diagnosed cases with fixed duration MDT, (iii) simplified case-management and (iv) monitoring progress through appropriate information systems. So far, this concept has proved to be valid and the prevalence pool has been reduced by more than 85% in a span of 15 years. The question that now arises is how to demonstrate whether or not this reduction in prevalence has had an impact on the transmission of the disease. Unfortunately, dependable tools for measuring infection and for monitoring incidence trends in leprosy are still not available. Assessing incidence requires special prospective studies which involve large amount of resources and would have to be repeated using consistent procedures over several years if trends are to be assessed.

The purpose of this report is to analyse trends in leprosy over the last 12 years in 28 endemic countries and to discuss the extent to which changes in the detection and in the profile of newly detected cases reflect changes in the transmission of the disease.

Intensification of leprosy control activities through expansion of MDT services to every available health facility in the country is an important step towards elimination. However, the availability of health services and their capacity to implement MDT services for leprosy vary widely in different countries. In theory, if all the cases were to be detected within the first year of onset of disease and treated with MDT, the impact on transmission should be visible within a few years. In practice, the detection of leprosy globally has remained unchanged over the last 10 years, in quantitative and to some extent even in qualitative terms. What is not clear is the extent to which these changes can be attributed to the level of transmission, improved case-finding, expansion of health services, changes in case definition, increased population at risk, or a combination of these factors.

During the early years after the introduction of MDT, the problem was mainly the burden of cumulative prevalence (10–12 million estimated cases and 5·4 million registered cases in 1985), and the main objective was to treat, and cure, the large number of already registered patients. At that time, it

could be estimated that the average duration of the disease (from diagnosis to cure) ranged between 15 and 20 years. The gap between registered and estimated cases was enormous and was most probably over-estimated. Before introduction of MDT, information on the number of new cases detected each year was rather scanty. Even so, one could estimate this figure to be between 250 000 and 300 000 globally at that time.

From 1985 to 1996, MDT was widely, but slowly, implemented to reach a coverage of 97% of all the registered cases, which is equal to about 75% of the estimated cases. As a result of this, the average duration of the disease (from diagnosis to cure) was reduced to between 2 and 4 years (taking into consideration defaulting and incomplete treatment), as shown by the annual prevalence reaching 1·4 million cases in 1996 (period prevalence including new case detection of 0·56 million cases during the same year).

Assuming that introduction of MDT was successful in ''clearing'' the accumulated backlog of prevalence, i.e. curing most of the already known cases, a new situation has now arisen. For the first time in the history of leprosy control, detection and prevalence are converging, and it is becoming increasingly obvious that detection to a large extent really reflects a hidden prevalence which was not very well perceived before. A large part of detection currently consists of cases accumulated over a period of time and therefore the situation should now be analysed from a different perspective. It is a fact that globally, and at national level in many countries, detection has been increasing significantly over the last 10 years to reach a plateau of about half a million new cases per year. How can this increase and its persistence be explained? Is the incidence of leprosy really increasing in many countries? Is it the result of the impact of the elimination strategy leading to stronger political commitment and improved coverage of health services? Is it just the effect of an improved information system, or changes in case-finding methods? Is it an after-effect of the ''cleaning of registers'' forcing some programmes to bring back some patients from the cleaned prevalence pool to the new detection pool? Was the leprosy problem so much underestimated that the backlog is much higher than expected? In all probability several of the factors mentioned above have contributed to the current situation. However, it is difficult to estimate the proportionate contribution attributable to any one of the above factors to the stagnation of case detection trends.

Available information on global leprosy trends, 1985–1996

Consistent information on leprosy covering a period of 12 years has been provided to WHO by the majority of national programmes. The top 28 countries have been included in this report and they represent 95% of the current leprosy burden in the world and 80% of the leprosy burden as it was in 1985. This information is presented in Table 1.

Between 1985 and 1996, while a steep reduction in prevalence can be observed (78%) in this group of top leprosy endemic countries, the trend in cases newly detected every year (absolute numbers and rates) is stable. Interpretation of this trend needs to take into consideration many factors, including the extent of the reliability and coverage of information systems. The weight of India in relation to global figures is so important that it could mask variations observed in other parts of the world. Table 2 shows leprosy trends in 27 endemic countries with the exception of India. The prevalence trend is steeply decreasing (70%), while the detection trend is significantly increasing, especially after 1991. When analysing indirect indicators such as detection of children below the age of 15 years, detection of multibacillary (MB) cases and proportion of disabled patients among newly detected cases, the situation seems to be even more interesting. While the child-specific detection rate per 100 000 population was 8·0 in 1985 and 8·9 in 1996 (1·1 and 2·3 excluding India), the peak of 15 per 100 000 was reached during 1991. The proportion of patients disabled at the time of diagnosis decreased from 9·7% to 5·4%, but excluding India, this proportion has increased from 6·8% to 10·3%. While the detection rate per 100 000 of MB leprosy was 5·9 in 1985 and 7·1 in 1996 (1·9 and 4·7 without India), the peak of 10·2 was reached in 1992. All these indirect indicators are traditionally used to interpret detection tends and assess the level of transmission of the disease.

Table 1. Leprosy trend in 28 endemic countries combined,[a] 1985–1996

Tableau 1. Tendances de la lèpre dans l'ensemble de 28 pays d'endémie,[a] 1985–1996

End of the year / Fin de l'année	Prevalence (rate per 10 000) / Prévalence (taux pour 10 000 habitants)	Detection (rate per 100 000) / Détection (taux pour 100 000 habitants)	New case-detection (rate per 100 000) / Détection de nouveaux cas (taux pour 100 000 habitants)					
			Children (below 15 years) / Enfants (moins de 15 ans)		Disabled (WHO Grade 2) / Incapacités (catégorie 2 OMS)		Multibacillary / Multibacillaire	
			Number / Nombre	%	Number / Nombre	%	Number / Nombre	%
1985	3 870 547 (20·2)	543 965 (28·4)	60 869 (8·0)	11·19	52 725 (2·8)	9·69	112 881 (5·9)	20·75
1986	3 940 462 (20·2)	568 583 (29·1)	67 597 (8·7)	11·89	53 876 (2·8)	9·48	117 922 (6·0)	20·74
1987	3 871 164 (19·4)	590 368 (29·6)	72 663 (9·1)	12·31	51 045 (2·6)	8·65	130 475 (6·6)	22·10
1988	3 643 687 (17·9)	548 642 (27·0)	71 432 (8·8)	13·02	44 881 (2·2)	8·18	118 377 (5·8)	21·58
1989	3 411 895 (16·5)	546 420 (26·4)	81 909 (9·9)	14·99	43 904 (2·1)	8·03	122 009 (5·9)	22·33
1990	2 882 077 (13·6)	567 411 (26·8)	83 220 (9·8)	14·67	45 118 (2·1)	7·95	150 629 (7·1)	26·55
1991	2 333 762 (10·8)	608 429 (28·2)	131 467 (15·2)	21·61	46 176 (2·1)	7·59	188 354 (8·7)	30·96
1992	1 806 352 (8·2)	661 549 (30·0)	110 041 (12·5)	16·63	49 875 (2·3)	7·54	223 849 (10·2)	33·84
1993	1 478 352 (6·6)	610 524 (27·2)	105 995 (11·8)	17·36	50 020 (2·2)	8·19	213 889 (9·5)	35·03
1994	1 162 333 (5·1)	549 100 (23·9)	94 989 (10·4)	17·30	43 043 (1·9)	7·84	191 329 (8·3)	34·84
1995	916 305 (3·9)	548 266 (23·4)	89 150 (9·5)	16·26	39 633 (1·7)	7·23	191 603 (8·2)	34·95
1996	837 571 (3·5)	544 639 (22·8)	85 002 (8·9)	15·61	29 488 (1·2)	5·41	168 406 (7·1)	30·92
Total		6 887 896	1 054 334	15·31	549 784	7·98	1 929 723	28·02

[a] Bangladesh, Brazil, Cambodia, Chad, Colombia, Congo, Egypt, Ethiopia, Guinea, India, Indonesia, Madagascar, Mali, Mexico, Mozambique, Myanmar, Nepal, Niger, Nigeria, Pakistan, Philippines, Sudan, Thailand, Venezuela, Viet Nam, Yemen, Zaire, Zambia.—Bangladesh, Brésil, Cambodge, Colombie, Congo, Egypte, Ethiopie, Guinée, Inde, Indonésie, Madagascar, Mali, Mexique, Mozambique, Myanmar, Népal, Niger, Nigéria, Pakistan, Philippines, Soudan, Tchad, Thailande, Venezuela, Viet Nam, Yémen, Zaïre, Zambie.

Table 2. Leprosy trend in 27 endemic countries combined,[a] India excluded, 1985–1996

Tableau 2. Tendances de la lèpre dans 27 pays d'endémie,[a] sans l'Inde, 1985–1996

End of the year Fin de l'année	Prevalence (rate per 10 000) Prévalence (taux pour 10 000 habitants)	Detection (rate per 100 000) Détection (taux pour 100 000 habitants)	New case-detection (rate per 100 000) Détection de nouveaux cas (taux pour 100 000 habitants) Children (below 15 years) Enfants (moins de 15 ans)		Disabled (WHO Grade 2) Incapacités (catégorie 2 OMS)		Multibacillary Multibacillaire	
			Number Nombre	%	Number Nombre	%	Number Nombre	%
1985	954 547 (8·3)	66 965 (5·8)	4 869 (1·1)	7·3	4 548 (0·4)	6·8	22 251 (1·9)	33·2
1986	923 462 (7·8)	61 583 (5·2)	4 597 (1·0)	7·5	4 697 (0·4)	7·6	21 592 (1·8)	35·1
1987	909 164 (7·6)	71 368 (5·9)	4 663 (1·0)	6·5	7 968 (0·7)	11·2	26 675 (2·2)	37·4
1988	808 687 (6·6)	74 642 (6·1)	5 432 (1·1)	7·3	6 961 (0·6)	9·3	28 317 (2·3)	37·9
1989	778 895 (6·2)	80 420 (6·4)	5 909 (1·2)	7·3	7 090 (0·6)	8·8	28 809 (2·3)	35·8
1990	752 077 (5·9)	86 411 (6·8)	7 220 (1·4)	8·4	9 043 (0·7)	10·5	35 189 (2·8)	40·7
1991	660 762 (5·1)	91 429 (7·0)	9 467 (1·8)	10·4	7 918 (0·6)	8·7	38 424 (2·9)	42·0
1992	639 352 (4·8)	114 549 (8·6)	10 041 (1·9)	8·8	11 038 (0·8)	9·6	54 279 (4·1)	47·4
1993	536 352 (3·9)	116 524 (8·6)	11 995 (2·2)	10·3	12 780 (0·9)	11·0	65 689 (4·8)	56·4
1994	422 333 (3·0)	122 100 (8·8)	12 989 (2·3)	10·6	13 013 (0·9)	10·7	63 229 (4·6)	51·8
1995	343 305 (2·4)	122 695 (8·7)	13 150 (2·3)	10·7	13 247 (0·9)	10·8	63 932 (4·5)	52·1
1996	283 778 (2·0)	129 337 (9·0)	13 359 (2·3)	10·3	13 381 (0·9)	10·3	68 203 (4·7)	52·7
Total		1 138 023	103 691	9·1	111 684	9·8	516 589	45·4

[a] Bangladesh, Brazil, Cambodia, Congo, Chad, Colombia, Egypt, Ethiopia, Guinea, Indonesia, Madagascar, Mali, Mexico, Mozambique, Myanmar, Nepal, Niger, Nigeria, Pakistan, Philippines, Sudan, Thailand, Venezuela, Viet Nam, Yemen, Zaire, Zambia.—Bangladesh, Brésil, Cambodge, Colombie, Congo, Egypte, Ethiopie, Guinée, Indonésie, Madagascar, Mali, Mexique, Mozambique, Myanmar, Népal, Niger, Nigéria, Pakistan, Philippines, Soudan, Tchad, Thailande, Venezuela, Viet Nam, Yémen, Zaïre, Zambie.

At first glance, one might think that incidence of leprosy is remaining the same, or is even increasing in some parts of the world, despite the considerable reduction in the size of the reservoir. This is in contradiction with information collected through some special studies which show that the incidence of leprosy is decreasing by about 10% a year. However, an increasing detection trend with a decreasing incidence trend is compatible when a significant number of backlog cases exist in the community. In one way, increasing detection trends provide reassurance, since they clearly demonstrate the effectiveness of the global elimination strategy in identifying the backlog cases for treatment with MDT. This is likely to be the scenario in countries which still have a high endemicity for leprosy and where the programmes are continually expanding their activities to previously uncovered areas, leading to improvement in their case-finding activities. However, considering that leprosy distribution is very uneven among countries and that different countries in the world started with different levels of prevalence and incidence, and considering the variations in the intensity of control operations among countries, it is useful to analyse the situation according to different country groupings and regions of the world.

AFRICA

Leprosy prevalence and detection have significantly decreased in some previously highly endemic countries such as Benin, Burkina Faso, Côte d'Ivoire, Kenya, Malawi, Togo and Uganda. In most of these countries, leprosy elimination was the result of large-scale implementation of MDT starting more than 10 years ago, increased coverage with BCG immunization and involvement of general health services in leprosy control activities.

On the other hand, countries presented in this study (Chad, Congo, Ethiopia, Guinea, Madagascar, Mali, Mozambique, Niger, Nigeria and Zaire) have not yet reached the elimination target. In most of these countries (Chad, Guinea, Madagascar, Mali, Mozambique and Nigeria) detection has considerably increased as a result of vigorous efforts to expand leprosy control activities and to implement MDT on a large scale during the 1990s. Preliminary information collected through special monitoring indicates that incidence of leprosy could still be very high in some districts of Guinea and Madagascar. In Ethiopia, where an excellent MDT programme had been implemented in the 1980s, it is not clear why the detection trend remains stagnant. It seems that, after the impressive results achieved with the MDT programme, lower priority was given to leprosy elimination activities. In Zaire, the detection trend is closely related to operational factors considering that less than 50% of the country is covered by leprosy control activities.

AMERICAS

While leprosy is declining in almost all countries of the Region, the weight of Brazil explains the increasing detection trend. The detection trend has been on the increase in Brazil since the beginning of the national programme. This has been analysed extensively, and the most likely explanation is that the increase is linked with the expansion of control activities and the number of health staff involved in the programme. Considering the geographical and demographic peculiarities of Brazil, one could expect that the detection will continue to increase over the next few years, along with implementation of the elimination programme in uncovered northern states.

SOUTH-EAST ASIA

With the exception of India, the leprosy trend in South-East Asia follows the same pattern as in Africa and Latin America. Declining detection trends were observed only in Maldives, Sri Lanka and Thailand. The detection trend is increasing in Bangladesh, Indonesia, Myanmar and Nepal. In Bangladesh, increased detection can be explained by the more recent and relatively late implementation of a national elimination programme. The Indonesian and Nepalese leprosy pattern could be explained by the slowly increasing geographical coverage. In Myanmar, the rapid expansion of leprosy elimination activities to

all townships started only in 1992, leading to an initial increase in detection followed by the current tendency to stabilize.

Levels of prevalence and detection in India are much higher than in any other country and thus are presented separately in Table 3.

Although the detection trend is declining in India, the current rate is still very high and the decline is not as fast as one could expect. This can be explained by the fact that over the last 40 years, efforts were mainly concentrated in the states which were originally considered as major endemic states. In these states (e.g. Andhra Pradesh, Maharashtra and Tamil Nadu), both prevalence and detection rates have significantly decreased. The profile of cases newly detected in these states (high proportion of single lesion leprosy, low incidence of MB, low disability rate) indicates that the disease is being diagnosed very early through a very active vertical programme involving thousands of workers. In this context, target setting for detection as well as low specificity of diagnosis could partly explain the slow decrease in trends. On the other hand, states which were originally not considered as highly endemic (e.g. Bihar, Madhya Pradesh and Uttar Pradesh) are now getting higher priority. In these states implementation or strengthening of leprosy elimination activities in recent years has led to an increasing detection rate, mainly of backing cases. The combination of these factors could explain the overall high rates and slow progress in India, which is a matter of concern. Considering that MDT on a wide scale has been implemented only recently in these states, and that the geographical coverage with MDT services is still low, it would be unrealistic to expect major changes in the epidemiological trend of the disease in the near future.

EASTERN MEDITERRANEAN

While leprosy is no longer a public health problem in most of the countries of this Region, it is felt that the disease has often been underreported. This renders trend analysis difficult. However, recent implementation of national elimination programmes in some countries, notably Sudan, explains why the detection trend is on the increase, though the levels of detection remain very low (around 2 per 100 000).

WESTERN PACIFIC

Remarkable results were registered in many countries of this Region, where leprosy was eliminated as a public health problem during the current decade. However, countries included in this analysis are reporting increasing detection trends. In Cambodia, this can be explained by the relatively more recent introduction of a national elimination programme. In the Philippines, despite the early implementation of MDT, the detection trend is increasing. This increase is linked with improved geographical coverage, implementation of community awareness campaigns and an improved information system.

Conclusions

Because data reproduced here cover several countries with large populations, it is very likely that changes in detection trends mainly reflect changes in the intensity of programme activities, rather than variations in the transmission of the disease. High and increasing detection rates are more often related to expanding geographical coverage of leprosy services. The main factor which contributes to increasing and then stabilizing global detection trends during the studied period is the expansion of geographical coverage with MDT services through dynamic national elimination programmes, the integration of leprosy activities within general health services and, more recently, introduction of elimination campaigns and special action projects with the specific aim of reaching uncovered areas and underserved populations. It can be estimated that before 1985, coverage with adequate MDT services was less than 20% which has steadily increased to reach around 75% in 1996.

The fact that the trend in the global leprosy detection has not changed over the last 12 years should

Table 3. Leprosy trend in India, 1985–1996

Tableau 3. Tendance de la lèpre en Inde, 1985–1996

End of the year Fin de l'année	Prevalence (rate per 10 000) Prévalence (taux pour 10 000 habitants)	Detection (rate per 100 000) Détection (taux pour 100 000 habitants)	New case-detection (rate per 100 000) Détection de nouveaux cas (taux pour 100 000 habitants) Children (below 15 years) Enfants (moins de 15 ans)		Disabled (WHO Grade 2) Incapacités (catégorie 2 OMS)		Multibacillary Multibacillaire	
			Number Nombre	%	Number Nombre	%	Number Nombre	%
1985	2 916 000 (38·6)	477 000 (63·1)	56 000 (18·5)	11·7	48 177 (6·4)	10·1	90 630 (12·0)	19·0
1986	3 017 000 (39·1)	507 000 (65·7)	63 000 (20·4)	12·4	49 171 (6·4)	9·7	96 330 (12·5)	19·0
1987	2 962 000 (37·6)	419 000 (65·9)	68 000 (21·6)	16·2	43 077 (5·5)	10·3	103 800 (13·2)	24·8
1988	2 835 000 (35·3)	474 000 (59·0)	66 000 (20·5)	13·9	37 920 (4·7)	8·0	90 060 (11·2)	19·0
1989	2 633 000 (32·1)	466 000 (56·8)	76 000 (23·2)	16·3	36 814 (4·5)	7·9	93 200 (11·4)	20·0
1990	2 130 000 (25·5)	481 000 (57·5)	76 000 (22·7)	15·8	36 075 (4·3)	7·5	115 440 (13·8)	24·0
1991	1 673 000 (19·6)	517 000 (60·6)	122 000 (35·7)	23·6	38 258 (4·5)	7·4	149 930 (17·6)	29·0
1992	1 167 000 (13·4)	547 000 (62·8)	100 000 (28·7)	18·3	38 837 (4·5)	7·1	169 570 (19·5)	31·0
1993	942 000 (10·6)	494 000 (55·6)	94 000 (26·4)	19·0	37 240 (4·2)	7·5	148 200 (16·7)	30·0
1994	740 000 (8·2)	427 000 (47·1)	82 000 (22·6)	19·2	30 030 (3·3)	7·0	128 100 (14·1)	30·0
1995	573 000 (6·2)	425 571 (46·0)	76 000 (20·5)	17·9	26 386 (2·9)	6·2	127 671 (13·8)	30·0
1996	553 793 (5·9)	415 302 (44·0)	71 643 (19·0)	17·3	16 107 (1·7)	3·9	100 203 (10·6)	24·1

not be interpreted as a weakness of the global elimination strategy. More detailed analysis shows that the detection trend is even on the increase in many of the endemic countries. With the exception of India, trends and patterns in newly detected cases are comparable in most countries. Africa, the Americas and South-East Asia show similar increasing trends and similar rates (detection rate around 10 per 100 000 population, child-specific detection rate of 2 per 100 000 population). The Eastern Mediterranean and the Western Pacific also show increasing trends but at a lower level. India alone, while showing a decreasing trend, presents a very high level of endemicity with a detection rate of around 45 per 100 000 population and a child-specific detection rate of around 20 per 100 000 population. The fact that in all the countries studied the specific detection of MB cases has increased should be interpreted with caution if we consider that the definition of MB cases has changed several times during the studied period. However, the number of skin-smear positive new cases has significantly decreased to reach an estimated number of about 70 000 in 1996. This indicates that important epidemiological and operational changes are occurring in the process of eliminating the disease.

While information is lacking on how to estimate the current annual incidence of the disease from case detection figures, it can reasonably be assumed that incidence represents no more than one-third of the annual detection. If this assumption is true, and if vigorous efforts such as leprosy elimination campaigns, including community awareness activities continue to be organized, then one could expect a rapid and considerable decrease in global detection rates in the next 2–3 years. However, it should be recognized that in a limited number of countries or areas where levels of endemicity are still very high, or where it will be operationally difficult to increase the geographical coverage, there are considerable challenges to achieving the elimination target on time.

Genetic traits in common diseases: is autoimmunity the price paid for eradicating infectious diseases?

The following, by A. G. Wilson and G. W. Duff of the Section of Molecular Medicine, Dept of Medicine & Pharmacology, University of Sheffield, Royal Hallamshire Hospital, Sheffield S10 2JF, is extracted from the *British Medical Journal*, **310,** 1482:

An important current topic of medical research is the localization of genes implicated in the susceptibility to common chronic diseases such as insulin dependent diabetes, rheumatoid arthritis, and multiple sclerosis. This has been greatly facilitated by the use of the polymerase chain reaction to characterise polymorphic microsatellite markers and the advent of automated technology and computer software to construct high resolution genetic maps covering the entire genome.

A recent example of the success of these methods occurred in the genome-wide search in families for genes conferring susceptibility to insulin dependent diabetes.[1] Population studies, based on epidemiological principles, test the association of disease with specific genetic markers, and recent advances have also been made with this approach.

Most of these common diseases are clearly polygenic, involving several loci, and many population association studies leave little doubt that an appreciable genetic component of immunopathology lies in the major histocompatibility complex. This is a four megabase stretch of DNA (about 0·1% of the human genome) located on the short arm of chromosome 6 and containing up to 200 genes, many of which are immunologically relevant. Within the major histocompatibility complex lies the gene for tumour necrosis factor α, a potent proinflammatory cytokine implicated in the pathogenesis and clinical manifestations of many inflammatory and infectious conditions.[2] In view of its chromosomal location and biological effects there has been speculation that polymorphism within the gene for tumour necrosis factor α may play a part in the genetic association of the major histocompatibility complex with at least some of these diseases.[3]

A biallelic polymorphism has been described in the gene for tumour necrosis factor α in a region that controls transcription.[4] The rarer allele, TNF2, is part of the HLA Al-B8-DR3-DQ2 haplotype,[5] which is associated with many autoimmune diseases.[6,7] A preliminary study in coeliac disease, which is

strongly associated with HLA-DQ2, found carriage of TNF2 in 96% of patients compared with 21% of controls, suggesting that a second susceptibility locus on this haplotype may lie close to, or within, the locus for tumour necrosis factor.[8]

In malaria high plasma concentrations of tumour necrosis factor α are associated with more severe disease, with the highest concentrations occurring in fatal cases of cerebral malaria.[9] A study of genotypes for tumour necrosis factor α in west African patients with malaria has shown that homozygosity for the TNF2 allele is associated with a sevenfold increased risk of death or severe neurological complications due to cerebral malaria.[10] Furthermore, the TNF2 allele in gene assays directs higher levels of transcription of the gene compared with the common allele, suggesting that this polymorphism directly affects production of tumour necrosis factor α.[11]

Malaria or systemic lupus erythematosus?

An interesting observation is the apparent protection from autoimmune diseases in areas of west Africa where malaria is endemic,[12] in contrast to the high incidence of systemic lupus erythematosus in Afro-American populations, who are mostly of west African descent.[13] This has led to speculation that high concentrations of tumour necrosis factor α induced by malaria in west Africa may protect against systemic lupus erythematosus. In support of this idea, protective effects of recombinant tumour necrosis factor α in the $(NZB \times NZW)_{F1}$ mouse model of lupus have been cited,[14] and infection of this strain with *Plasmodium berghei* prevents the development of the lupus-like disease.[15] The TNF2 allele may be responsible for the lower incidence of lupus in Africa, resulting from endemic malaria, while the absence of this stimulant of the production of tumour necrosis factor α allows for the increased incidence of this disease in Afro-Americans. If this is correct it would be a good example of the old clinical adage that "autoimmunity is the price paid for eradicating infectious diseases."

Despite the adverse effects of homozygosity in malaria, TNF2 is maintained at a similar frequency in west African and northern European populations, which suggests that compensatory pressures in Africa exist to maintain the allele. Perhaps it has beneficial effects in other important infectious diseases such as measles, meningococcal disease, leprosy, or tuberculosis. There may also be heterozygous advantages.

The efficacy of treatment with antibodies to tumour necrosis factor α is being investigated in several diseases and has been shown to be beneficial in rheumatoid arthritis.[16] Determining patients' genotype for tumour necrosis factor before starting treatment may permit the selection of patients who are genetically predisposed to produce high concentrations of this cytokine and who might therefore benefit most from this treatment. The prospect of targeting treatment at those predicted to gain most therapeutic benefit clearly has important clinical and economic consequences, particularly in diseases of high prevalence such as malaria. Clinical benefits may result from this research by the end of the decade.

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WHO Report of the Second Meeting of the Leprosy Elimination Advisory Group (LEAG), 14 October 1996, New Delhi, India

The participants were welcomed to the meeting by Professor M. F. Lechat (LEAG Chairman) and Dr S. K. Noordeen, Director of WHO's Action Programme for the Elimination of Leprosy (LEP). Dr Noordeen then reviewed the current world leprosy situation. The total numbers of estimated and registered cases in the world have continued to decline and currently stand at 1·3 million and 940 0000 compared with 10–12 million and 5·4 million respectively in 1985. Thus far 8 million cases have been cured by MDT, reducing the leprosy burden by 80–85%, but we will need to reduce it by 97% to reach the goal of 1/10 000 by the year 2000. An additional 2 million cases (1·5 million from South-East Asia) will be added to the total between now and the year 2000, with over 500 000 now being diagnosed annually. To achieve elimination, our efforts must be intensified and strategies utilized to reach every patient in every village; 60% to 65% could be reached by current control efforts, another 30% by LEC and 5–10% by SAPEL projects. There is excellent commitment to the goal, and at a separate meeting the 14 health ministers attending the Conference all agreed to fully cooperate in reaching it.

In discussion following Dr Noordeen's presentation three questions were raised. One concerned the accuracy of the prevalence and detection figures, but all agreed that the current approach to data collection by countries and through other documentary sources is the best we can do at this point. The second related to the extent of over-diagnosis of paucibacillary (PB) disease, and the third raised the issue of recycling patients, i.e., repeatedly re-treating cases who do not quite receive 6 doses of MDT within 9 months (PB) or 24 doses within 36 months (MB). As regards the second question, efforts to improve diagnosis and simplify treatment of single-lesion leprosy are underway, while the third question was dealt with in part by the Chemotherapy of Leprosy Study Group in 1993, i.e., evaluation of each case to determine if they need re-treatment. Nonetheless, the group felt that both issues should be addressed in the upcoming 7th Expert Committee Meeting.

The main headings of the report include—report of Special Action Projects (SAPEL), progress with Leprosy Elimination Campaigns (LEC), Task Force on Monitoring and Evaluation (MEE), Capacity Building and Health Systems Research (CBH), Drug Supply Management, Post-elimination issues and leprosy elimination in the WHO Regions. The section on drug supply management is of considerable practical importance and reads as follows –

An overview of this topic was given by Dr Daumerie. Careful management of the available drug

supply is vital if waste is to be avoided. In particular, countries are encouraged to utilize the oldest stocks of drugs first, before they expire. Reviewing 1996, it was noted that the number of requesting countries is increasing (40) and MDT coverage is over 90%, packaging of drugs has improved and the price has been reduced. MDT drugs are now shipped as perishable goods and more than 7.5 million blister packs were delivered in 1996, which provided treatment for about 920 000 patients. Distribution at the sub-national level is still not adequate, but slow progress is being made in making MDT available at all health centres. Various quality control steps are also in place, including batch testing, field testing of MDT from various manufacturers and package testing.

Monitoring of the drug supply is an important part of the distribution. Positive points insofar as monitoring is concerned are the improved quality of treatment and motivation of health workers. MDT blister packs are now available at the national level in all endemic countries, and distribution to patients is free. Furthermore, the reporting and monitoring systems have improved even in the difficult countries. The availability of buffer stocks in the various countries could help in decentralizing MDT treatment. Negative points in the monitoring system include difficulties in accurately estimating MDT needs and the large quantities of loose drugs (i.e., those not in blister packs) available in some areas, in particular among other programmes which use rifampicin, such as tuberculosis. There continues to be some lack of coordination with government and other agencies which provide MDT, and difficulties remain in updating information on the drug flows. Finally, there is often a lack of involvement of general health services.

Actions being taken to improve drug supply management include providing more information on availability of MDT, widely distributing guidelines, posters and a pocket guide, and implementing standardized procedures for assessing drug supply. MDT monitoring teams will be set up to review the situation at the country level, and the use of GIS will be promoted as will the use of MDT at the most peripheral levels.

Since 1995, about 1·5 millions patients are treated annually with MDT and about 700 000 patients are cured annually. Current global stocks of MDT are 13 million blister packs, or the equivalent of 1·5 million patient-years of treatment. The global buffer stock is sufficient and national managers can be confident that it is now possible to implement MDT in every health facility. Nonetheless, there is a need to maintain the highest possible coverage with MDT and to improve involvement of national managers in the drug supply. Simplification of the global information system on MDT management would help, as would improved and focused monitoring at the national level.

During the discussion that followed the presentation, it was noted that buffer stocks of drugs are vital because of occasional blocks in the government supply. It was also noted that storage is sometimes a problem, particularly at the peripheral level where proper storage may not be available. As a remedy for this, it was suggested that stocks be kept at a more central level, where proper facilities are available, and be sent out somewhat closer to the time they will actually be used.

Currently MB blister packs cost US$1·72 each, or about US$40·00 for 24 packs, while PB blister packs cost US$0·5 or US$3·0 for 6 packs. At the present time WHO is providing 100% of the drug needs in 22 of the 40 countries where the drugs are distributed.

Annex 1 (pages 10 + 11) of this Report gives the Recommendations of the *2nd International Conference on the Elimination of Leprosy*, 11–13 October 1996, New Delhi, India, which read as follows:

The Second International Conference on the Elimination of Leprosy, convened on the initiative of the World Health Organization in New Delhi, India, from 11 to 13 October 1996, mindful of the commitment of all Member States of WHO, under World Health Assembly Resolution WHA44.9, of 1991, ''to continue to promote the use of all control measures including Multidrug Therapy (MDT) together with case-finding in order to attain the global elimination of leprosy as a public health problem by the year 2000'', endorses the updated WHO global strategy and the intensified plan of action, and RECOMMENDS that:

- All parties concerned—national governments, non-governmental organizations and international agencies—should recognize the unprecedented opportunity available now to reach the goal of

eliminating leprosy as a public health problem, particularly in the light of the remarkable progress made so far, and that they intensify their political commitment and efforts to reach the remaining patients before the year 2000, bearing in mind that there is no room for complacency if the goal is to be attained.

- The remaining problem of leprosy treatment will be far more difficult as it includes hitherto neglected areas, population groups and communities. It is important that programme managers develop special intensive operations to reach them through such mechanisms as leprosy elimination campaigns (LEC) to detect hidden cases and special action projects (SAPEL) to reach difficult-to-access patients among under-served population groups such as nomads, refugees, migrants, etc.
- Ministries of Health in endemic countries should take immediate steps to further involve health personnel from the general health services in the treatment of leprosy patients, as well as in case-detection, so that these activities are adequately integrated into the general health services. Even as integration within the general health services is achieved, the quality of services provided to patients should be assured.
- As the technology employed to reach the leprosy elimination goal is essentially through the treatment of patients with multidrug therapy (MDT), it is extremely important that the free supply of WHO recommended MDT drugs in blister packs to patients be continued without interruption to ensure every patient has access to MDT.
- In order to ensure that all patients have access to MDT and that the progress being made towards leprosy elimination can be accurately assessed, the special initiative of leprosy monitoring (LEM) should be implemented as soon as possible.
- In view of the continued social problems faced by persons affected by leprosy, it is highly important to further intensify our efforts at creating community awareness of the disease and its curability, and to mobilize community action towards the elimination of leprosy. It is important that persons affected by leprosy be actively involved as partners in this process.
- Even as leprosy patients are being cured of the disease, many of them continue to face problems in rehabilitating and reintegrating themselves within their communities, and consequently every attempt should be made to bring persons disabled due to leprosy and their rehabilitation within the general ambit of all disabled in the community and within existing community-based rehabilitation programmes.
- At this critical stage in the progress being made towards reaching the target, there is an urgent need for all to step up the coordination and mobilization of the resources needed—finance, manpower and planning for the future. This is particularly important for all partners, including governments, international donors and nongovernmental organizations.
- It is important that research activities in leprosy be continued, especially with regard to the operational aspects, chemotherapy and treatment of complications of leprosy. The understanding of the basic biological mechanisms of this disease is important for developing potential tools that may lead to eventual eradication.
- Countries, as they reach the elimination goal at the national level, should focus their attention on the target of elimination at the sub-national levels, and sustain leprosy treatment and rehabilitation activities. It is important to ensure that services are capable of continuing to detect and treat new cases, and to respond to physical and social needs faced by individuals who have been affected by the disease. The efforts to ensure elimination as a public health problem will lay the foundation for our ultimate vision of the total eradication of leprosy in the future.

WHO Meeting on Chemotherapy Research in Leprosy, Madras, India, 6–7 January 1997

About 30 Principal Investigators Experts and WHO Leprosy Staff met for two days in the ICMR Tuberculosis Research Centre, Chennai (Madras) to assess the current status of WHO-organized drug trials in the chemotherapy of leprosy.

In his opening address, Dr S. K. Noordeen commented that, although the first generation of anti-leprosy chemotherapy regimens (WHO MDT) was giving good results, an interesting stage had been reached in the investigation of second generation regimens. However, although we now possessed 'more than enough' anti-leprosy bactericidal drugs, it was not possible to try out all possible combinations, to find which were the most effective and acceptable, because we were limited both by the shortage of suitable trial patients and by a shortage of animals and animal facilities. Therefore a careful assessment of current data was desirable.

Before reporting on experimental chemotherapy results, Dr Ji noted that the main problems with WHO MDT were to ensure that drugs were locally available for every patient, and that the full course of all the prescribed drugs was taken by each patient. In low prevalence areas, drug regimens should be designed for easy administration by non-specialists. He then listed six objectives for second generation MDT regimens, some general, some for specific chemotherapeutic or field situations. All new regimens should be as least as active as standard WHO MDT.

Since 1990, various regimens had been studied in nude mice, involving the standard drugs, rifampicin, clofazimene and dapsone and the 'new' drugs ofloxacin, minocycline and clarithromycin. Experimental chemotherapy had its own limitations, in that normal, immunocompetant mice could only be used to detect killing of viable *M. leprae* by 4 orders of magnitude (10^{-4}), and nude mice to detect killing of about 6 orders of magnitude (10^{-6}). Nevertheless, such studies confirmed that rifampicin was more bactericidal than the 'new' drugs, and it remained essential to prevent the development of rifampicin resistance. As a single combined dose of ofloxacillin and minocycline, with or without clarithromycin, did have some significant bactericidal activity, such combinations could be used to replace clofazamine when patients refused the latter drug because of its effect on skin colour, or rifampicin in those same cases of rifampicin resistance, allergy, or toxicity. Surprisingly, 12 weeks of daily dapsone and clofazamine given to lepromatous mice resulted in a kill of more than five orders of magnitude (10^{-5}), the number of viable leprosy bacilli falling to the limits of detectable levels. This result suggested that the duration of treatment with clofazemine and dapsone could be somewhat shorter than two years without risking the emergence of rifampicin resistance should relapse occur (although it gives no indication of the likely relapse rates obtained by shortening WHO MBL MDT—Reviewer's Comment).

The rest of the first day was spent on the controlled chemical trial in single lesion paucibacillary leprosy (smear–negative T7, B7 and Indeterminate) of a single combined dose of rifampicin 600 mg, ofloxacillin 400 mg and minocycline 100 mg (adult dosage) compared with standard WHO PBL MDT. The trial design was 'double-blend', with placebo tablets being given to the trial regimen group for six months, with a follow-up period of 1 year after completing treatment, individual patients being studied for a total of 18 months. Altogether 1,484 patients had been admitted to the trial in nine centres in India, and progress reports were submitted by the Principal Investigators.

Dr Pamikar presented an analysis of 1011 patients who had completed their 18 months in the trial, more than 500 on each regimen. A simple method of scoring five different measures of clinical improvement was presented, including how invisible the lesion was, its degree of infiltration and of hypopigmentation, its size and the depth of hypo- or anaesthesia remaining. Only 4 'ROM' and 5 WHO regimen patients showed no improvement. However, two parameters) and the total score (from adding together the scores of all five parameters/showed a mild but statistically significant greater improvement among the WHO MDT patients compared to the ROM patients; three parameters showed no significant difference between the two regimens. In total, 9 patients suffered from mild reversal reactions and 12 (9 WHO and 3 ROM) developed drug reactions. It was hoped that all 1,484 patients could be analysed in time for the 7th Expert Committee on Leprosy, meeting in Geneva at the very end of June.

If the full analysis confirms the preliminary findings, then a single day's treatment of triple drug therapy will have been shown to yield a good clinical response in single lesion paucibacillary leprosy, although slightly inferior to standard PBL MDT. (What the trial has not attempted, is to assess whether there is any significant difference in the long-term relapse rates between the two regimens; it is to be

hoped that some of the collaborating centres will continue such long-term follow-up of the trial patients, to obtain data on this most important parameter—Reviewer's Comment).

The second day was spent in reviewing two other WHO drug trials, and a study of MB patient defaulters.

The Ofloxacillin Trial protocol was written in 1988, and intake of patients commenced in 1992, with 15 centres collaborating from three continents.

In MB leprosy, untreated patients with a bacterial index of 2+ or greater were eligible for admission, by random distribution, to one of four regimens, either WHO MBL MDT for 2 years (the control regimen), WHO MBL MDT for 1 year, WHO MBL MDT for 1 year plus ofloxacillin 400 mg daily for the first 28 days, or rifampicin 600 mg plus ofloxacillin 400 mg both drugs daily for 28 days (the three trial regimens. Intake was completed (of 1651 MB patients) by June, 1994; therefore all trial patients have completed their course of chemotherapy, and are now under long-term follow-up to assess relapse rates between the four regimens.

In PBL, a total of 1815 patients had been admitted, allocated by random distribution to either WHO PBL MDT (the control regimen) or to a trial regimen of rifampicin 600 mg and ofloxacillin 400 mg daily for 28 days. Long-term follow-up to assess relapse rates is likewise underway.

In both the MBL and PPL trials, the regimens are also being assessed for incidence of drug toxicity and of reactions, and their general acceptability.

The more recent trial, a second ''ROM'' study, has commenced in three field programmes. The trial, which is uncontrolled, consists of monthly doses of rifampicin, ofloxacillin and minocycline. In MBL, half the intake will receive 24 doses, and half 12 doses. In PBL, half will receive six doses, and half three doses. Every drug administration will be supervised, with patient contact every 4 weeks or month. Long-team follow-up is planned. To date, the ROM regimen has been well accepted and is technologically very simple.

Finally, three studies were presented of the subsequent fate of patients who had absconded from WHO MBL MDT before completing 24 doses. Defaulters could be difficult to trace because of incorrect or wrong addresses. Most of those traced showed a continuing fall in their BIs, and many had become smear negative, confirming how 'robust' standard MBL MDT. It is, of course, possible is (as one presenter suggested), that patients who had run into trouble had already reported back, but the general impression was of continuing improvement. Further studies, especially long-term studies over 5–10 years would be of interest.

WHO should be thanked for organizing such a stimulating and informative meeting.

4th International Leprosy Meeting, Istanbul, Turkey held 28–30 April 1997

This international meeting was organized by Professor Türkan Saylan and colleagues from the Istanbul Leprosy Hospital and the Turkish Association for Leprosy Relief Work. Its main topic was ''Where are we in the struggle of leprosy while approaching to 2.000?'' Thus the purpose was to consider lessons learned from the past 20 years of leprosy work in Turkey and their implications for the years ahead.

Participants included leprosy experts from various parts of Turkey and colleagues from overseas, the chief of whom was Dr. S. K. Noordeen, Director of the W.H.O. Programme for the Elimination of leprosy. Other contributors came from Denmark, Ethiopia, India, the Netherlands, the United Kingdom and the United States of America. All had earlier been involved as facilitators in the Turkey programme. The meeting was formally opened by speeches from the Rectors of Istanbul's two main Universities followed by the reading in absentia of an address submitted by Dr. Paul W. Brand that emphasised the need to preserve with leprosy work until all problems were seen to have been resolved. Mrs. Rina Perolini–Bohner represented Emmaus Suisse and spoke of their support of the work in Turkey over many years.

In his first address to the meeting Dr. S. K. Noordeen described the benefits of setting the year 2,000

as a target for leprosy elimination as a public health problem, stressed the success of MDT in drastically reducing the disease endemicity and spoke of remaining challenges: those of reaching patients not yet having access to MDT and of improving rehabilitation of the disabled. He referred to the awakening of a scientific outlook towards medical aspects of leprosy over the past 150 years its emphasis being more towards studying the descriptive aspects of leprosy, including the various clinical manifestations, and less towards findings ways to effectively deal with the disease situation in the individual and the community.

Meeting sessions focused on the history and development of leprosy programmes in Turkey and elsewhere, on state of the art treatment of leprosy, on current drug trials, on action to counter eye and nerve impairment and on the contribution of reconstructive surgery. The final day was spent in a visit to the Istanbul Leprosy Hospital, with further presentations regarding leprosy work in Turkey and the training programme offered by ALERT, Ethiopia. At a closing forum, participants summarised their conclusions as follows:

1 It is clear that Turkey has made phenomenal progress in reducing leprosy dramatically during the past 10 to 15 years, both in regard to the incidence and prevalence burdens and in regard to new case occurrence. It is vital that the pressure to identify and treat the remaining cases is maintained. An objective is to identify and treat new cases before they develop nerve function impairment. Hence the importance of community understanding that cure is possible and recognition of the early signs of leprosy.
2 WHO-recommended MDT remains the centrepiece of leprosy chemotherapy. However there is considerable promise of improved drug regimens for the future involving newer drugs such as Ofloxacin, Minocycline and Clarithromycin.
3 It is important that persons affected by leprosy (PALs) and their family members have opportunity to learn how they can help themselves and one another and are encouraged in self-reliance where ever feasible. Initiatives of IDEA (International Association for Integration, Dignity and Economic Advancement) provide welcome examples of mutual support activities.
4 Staff activities both to prevent impairment and handicap, and to rehabilitate those already handicapped, involve teamwork so that social, psychological and functional problems are countered. Social help needs to be offered together with action to prevent disability. Turkey is to be congratulated on the effective teamwork that has already been established between social workers, psychologist, ophthalmologists, surgeons, physiotherapist, nurses, shoemakers and dentists. Many experts contribute their services on a voluntary basis.
5 The importance of eye care is emphasised. Ophthalmologists are few and where there is no nearby support to overcome developing eye problems, blindness may result. This is potentially catastrophic where accompanied by hand or foot sensory loss. Hence the urgent need for the training of general health workers in eye care. It is proposed that specialist eye care training be given to nurses so that they can become a local resource.
6 One aim of rehabilitation is that PALs become economically self-supporting. A further aim is that family members of disabled or elderly PALs can be helped to acquire a profession by which they will be able to give needed financial and social support to disabled or elderly PALs.
7 The tasks of elimination of leprosy and support for the leprosy-affected will not be complete until no new cases emerge and existing PALs receive needed support throughout their lifetime. These needs call for involvement of young people in the struggle and for support and treatment to be available in integrated settings. Each country where leprosy is endemic needs to set its own objectives and to tailor these to its own situation taking into account the local, social conditions and the levels of impairment of those affected.
8 It is at most importance for the leprosy workers and their programs to be supported by the donor NGO's specially ILEP group as the work of leprosy due to the PALs continuous.
9 In conclusion, Dr. Noordeen stated that the phenomenal progress made so far should not lead to any complacency as this is the time to redouble our efforts to reach the year 2000 target and further ensure that progress made is sustained beyond the year 2,000 so that we can look forward to a totally leprosy-free world some time during the early part of the next century. In congratulating Professor Saylan and

Turkish leprosy workers on their achievements he said. ''This is the kind of story that I want to see in every country''.

Source: Professor Turkan Saylan, Cüzzamla Savaş Derneği Istanbul Lepra Hastanesi, Bakirköy, 34747 Istanbul.

Turkey has a total of 2,953 registered of which 2,596 are under the care and supervision of the Instanbul Leprosy Centre. Only 81 patients remain on multiple drug therapy, 1,624 having already completed treatment. In 1996, only 20 new cases were registered for the whole country. It is considered that the leprosy endemic is declining to very low levels and the main problems which now call for attention centre on the large number of patients with grade 2 disability, many of whom are aged 65 or more. The programme is supported by Aide aux Lépreux Emmaüs-Suisse (ALES) and the Novartis Foundation for Sustainable Development (previously Ciba-Geigy Leprosy Fund). A. C. McDougall.

Compliance becomes concordance

The following is extracted from the *British Medical Journal*, **314,** 691:

At long last the ''compliance problem'' may be getting a new name and, with it, a new view of the patient's role in the doctor-patient relationship. A report published this week by the Royal Pharmaceutical Society of Great Britain's working party on medicine taking recommends that ''concordance'' should replace the term ''compliance.''[1] Although substitute terms have been suggested and used previously without much impact, this eloquent analysis of the importance of a new concept by a highly visible and distinguished panel may hold the promise of change. Moreover, the panel recommends a £1·8 m ($2·7 m) research budget to support analysis of the problem and training of health professionals.

Compliance has long been criticised as denoting obedience—''following doctors' orders.'' Although many researchers and practitioners have carefully avoided the term,[2] the common alternatives—''adherence'' or ''cooperation''—do not take the user very far from compliance. One member of the working party, David Sackett, in his 1976 landmark publication, *Compliance with Therapeutic Regimens*, had already anticipated the approach advocated by the Pharmaceutical Society's report.[3] Included in the book were sensible ideas such as the ''tailored consensual regimen,'' the need for a no fault approach to behaviour relating to following a regimen,[4] and consideration of the effect of frequency of administration, side effects, delivery system, and the like—all aspects of the medication that affect compliance.[5] A subsequent publication raised the idea of a clinically relevant definition of adherence, based on the properties of a particular drug and not solely on the doctor's instructions.[6] Thus if seven days are sufficient to achieve the therapeutic effect of a drug then patients who stop the medication after ''only'' seven, eight, or nine days should not be deemed to be non-compliant even if it was prescribed for 10 days.

Despite the predominance of the term compliance, interventions have not all been aimed at the patient. Manufacturers, for example, have responded with less complex delivery mechanisms such as patches, more convenient doses such as sustained release drugs, incentives for patients to fill their first prescription and to get refills, advertising to increase the perceived value of the drug, and direct patient education. In part these developments indicate that the manufacturers understand clearly the effects of non-compliance on drug sales. But they also suggest that clinicians value drugs with features that enhance compliance.

Changes in drug trials reflect recognition of the effect of compliance on statistical power and interpretation of results.[7,8] After initial resistance to including compliance experts, some investigators began to include them when planning the trial rather than attempting to fix problems later.[9] Another approach has been pre-randomisation screening of potential participants, usually with a placebo. This approach assumes that non-compliance is a general characteristic of the person: thus a pretrial test of drug taking can reveal non-compliers.

The change in terminology will have an impact only if the culture change that the working group is advocating succeeds and clinicians take a more egalitarian view "of the relationship between prescribing and medicine-taking, between patient and prescriber."[10] It is possible to envisage doctors and patients engaging in more productive discussion of medication regimens, but the barriers are substantial. A prescription is a traditional means of ending a consultation, after most of the time has been spent on diagnosis. Perfunctory questioning about the drug at the next visit may lead patients to assume that the doctor does not place high priority on drug taking. Clinicians may simply assume the patient's compliance and see any continuing symptoms as indicating the need for more or a different medication.

More time spent should be spent assessing not only the best medication for a particular condition but also the best for a particular individual with a certain lifestyle and preferences. The concept of concordance suggests frank exchange of information, negotiation, and a spirit of cooperation. Compared with the US, conditions in Britain favour this approach. Patients and practitioners are more likely to have known one another for longer, dispensing is less impersonal, and ancillary personnel are available for follow up.

Moreover, evidence of effectiveness is available from rigorous trials, and no single method of improving compliance appears to be inherently superior.[11] With coaching and a non-judgmental attitude from the prescriber, patients are more likely to describe drug taking truthfully. Patients can be informed about dosing options and asked what would work best for them. Initial prescriptions can be regarded as a trial, not only of the drug's effect but also of the feasibility of taking it. Treating the patient as a decision maker is a fundamental step away from the compliance model.

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PATRICIA DOLAN MULLAN
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'Basic' elimination of leprosy in China

A remarkable contribution by He Da-xun and Ye Gan-yun, respectively Vice-president and President of the China, Leprosy Association, in the latest edition of *Indian Journal of Leprosy*, Volume **68**(4),

Oct-Dec 1996, describes the intention of the Ministry of Public Health to achieve 'basic elimination of leprosy' by the year 2000, with a reduction of prevalence to, or below 0·01‰ (< 1 case per 100,000 of the population). This is of course a higher target than that of WHO for elimination at less than 1 case per 10,000 of the population. The authors outline the variable prevalence situation in different parts of China which indicate that ''... it would be more reliable to calculate and evaluate the criteria for basic elimination of leprosy on a county basis.'' Up to now, Shanghai and three provinces have been approved by the Ministry of Public Health as having already met the criteria for ''basic'' elimination. The article concludes with emphasis on the attention which is being given to improving the quality of MDT implementation, epidemiological surveillance, overcoming irrational fear and discrimination and actively extending the rehabilitation programme - ''... so as to strike a blow for eradication of the disease from China biologically, psychologically and socially.''

Further enquiries; Professor Ye Gan-yun, Chinese Academy of Medical Sciences and Peking Union Medical College, 12 Jiangwangmiao Road, Nanjin-210 042, People's Republic of China.

15th International Leprosy Congress, Beijing, China, 7–12 September 1998

MESSAGE FROM THE ILA PRESIDENT

The first International Leprosy Congress held in Berlin in 1897 opened in the era of modern leprosy control. The first century of that period is now closing, with gratifying reduction in the global leprosy burden. However, there is much more to be done. We must keep leprosy, as an infectious disease, firmly under control. More significantly, we must strengthen and improve measures to deal with leprosy as a disability producing disease. These are tasks we must still face in the second century of our modern fight against leprosy.

The 15th and ''Centennial'' Congress is being organized under the main theme of ''Working toward a World without Leprosy.'' The members of our association have been the main force behind the great achievements so far, and no doubt will remain so in the new century. The last few congresses have become much more than a meeting of our members, non-member participants outnumbering members two or even three to one. These are mostly field workers, both medical and nonmedical, of the leprosy-endemic countries. Their share of responsibilities are bound to increase. The 15th International Leprosy Congress intends to meet their interests and needs as much as those of our own members.

I extend my cordial invitation to all those interested and concerned in solving leprosy problems. Let us make the Beijing Congress an opportunity to renew our commitment to eradicate leprosy during the next century.

Yo Yuasa
President

CONGRESS ISSUES

Presentations and discussions at the Congress will be organized around three groups of issues related to the theme of the Congress ''Working toward a World without Leprosy.'' They are, the control of the disease, including the progress toward elimination of leprosy as a public health problem and sustainability of the control service after that, social aspects and rehabilitation, and causative organism and host response. Each group of issues will be dealt with by keynote addresses, panel discussions, workshops and consensus forming sessions, in addition to oral and poster presentations of individual papers in concurrent sessions. Maximum opportunities will be given to the Congress participants to interact at various plenary sessions.

[There will be no pre-Congress workshops.]

POSTER SESSIONS

Special attention will be given to poster presentations in order to maximize the personal discussions and explanations of participants' research and work. The Organizing Committee will provide a well-planned schedule of poster presentations during the Congress in connection with Congress themes.

TEACHING & TRAINING SESSIONS

Teaching sessions will be held on Tuesday, Wednesday and Thursday evenings at the Convention Center.

EXHIBITS

Exhibitions will be arranged for organizations or institutions wishing to display teaching and learning material, including books, video tapes and compact discs, footwear, medical supplies and equipment and other items of interest to participants. If you plan to exhibit please request information on the enclosed form.

Congress Organizing Committee:

Dr Yo Yuasa, Dr Pieter Feenstra, Dr W. Felton Ross, Dr Robert C Hastings, Dr Wayne Meyers, Dr Michel Lechat, Dr J.-P. Shenkelaars, and Dr S. K. Noordeen.

Chinese Organizing Committee:

Prof. Chen Min Zhang, Prof. Yin Da Kui, Prof. Dai Zhi Cheng, Prof. Li Shi Chuo, Prof. Zhao Tong Bin, Prof. Ye Gan Yun, Ms Sufet Ma Haide, and Ms Lu Man Hua

Dates: 7–12 September 1998

Location: Beijing International Convention Center and Beijing, People's Republic of China

Congress Language: English

Posters/Exhibition Space: Posters illustrating participants' work and research will be on exhibit throughout the Congress. In addition, paid exhibit space can be reserved for product or organization displays. For exhibit space costs and information, write separately to the Secretary for Administration

Free Communications:
A book of abstracts will be part of each registration packet

Social Events/Tours: A reception and dinner will be held for conference participants

Registration/Fees/Scientific Abstracts: in order to receive information regarding fees and registration, and for information about submitting abstracts write to: Secretariat; 15th International Leprosy Congress, c/o Sasakawa Memorial Health Foundation, 3-12-12 Mita, Minato-ku, Tokyo 108, JAPAN.

***Leprosy Review* poster: Taking slit-skin smears**
The poster included with this issue of the Journal is 'Taking slit-skin smears'. The next poster will be 'Staining slit-skin smears'. We hope that these two combined will help the quality of slit-skin smears taken.

Poster notice and questionnaire: See Editors Choice, p. 194