WORLD HEALTH ORGANIZATION
ORGANISATION MONDIALE DE LA SANTE

DISTR. : LIMITED
DISTR. : LIMITEE

WHO/CTD/LEP/90.3

ENGLISH ONLY

REPORT OF THE CONSULTATION ON TECHNICAL AND OPERATIONAL ASPECTS OF LEPROSY

Male, Maldives, 11-15 June 1990

CONTENTS

1. INTRODUCTION, BACKGROUND AND OBJECTIVES

The WHO Consultation on Technical and Operational Aspects of Multidrug Therapy (MDT) in Leprosy was held in Male, Maldives, from 11-15 June 1990.

The meeting was opened by the Hon. Abdul Sattar Moosa Didi, Minister of Health and Welfare, Maldives. In his opening address, he thanked WHO for organizing the meeting in Maldives and welcomed the participants. He expressed deep satisfaction over the excellent progress that is being made in leprosy control through MDT in several countries, including Maldives.

In his message to the meeting, Dr U Ko Ko, Regional Director, WHO, South-East Asia Region, expressed the need to further improve the coverage for MDT in view of its excellent performance. The WHO South-East Asia Region contributed to about half of the world's estimated 10 to 12 million leprosy cases, and with the possibility of reducing the case load by as much as 80-90% through MDT, the task ahead was truly challenging.

Earlier, Dr S.K. Noordeen, Chief, Leprosy Unit, WHO, Geneva, on welcoming the participants and others, pointed out the exciting period leprosy control was passing through, largely as a result of implementing MDT. He also pointed out problems faced by the leprosy programmes on extending MDT further, in spite of the remarkable successes achieved in certain areas in reducing the disease.

The WHO-recommended MDT for leprosy has been in use worldwide since 1983. While the number of registered cases worldwide was 5 300 000 in 1985, as a result of the implementation of MDT, it is now 3 800 000. At present 808 000 cases have completed MDT and 1 750 000 patients are on it.

The implementation of MDT over the past eight years has demonstrated the safety and acceptability by patients and health workers, the absence of early relapse and feasibility under a variety of situations. However, the field workers as well as programme managers have faced a number of technical and operational problems in implementing MDT in both vertical and primary health care approaches.

It was therefore felt necessary to review the experiences gained over the last eight years with MDT, to discuss the important technical and operational problems and to find practical solutions so that MDT coverage could be increased and extended to even operationally difficult areas and situations.

With the above aims in mind, the consultation was organized in Male, Maldives with representation from large national leprosy programmes, and major projects implementing MDT with support from governmental and/or nongovernmental organizations.
The consultation worked on the following objectives:

1. To review the state of the art in chemotherapy of leprosy;

2. To review technical problems in applying MDT;

3. To review operational problems in implementing MDT;

4. To review the implications of MDT in the application of standard operational and epidemiological indicators for monitoring and evaluation.

2. SUMMARY OF PAPERS PRESENTED ON GLOBAL PROGRESS AND LARGE NATIONAL PROGRAMMES

2.1 Global progress on MDT implementation: Dr L. Lopez Bravo, WHO, Geneva

The MDT coverage by WHO regions as of October 1989 is as follows:

WHO Regions	No. of Registered cases (x1000)	No. of cases on MDT	% of reg. cases on MDT	No. of cases completed MDT
Africa	496	88 486	17.8	96 297
Americas	332	61 446	18.5	21 837
Eastern Med.	103	37 846	36.8	14 944
Europe	14	4 992	35.0	234
South-East Asia	2 907	1 738 370	59.8	1 009 150
Western Pacific	194	56 361	29.0	39 602
TOTAL	4 046	1 987 501	49.1	1 182 064

Out of 105 leprosy endemic countries (prevalence rate of at least 0.1/1000) only 33 countries have an MDT coverage of more than 75%. The percentage of cases benefiting from MDT out of all cases registered so far (cases presently on MDT plus cases who have completed MDT) has steadily progressed from 1.64% in 1985 to 60.6% as of May 1990. About 1.2 million cases have completed MDT. While the progress of MDT coverage in the South-East Asia, Western Pacific, Eastern Mediterranean and European regions of WHO can be considered satisfactory, the coverage is comparatively low in Africa and Latin America. The main reasons for the slow implementation of MDT in Africa are: inadequate political commitment, weak health infrastructure and serious operational problems. The main reason for the slow implementation in Latin America is the fact that national health authorities and dermatologists have not yet fully accepted the WHO-recommended MDT regimens. This situation, however, is gradually changing.

2.2 Implementation of MDT in large national programmes: Dr U Tin Myint, Myanmar

Magnitude of the problem

Total registered cases, 155 587 (as of 1988).
Prevalence, 3.99/1000.
6 high endemic regions constitute 60-70% of total patients.

By the time MDT implementation was considered in Myanmar in 1987 the following developments had taken place:

(a) The leprosy control programme was integrated into primary health care.

(b) 50% of the trained leprosy workers were deployed as multi-purpose workers.

(c) A special rifampicin plus dapsone treatment regimen was in operation.

Operational problems

(a) Manpower - shortage of trained workers.

(b) Resource constraints - shortage of drugs and the fact that the entire drug requirement is dependent on external donors.

(c) Training of workers - there is a lack of training curriculum for different categories.

(d) Lack of political commitment - the leprosy programme has to compete with other programmes such as immunization and diarrhoea which are favoured by the national/political set-up.

(e) Monitoring of MDT - misuse of rifampicin.

Technical problems

(a) Lack of laboratory facilities.

(b) Open-end duration of treatment for MB cases, i.e., until smear negativity - which can sometimes take 5-7 years - poses problems in terms of case-holding.

(c) Surveillance - the need for annual review of patients puts a large burden on meagre staff and necessitates extra manpower. Can surveillance be done once in two or three years?

(d) Case-finding - so far only 35% of estimated cases are detected and only 50% of those detected are on MDT.

(e) Complications after MDT - though not a serious problem, a practical set-up to deal with complications is required.

(f) Need for indicators for monitoring and evaluating MDT programmes.

2.3 Implementation of MDT in large national programmes: Dr B.N. Mittal, India

Magnitude of the problem

Estimated cases - 4 million, of whom 20% are considered infectious, 15% are children and 15-20% suffer from deformities.

Out of 435 districts, 196 have a prevalence of 5 or more per 1000 population. 239 districts have a prevalence of less than 5/1000.

About 435 million people live in the 196 high prevalence districts. As of January 1990 there are 2.6 million registered cases. 0.4 million new cases were detected in 1988-89 and 0.6 million were discharged.

Infrastructure: An extensive and generally adequate infrastructure available:

District leprosy units	-	243
Leprosy control units	-	704
Urban leprosy centres	-	931
Survey, education, treatment centres	-	7000
Temporary hospitalization wards	-	287
Reconstructive surgery units	-	75
Rehabilitation promotion units	-	13
Training centres	-	49
Sample survey assessment units	-	37

MDT coverage

(a) 65% of registered cases are covered by MDT.

(b) 130 endemic districts with a population of 283 million and 2.15 million patients under MDT.

(c) 33 low endemic districts are being brought under MDT with the help of the existing primary health care set-up.

(d) In non-MDT districts leprosy patients who are not responding to dapsone monotherapy are being identified and put on MDT.

(e) The epidemiological impact assessed in 12 districts which have completed more than 5 years of MDT shows: (i) reduction in annual new case detection rate; (ii) reduction in MB ratio and child rate; (iii) reduction in deformity rate.
There is also a steady increase in the number of leprosy-free villages.

(f) All the 196 endemic districts will be covered by MDT by the year 1992. This will cover 90% of the patients in the country.

Budget: The budget allocation from the Central Government for NLEP was about US$11.78 million for 1989-90. The States/Union territories spend twice this amount towards the cost of the existing infrastructure.

Operational problems

(a) shortage of manpower and difficulties in training;
(b) availability of drugs;
(c) transport;
(d) need for improvement in laboratory services;
(e) supervision needs strengthening;
(f) urban leprosy control - need for development of separate strategies;
(g) financial constraints;
(h) intersectoral coordination;
(i) community participation.

Technical problems

(a) classification - problem of misclassification of MB cases as PB;
(b) persistence of lesions in PB cases;
(c) care of complications - there is a lack of adequate facilities in some areas and under-utilization of facilities in other areas;
(d) prevention of complications, e.g., disability prevention;
(e) lack of information system;
(f) surveillance - there is a need for proper planning and adequate resources.

2.4 Implementation of MDT in large national programmes: Dr (Mrs) Ngeri Benebo, Nigeria

Magnitude of the problem

(a) Nigeria has the second biggest leprosy control campaign in the world next to India.

(b) The known prevalence rate in 1988 ranged from 0.09 to 10.4 per 1000. The actual prevalence is expected to be higher.

(c) In 1988 - 5726 new cases were detected of whom 25% were MB.

(d) MDT was introduced in 1985 but coverage is still low - in 1989 the MDT coverage was only 4.3%.

Operational issues

(a) In 1988, a National consensus was reached and a National Tuberculosis and Leprosy Control Programme was established.

(b) External assistance - since the Government resources are limited Nigeria solicited assistance from international agencies and has been able to get assistance pledged for every state. The WHO-sponsored Interregional Conference on Leprosy Control in Africa held in Brazzaville in November 1989, played a crucial role in the involvement of international agencies.

(c) It is planned to operate the national TB and leprosy control programme within the framework of primary health care. The programme is partially integrated in some states. Local government area supervisors and TBL control officers undertake definitive diagnosis and classification of cases and prescribe MDT.

(d) "MAMSER", an organ of the Government also assists with the health education of the community.

(e) There are great difficulties in the procurement and distribution of drugs, vehicles, equipment and other inputs. The Government is seeking the assistance of international agencies to supplement these items.

(f) There is a shortage of trained and motivated staff and lack of adequate supervision which needs to be solved.

(g) Coordination between NGOs and the Government - some NGOs are doing independent work in Nigeria. Efforts are now made to pool the resources of the Government and NGOs to cover entire states and implement MDT. This is a collaborative working relationship which has greatly contributed to the progress made so far.

Technical issues

(a) Misclassification of cases and misdiagnosis. In most programmes, due to the lack of adequate laboratory back-up, mostly clinicial diagnosis and classification is relied upon.

(b) Persistence of skin lesions in PB cases.

(c) Inadequate and poor management of complications such as reactions, neuritis.

(d) Lack of referral facilities: As a result of this, every effort is being made to have competent health workers in the field who would be able to detect complications early and manage them appropriately.

(e) The treatment compliance in Nigeria is excellent - close to 100%, because of a happy misconception that dapsone increases fertility and virility and rifampicin cures sexually transmitted diseases.

(f) There is a need to develop health systems research which can give essential, feasible and economically affordable solutions to problems of leprosy control in order to improve efficiency and effectiveness of MDT.

2.5 Discussion on papers presented

During the discussions the following points were brought out:-

(a) The skin smear services in general were unsatisfactory.

(b) There is a need to specify criteria to classify leprosy on clinical grounds rather than on bacteriological results exclusively.

(c) It may be sometimes easier to train laboratory technicians than to train workers in accurate clinical diagnosis.

(d) Even in places where a primary health care system is involved in leprosy work, skin smear services will be important.

(e) There is a need to develop integrated laboratory services.

(f) There is a need to define more precisely "cure" in leprosy in order to resolve the problem of duration of treatment. It is also necessary to consider whether it is reasonable to stop treatment when the skin smear is still positive.

(g) There is a need for more trials on fixed duration treatment for MB leprosy.

(h) The problems of reactivation, relapse, reactions and deformities occurring after stopping of treatment need to be looked into.

(i) The reporting systems should be simple.

(j) It must be realized that what is ideal may not always be practical or feasible.

3. SUMMARY OF PAPERS PRESENTED ON MULTIDRUG THERAPY IMPLEMENTATION WITHIN INTEGRATED PROGRAMMES

3.1 Dr Charoon, Thailand

The Leprosy Control Programme was launched in 1955 as a vertical programme and as an integrated programme in 1971. MDT was introduced in 1984. Six out of 73 provinces are still having specialized services. Up to December 1989, 24 946 cases had received MDT, of whom 13 896 were followed up at least once. The number of relapses is 116 or 0.8%.

In 1988, there were 2176 new cases. The new case detection rate was 0.04/1000. Bacteriological examination coverage was 97.2%.

In 1989, a national rehabilitation programme was launched. In order to provide care and disability prevention "self-care clinics" were started in selected health infrastructures and programmes of group education for patients and their families were also started.

3.2 Mr Tadele Tedla, Ethiopia

An organized leprosy control programme was first started in Ethiopia in 1956 after passing through different approaches - leprosaria, mobile market-clinics and vertical services. In 1983, it was decided to gradually integrate leprosy control into general health services using MDT. Prior to implementation of MDT, the following preparatory stages were undertaken:

(a) Manpower training and health education:

- Refresher training was given to all staff working in the former leprosy control programme so that they could be integrated as multipurpose workers in the general health services.
- Inservice training in leprosy control was given to all health personnel in the general health services where MDT implementation was planned.
- All the old leprosy and general health services staff to be involved in MDT were given training in information, education and communication strategies.

(b) Steps were taken to introduce and integrate leprosy control into the curriculum of all medical and paramedical schools.

(c) Awareness and health education was given to the communities, the leprosy patients and their families.

(d) Manuals, guidelines and directives on MDT were distributed to all leprosy control and health staff in the general health services.

(e) Drugs, vehicles and equipment for MDT was procured by the National Leprosy Control Programme at headquarters and promptly distributed.

(f) Criteria for selection of patients for MDT were set for peripheral level staff.

(g) At the district and peripheral levels, an accountable person for the leprosy control programme was assigned.

(h) A system of monitoring of MDT was established.

(i) The number of treatment centres was increased to 848, of which 54% carried out integrated services while 46% rendered vertical services.

The results of MDT implementation;

(a) Cumulative MDT coverage (1983-1989) is 66.2% of the total registered cases. The number of patients who received MDT is 53 591.

(b) Cumulative MDT completion is 60% of the total MDT cases.

(c) Fixed duration, low level toxicity and easy acceptance of MDT justify its implementation within the general health services.

(d) The total number of patients in Ethiopia has decreased from 80 927 in 1983 to 24 399 in 1989. The new case detection rate has decreased from 1.9/10 000 population in 1983 to 0.7/10 000 population in 1989. The prevalence rate has decreased from 25/10 000 population in 1983 to 5/10 000 population in 1989.

(e) In 1989, out of a total of 24 399 registered cases, 17 147 or 70.2%, received MDT and the remaining 7252, or 29.7%, received dapsone monotherapy.

3.3 Dr Mputu Luengu Boyau, Zaire

Zaire has 306 health districts containing 6000 health centres. Each health centre caters for 5000 people in rural areas and 10 000 in urban areas.

MDT was introduced in Zaire in a few patients in 1983 using the short duration regimen recommended by Professor Pattyn.

The WHO-recommended MDT was introduced only in 1988.

MDT coverage in 1987 was 7.15%; and in 1988, 27%.

A national strategy was developed with the objective of MDT coverage of 90% of detected cases by 1997. Each year 45 health districts will be covered.

Operational problems

(a) The programme is integrated into the primary health care system and the nurse in charge of a health centre is responsible for the treatment of leprosy. Since the workload for the nurse is heavy there is a tendency to neglect leprosy treatment.

(b) The primary health care policy in Zaire requires that the patient contributes to the cost of his treatment. The concept of free treatment for leprosy is in contradiction to this.

(c) Out of 306 health districts only 180 are operational. This will seriously affect MDT coverage.

(d) During the rainy season, some of the health districts are inaccessible for 3-6 months of the year as they are situated in forests and mountainous and swampy areas. There is also the problem of giving MDT to nomadic populations.

3.4 Dr Viardo, Philippines

The basic health care system in the Philippines is carried out through 8842 'Barangay' (village) health stations, 1962 health centres and 152 primary hospitals. There are eight regional leprosaria with a total of 4000 beds. Leprosy control was integrated into general health services in the early 1980s.

MDT was implemented on a pilot basis in two provinces in 1985. This was preceded by about two years of preparatory phase. The study indicated that MDT could be successfully implemented in an integrated system under well-defined considerations such as sustained administrative and political commitment, well trained health workers, adequate drug supply, community support and continuous supervision and monitoring.

In 1986, a decision to extend MDT countrywide was taken and July 1988 was set as a target date for nationwide implementation.

Experiences on MDT implementation

(a) The number of estimated cases in 1986 was 35 000-50 000. At least 30-35% of these were eligible for release from treatment. Out of the 25 617 registered cases as of 1987, 21 158 were put on MDT by the end of 1989 giving a MDT coverage of 81.6% registered cases.

(b) 91% of all categories of health personnel involved in MDT received at least one training session on MDT implementation.

(c) A joint WHO/MOH team assessed the nationwide MDT in 1989 and found it to be quite satisfactory and that there was high quality of work being done. The success of the integrated approach was ascribed to:

- high level of interest and commitment of provincial health officers;
- the excellent inputs into training at all levels;
- very good teaching materials written in simple language and suited to local conditions.

The weak points of the programme were:

- low case-finding activities;
- unsatisfactory records and reports.

These factors were related to the emphasis on treatment delivery and operational implementation.

3.5 Discussion on the papers presented

During discussions on the above papers, the following points were brought out:-

(a) In most countries the only feasible method of implementing MDT is through integration into general health services. However, the local situations and the local context need assessing.

(b) Integration does not mean abandonment of specialized leprosy services.

(c) The process of integration needs to be thoroughly planned and this planning may take a considerable period of time.

(d) In some situations, integration could be started by integrating specialized leprosy activities such as laboratory techniques, rehabilitation or reconstructive surgery into the general health services.

(e) In countries running vertical programmes for leprosy, integration must be differentiated from involvement. All attempts must be made to involve general health services into leprosy activities.

(f) As the leprosy case-load declines, leprosy programmes could try reverse integration - use the available facilities and manpower for control of other diseases such as TB or blindness. In this situation, leprosy staff need to be trained as multi-purpose workers.

4. SUMMARY OF PAPERS PRESENTED ON IMPLEMENTATION OF MDT IN SPECIFIC PROJECTS

4.1 Dr M. Becx, ALERT, Ethiopia

The ALERT programme covers Addis Ababa City and Shoa Region with an estimated population of 1.1 million. Leprosy diagnostic and treatment services are provided through 286 centres - 60% of them attached to general medical services and 40% run as special leprosy clinics.

Since 1983, 800 to 1200 new cases have been detected each year, 40 to 45% of them being MB.

MDT implementation

(a) MDT has been initiated in phases since 1983. The entire area was brought under MDT as of January 1988.

(b) Prior to starting MDT - a total of 5337 PB cases and 2392 MB cases who had received adequate dapsone monotherapy and were clinically/bacteriologically inactive, were released from treatment. Out of these patients released from treatment, 61 PB and 272 MB relapses have occurred giving a relapse rate per 1000 patient years after release from treatment of 6.5 for PB and 22.9 for MB cases.

(c) Up to 1990, a total of 14 270 patients were put on MDT and 9305 were released from MDT treatment. 1713 patients did not complete treatment, i.e., 12%. At present, 293 PB and 2959 MB cases are on treatment of whom 92% are on MDT and 8% on dapsone monotherapy.

(d) A cohort of PB cases who received MDT shows that 9.1% of cases did not complete their MDT (6 doses within 9 months). A cohort of MB cases shows that 20% of cases did not complete their MDT (24 doses within 36 months).

(e) 40% of new MB cases started on MDT had to continue treatment after 36 doses of MDT since their skin smear was still positive. 10% of the cases were positive at the end of five years. Patients with BI of 2+ at the completion of five years were released from treatment.

(f) Among total cases started on MDT - 54 relapses were diagnosed (21 PB and 33 MB). The criteria for diagnosis of relapse: (i) PB: new clinical activity more than one year after release; (b) MB: A BI of 2+ in 2 consecutive smears. On a more thorough clinical, bacteriological and histopathological examination, it was noticed that some of these cases were diagnosed as relapse without sufficient evidence. However, in 36 patients, the diagnosis of relapse was certain giving a relapse rate of 0.4% for PB and 0.28% for MB. It works out to 1.2 per 1000 patient years for PB and MB (total) cases.

(g) Since the introduction of MDT, there has been a decline in ENL reactions and an increase in reversal reactions. About 40% of new BL cases and 25% of BT cases are either diagnosed or develop reactions. Most of the reactions were treated in the field with Prednisolone.

Operational/technical problems

(a) Open-ended duration of treatment for MB cases - the regularity decreases after two years.

(b) Occurrence of reversal reaction in PB cases after release from treatment. This occurred in about 25% of BT cases. 50% of the reactions occurred more than six months after release.

(c) Persistence of clinical activity in PB cases at the end of six months.

(d) Difficulty in maintaining uninterrupted compliance due to circumstances such as famine, war, floods, late stages of pregnancy and immediate post-partum.

(e) Difficulties of accessibility to general medical service.

(f) Difficulties in differentiating reversal reaction and relapses in PB cases and difficulties in diagnosis of relapse in MB cases.

(g) Classification of patients - need for clinical criteria rather than heavy dependence on bacteriological examination especially in view of poor laboratory services.

4.2 Dr Li Huang, People's Republic of China

The National Leprosy control efforts have been going on in China since 1955. The prevalence has decreased to 0.1/1000 in most parts of the country except in South-west provinces (Yun-gui Plateau and Sichuan Basin) where it remains between 0.1 - 0.3/1000 and constitutes about 60% of known cases in China.

The health system in China operates through a nationwide three-tier rural-oriented health structure. The Government provides free medical care plus living allowance for all leprosy patients.

In 1985, the Government signed a five-year collaborative agreement with WHO for implementation of MDT in Yunnan, Guizhon and Sichuan provinces, covering a population of 18.7 million with about 6000 patients of which 60% were MB. This constitutes about 10% of total known cases in China.

The aim of MDT implementation is to reduce prevalence by 90% over five years through MDT and active case-finding. It is ultimately aimed to integrate leprosy control into the primary health care system.

Results

(a) As a result of screening old patients for MDT, there was a sharp decrease of prevalence in the first two years of MDT implementation but, because of the steady inflow of new cases and a high percentage of MB cases, this decline has been levelling off.

(b) A system of cross-checking of skin-smears in relation to MDT was introduced.

(c) From the study, it is apparent that BI steadily declines after MDT and it may be possible to have short or fixed duration of treatment (24 months) for MB cases.

(d) After five years of control with MDT, there was no decline in the case-detection rate in the control areas.

Suggestions for improvement

(a) Further strengthening of health education to the public and general medical profession at all the three levels of the health system.

(b) Adequate refresher courses and inservice training for the different levels of leprosy personnel.

(c) Emphasis on disability prevention, early recognition of relapse reaction and neuritis.

(d) Because of the very low level of early relapses it is recommended that the surveillance period should be extended beyond five years to about ten years for MB and five years for PB cases. Prolonged surveillance will also benefit detection of new cases.

(e) The sub-district health centre should play a more important role in case-finding, surveillance, prevention of deformities, treatment of reactions and ulcers.

4.3 Dr Ana Maria Zulueta Rodriguez, Venezuela

Through a collaborative programme with Americares, a voluntary agency from USA, a new therapy strategy has been underway in Venezuela since 1985. The therapy involves a modified MDT regimen: rifampicin 600 mg once a month; clofazimine 600 mg once every 15 days; dapsone 100 mg daily.

Rifampicin and clofazimine are given supervised whereas dapsone is given unsupervised but the compliance is monitored by periodic urine tests. The same regimen is applied to both PB and MB cases. However, the duration of treatment for MB cases is a minimum of two years and PB cases a minimum of one year.

The programme was designed to be developed in three continuous stages during a three-year period progressively incorporating groups of services from the various federal entities. During the first year, 2350 patients from six services were included and in the second year 3660 patients from eight services were included.

The results in terms of MDT coverage, compliance of patients and release from treatment have been satisfactory. The MDT coverage as well as patient compliance was over 80%. Less than 10% of patients complained of side-effects. A total of 1001 new cases were detected in the 14 services during a five-year period. 57% of the new detections were classified as MB and 43% as PB. Up to the end of 48 months of surveillance of those patients released from control, there have been no relapses.

4.4 Dr T. Chiang, Pakistan

Leprosy in Pakistan is predominantly a problem among immigrants from India, Bangladesh, Afghanistan and to a lesser extent, Iran. However, indigenous foci exist in all provinces.

Karachi, the largest city in Pakistan has a population of over 10 million and contributes to the highest number of new cases per year - 57% in 1988 as well as the highest number of patients under treatment - 59% in 1988. Leprosy control in greater Karachi is exclusively in the hands of a NGO - the Marie Adelaide Leprosy Centre. In 1982, an MDT policy was launched with the formation of a National Leprosy Control Board. A manual of guidelines for implementation of MDT has been printed.

Leprosy control in Karachi has passed through different phases:

(a) From 1983-1987 the city was divided into zones of approximately 500 000 population and each zone (sub-centre) staffed by one trained leprosy technician and support staff. The leprosy technician is responsible for case-finding, case-holding and health education. With this system, MDT was given to a limited number of patients while most patients were still on dapsone monotherapy.

(b) From 1987-1989, as advised by WHO, surveys were discontinued and more patients put on MDT. Voluntary reporting was encouraged through publicity and health education. However, self-reporting did not increase and the large number of patients on MDT proved difficult to manage.

(c) From 1990, for the reasons mentioned above, it was decided to revert to the old methodology with an idea of a phased MDT implementation employing case-finding and MDT simultaneously.

Problems encountered in the implementation of MDT

(a) A large and rapidly growing population of Karachi with a large number of temporary squatter settlements.

(b) A high degree of stigma.

(c) Economical factors - taking treatment for leprosy does not have the same priority as for food, shelter and jobs.

(d) Bad public transport system.

(e) Constant curfews and disturbances.

Plans for the future

(a) Open new control units.

(b) Increase the mobility of the present staff.

(c) Discharge 85% of patients presently under treatment.

(d) Achieve 85% self-reporting of cases.

(e) Educate 85% of patients on self-care after stopping treatment.

In conclusion, it must be stressed that leprosy control is included in the national 7th five-year plan for the first time. This gives the possibility of greater political commitment and additional Government funding.

4.5 Dr D. Lobo, Madras, India

Madras is the first metropolitan city in India to be fully covered by MDT. A rapid survey of the entire city population (estimated 4 million) was completed in 1989 followed by screening/registration of patients. A 14-day intensive therapy of daily rifampicin, clofazimine and dapsone was completed in May 1990.

Gremaltes, a nongovernmental organization supported by the German Leprosy Relief Association, has been doing urban leprosy control in Madras since 1973. Over a 17-year period, it has detected 38 017 cases of leprosy, of whom 28.3% were detected through slum survey, 25.4% through school surveys, 8.4% through contact survey and 37.9% through voluntary reporting. The percentage of voluntary reporting proves that non-survey techniques of case-detection can be effectively used in urban areas. Nearly 40% of registered cases (1973-1990) have not completed their treatment; most of them belong to the dapsone monotherapy era prior to 1983. Case-holding is thus difficult in urban areas due to factors like floating population, constant shift of residence, multiplicity of medical facilities and general practitioners available etc. These factors have an important bearing on planning for MDT. Sample studies to determine incidence in slums and new case-detection rates among schoolchildren have not shown any decline over the last 5-7 years, indicating that there is still a significant pool of infection.

Results of a rapid survey

A total of 3516 new cases were detected through a rapid survey thus proving the effectiveness of such surveys in urban areas. However, there is a tendency of over-diagnosis by paramedical workers due to factors such as high target fixation, lack of proper training and a tendency to err on the side of over-diagnosis. The system of target fixation needs to be reviewed and rationalized. There is need for a clear definition of an 'active' case of leprosy and a proper training of staff.

Some operational/technical problems

(a) staff recruitment, placement and training:

(b) need for determining an optimum paramedical worker: population ratio for urban areas;

(c) need for district leprosy officers to have the authorization to hire vehicles if there is a vehicle shortage or breakdown;

(d) difficulties to do surveys in upper middle-class and affluent areas;

(e) lack of adequate facilities for care of complications;

(f) inadequate laboratory facilities and shortage of trained laboratory technicians;

(g) there is a need for studies to determine the value of the 14-day intensive therapy as practised in India;

(h) lack of cooperation from general medical practitioners;

(i) social problems related to stigma;

(j) magnitude of the population and its growth.

There is a need to work out separate guidelines for MDT implementation in urban areas. It should be emphasized that there are certain advantages in urban areas such as good public transport networks, multiplicity of aids and means of information, education and communication, large general medical infrastructure and general medical practitioners, large numbers of service clubs, youth and womens' associations, schools, colleges and professional institutions, all of which can be mobilized to complement and supplement MDT implementation.

4.6 Dr P.A. Orege, Alupe, Kenya

The Alupe Leprosy and Skin Disease Research Centre conducted a pilot study to evaluate the effectiveness of MDT under field conditions. 184 PB and 54 MB cases were included in the study from six districts of western Kenya. PB patients were divided into two groups - one which received WHO-recommended regimen and the other a modified MDT, i.e., rifampicin 1500 mg at the start and at three months plus unsupervised dapsone. The regularity of PB cases was 85-90% whereas only 42.6% of the MB cases were regular.

The findings of the study proved that MDT is effective, acceptable and feasible. However, it is necessary to give due importance to certain operational and technical issues prior to implementating MDT:

(a) availability of adequate resources - money, manpower and materials:
(b) training, re-training and re-deployment of staff;
(c) obtaining cooperation from relevant health and administrative authorities;
(d) cooperation from community leaders:
(e) accessibility of treatment points to patients;
(f) referral facilities to deal with complications such as reactions, neuritis and ulcers.

Some external (contextual) factors affecting the Leprosy Control Programme in Kenya:

(a) physical/environmental factors such as periodic floods and poor road network;

(b) cultural factors like stigma, superstitions, language barriers;

(c) sociological factors like poverty, illiteracy and traditional systems of medicine;

(d) political factors - lack of political will and priority for leprosy;

(e) sometimes clinic visiting days are set up without taking into account patients convenience;

(f) poor communication between headquarters and peripheral health units.

The majority of the above problems could be tackled, so that the programme can continue.

4.7 Discussion on operational and technical issues

Operational issues

(a) Infrastructure - depends on whether the programme is vertical or integrated. The infrastructure needs to be planned in relation to endemicity, accessibility, workload per paramedical worker and manpower resources. Most leprosy control programmes are male-dominated. As there is no scope for manpower reserves the programme suffers when staff go on leave.

(b) Manpower: requirement; recruitment; placement; deployment and training requires careful planning.

(c) Logistics of supply of drugs and other materials: The purchase of drugs and other materials needs to be done sufficiently in advance so that supply is continuous and transport and delivery prompt. Attention must be given to quality and reserve stocks.

(d) Patient compliance: Indepth studies must be done for reasons of poor compliance and more attention given to absentee motivation.

(e) Defaulter retrieval: There is need for cross-notification of migrated patients and patient/family education. In low endemic areas in India, travel cost is given to the patient when he attends clinics. This could be considered in other countries also.

(f) Monitoring of drug intake: It is necessary to periodically monitor unsupervised treatment by tablet counting and urine testing.

(g) Supervision - must include sample cross-check of diagnosis and classification and quality - control of skin smear.

(h) Guidelines for screening of cases for MDT, release from treatment and release from control need to be clearly defined.

(i) Guidelines regarding contra-indications such as hepatitis, gross anaemia and active TB need to be clearly defined to the staff. Similarly, the staff should be familiar with the toxic side-effects of anti-leprosy drugs.

(j) Activities during surveillance and maintenance phase should be worked out.

(k) Studies on the role of stigma on the implementation of MDT need to be done.

(l) Urban leprosy control: There are special issues and problems related to urban areas. Separate guidelines for urban areas need to be worked out.

Technical issues

(a) need for the definition of an 'active' case of leprosy:

(b) need for clinical criteria for classification into PB and MB;

(c) need for definition of regularity and what is the maximum acceptable break from treatment allowed;

(d) Need for determining the value of the 14-day intensive therapy as practised in India. It has been calculated that withdrawal of this 14-day intensive therapy will save about two million rupees per MDT district.

(e) Treatment - define duration for MB cases;
- define compliance and adequacy;
- need for guidelines for treatment of relapses;

(f) Follow-up - need for clear criteria for follow-up in relation to clinical and bacteriological status;
- draw up the content and organization of follow-up in terms of duration.

(g) Lepra reactions: need for guidelines for early diagnosis and standardization treatment.

(h) Assessment of magnitude of the problem and need to standardize methodology of sample surveys.

(i) Information systems - need for have relevant indicators for epidemiology, supervision, evaluation and compliance. There is need for simplification of the information systems.

(j) Integration - the type, levels and methods of integration will vary from country to country or even within parts of the same country.

5. SUMMARY OF PAPERS PRESENTED ON RESEARCH AND TRAINING IN RELATION TO MDT

5.1 Research progress in chemotherapy of leprosy: Professor J. Grosset, Paris, France

The concept and implementation of MDT has given new hopes for controlling leprosy as a major public health problem. The present MDT regimen consists of a combination of one strongly bacteriocidal drug - rifampicin and two reliable bacteriostatic drugs - clofazimine and dapsone. The duration of treatment for MB leprosy with the three-drug regimen was arrived at the recommended minimum two years in order to allow enough time for rifampicin-resistant strains of M. leprae to be killed by the two bacteriostatic drugs. It is believed that clofazimine and dapsone-resistant strains would be killed by rifampicin with a few weeks. It was therefore reasonable to expect that a combination of two bacteriocidal drugs should be able to quickly eliminate the respective resistant strains and thereby give the possibility of further reducing the treatment duration.

This possibility is turning into a reality with new drugs proving to have bacteriocidal activity against M. leprae:

1. Fluoroquinolones - ofloxacin/pefloxacin
2. Minocycline - a tetracycline group
3. Clarithromycin - macrolide group

Protocols for trials using a combination of rifampicin and fluoroquinolones are already underway and if proved effective there is hope that the duration of treatment for leprosy will be further reduced.

5.2 THELEP-supported field trials on MDT: Dr S.K. Noordeen, WHO, Geneva

In 1981, when recommendations for MDT were made, there was insufficient scientific background to support the safety and efficacy of MDT in leprosy but in the prevailing circumstances it was necessary to start MDT. As of now, about 3.2 million patients are either receiving or have completed MDT globally in 105 countries.

Two THELEP-supported trials were conducted in Karigiri and Polambakkam, India, using WHO recommended MDT as well as a modified WHO regimen involving the administration of injectionable acedapsone. Treatment was given up to smear negativity. Seven patients are still on treatment as their smear is still positive. A total of 2241 patients were included in the two trials. The results showed as follows:

(a) Attendance rate - during treatment: 90-95%; during follow-up: 85-95%

(b) There were 65 ENL and 54 reversal reactions. Nine reversal reactions occurred after release from treatment.

(c) Side-effects were extremely few.

(d) The most important result of the trial on relapse following completion of treatment indicates that relapses with MDT have so far been nil. In a similar situation with dapsone monotherapy there would have been about 180 cases of relapse.

The above trials have proved the safety and efficacy of MDT as well as its acceptance by the patients and workers.

5.3 Whole population chemoprophylaxis trial in the Maldives: Mr Ibrahim Saheem, Male, Maldives.

The Republic of Maldives consists of a group of 1500 small islands of which 200 are inhabited. With a population of approximately 250 000, it has a low leprosy prevalence (80 of the 202 inhabited islands are free from leprosy). About 300 patients are presently on treatment - all of them are receiving MDT. In view of the low case-load and the convenience of small independent close-knit islands, the Government of Maldives, in collaboration with WHO, plans to start a chemoprophylaxis programme. The entire population will be given a single dose of 600mg rifampicin with the hope that this dose will eliminate M. leprae from the few people who might be incubating leprosy. The aim of the programme is total eradication. The implementation of the chemoprophylactic drug regimen will be done using the existing health structure and the active involvement of the respective island chiefs.

5.4 Training in leprosy in relation to MDT: Dr Haider, Khartoum, Sudan.

(a) training affects knowledge and attitudes of health personnel;
(b) affects quality of services;
(c) affects treatment/patient compliance.

There are many national and international training institutions to meet the needs of leprosy control programmes. Some of the deficiences are:

(a) the duration and content of courses varies widely;

(b) most of the training is vertical-oriented and inadequate;

(c) there is a need for training of trainers;

(d) the implementation of MDT requires additional training and new training strategies. Additional staff are needed who require training.

(e) the above institutions do not cater to the training needs of general health institutions and medical faculties with regard to leprosy. The curricula of these institutions do not give adequate importance to leprosy. This results in a largely ignorant, biased and prejudiced medical and health professional cadre.

(f) there is a need for competant, knowledgeable and motivated leprosy trainers who are accepted in medical colleges and general hospitals.

Role of WHO and NGOs in training

(a) assist countries and individual training centres in developing work plans for leprosy training;

(b) develop curricula for medical schools and general health training institutions;

(c) assist countries in training of trainers;

(d) provide teaching and training aids.

6. MDT FOR ALL - TARGET ORIENTED LEPROSY CONTROL PROGRAMMES IN 1990s: Dr Y. Yuasa, Sasakawa Memorial Health Foundation, Japan

For over 40 years it has been said that leprosy is curable and deformities are preventable without actually curing many patients or preventing development of deformities. MDT offers a practical means of realising these slogans. It must be regarded as a basic right of every leprosy patient to receive MDT.

In countries with serious constraints and limitations, attempts must be made to implement MDT, at least minimally, making appropriate practical adjustments. Even such a minimal or limited MDT programme is better than no programme at all.

There are two aspects of leprosy as a disease:

(a) It is an infectious disease;

(b) It is a deformity/disability-producing disease. For most national leprosy or public health programmes the infectious disease control will have greater priority to deformity/disability prevention or care. It must be further realised that leprosy is not top priority among the long list of health problems in many leprosy endemic

countries. Hence, our intention should be to develop a practical and feasible programme of case detection and treatment delivery and treatment compliance rather than develop an ideal programme which requires many inputs and infrastructure. NGOs and voluntary agencies must also give priority to controlling M. leprae infection and develop the concept of public health approach to leprosy which means that their traditional aims, objectives and role need to be changed. The open-ended duration of treatment recommended for MB cases, i.e., until skin-smear negativity needs to be questioned and reviewed and we should determine a fixed duration of treatment so that optimal use is made of meagre resources.

The cost of MDT implementation per patient needs to be estimated and a breakdown of costs under headings such as drugs, care/prevention of complications, training, operational, etc., made. Staff salaries should be excluded as it is assumed that staff will be paid whether they are involved in MDT or not.

It is estimated that for fixed duration regimens (6 months for PB and 24 months for MB) the average cost will be US$100.- per patient. With regard to cost-effectiveness, for example, active case finding methods will be found not to be cost effective. The only feasible and best cost-effective method would be "passive case-finding" through public awareness and education resulting in voluntary reporting of cases.

Activities such as care, surgery, physical and social rehabilitation are outside the scope of MDT from a purely public health and disease control point of view. Total care of leprosy patients is just not feasible, practical or possible given the severe financial and resource constraints operating in several leprosy endemic countries.

It is necessary to find the right answer to the question, "who should implement MDT?" If MDT is accepted in a public health programme of an infectious disease control of an entire country, the service that is most appropriate to implement MDT is the general health service. This will require involvement, motivation and training of general health service staff and some additional inputs, technical support such as an uninterrupted supply of drugs.

If there is already a functioning vertical programme:-

(a) If the level of the vertical service is superior to that of the general health service, the vertical service should implement MDT but actively involve the general health service in areas not covered by them.

(b) If the level of vertical service is poor, immediate steps should be taken towards integration. It should be realised that integration does not mean abandonment of specialised services for leprosy.

(c) The NGOs may take up such specialised services.

A nationwide MDT coverage can be implemented in two stages:

Stage I: Give MDT to the large backlog of old patients in order to reduce the accumulated case-load and bring down prevalence rates. Case detection activities should not be emphasized at this stage. Importance should be given to case-holding. The aim of this stage should be to bring down prevalence rates close to incidence rates to about 3.1 or less. This stage is best tackled as a national project of 3-5 years duration with centralized national budget and strong national management structure.

Stage II: Give MDT to all new cases and relapsed cases as well as those existing cases who have not yet been registered. Case-detection activities must be as important as case-holding. This can be conducted as a routine general health service programme at the provincial/district/peripheral level without a special national budget and national structure.

Stage II may last for five years. Its aim should be to drastically bring down incidence rates and put leprosy infection firmly under control.

The slogan for the 1990s should be "MDT for all leprosy patients by the year 2000".

7. REPORT OF GROUP DISCUSSIONS

7.1 Technical/operational aspects

7.1.1 Planning

Before implementation of MDT a national policy should be formulated including the administrative set-up for the delivery of the services. MDT can be implemented within the national health care structure as it exists in respective countries, provided certain prerequisites are met. The structure should depend on the national policy. National policies should envisage priorities for implementation of MDT. Support from NGOs should be sought to supplement the governmental efforts. Intersectoral coordination and review involving the relevant sectors outside health should be planned for the benefit of the programme. When an area has been identified for implementation of MDT prerequisites for effective implementation are: (i) the availability of guidelines; (ii) adequate supplies of drugs and funds; and, (iii) trained manpower.

Provision should be made to cover inaccessible areas and a mobile population in an area taken up for MDT. All registered cases should be screened to validate classification and disease activity and to identify patients requiring MDT.

7.1.2 Implementation

(a) Case-detection: 'Passive' case-detection is recommended which can be achieved: (i) with the implementation of a good treatment programme and, (ii) with increased self-reporting of leprosy patients through education of all groups of population including health workers. 'Active' case-detection should be confined to: (i) surveys of household contacts of leprosy patients; (ii) school surveys if the prevalence of leprosy is high and surveys of schoolchildren as part of their regular health examinations and, (iii) systematic medical examinations where screening for leprosy should form part of the examination.

(b) Selection of cases for MDT: In order to achieve effective MDT coverage of the maximum number of leprosy patients in a programme, the following patients should be given MDT:

Among PB patients - all newly diagnosed cases and relapses.
- previously dapsone monotherapy treated cases not yet released from treatment.

Among MB patients - all newly diagnosed cases and relapses.
- non-MDT treated patients who are skin-smear positive.

If resources permit - all non-MDT treated MB patients who are skin-smear negative.

(c) Bacteriological examinations

Skin-smear: In a leprosy control programme, a reliable skin-smear service is of prime importance: (i) for early diagnosis of MB cases; (ii) to classify into PB and MB; (iii) to assess the effect of chemotherapy during treatment; (iv) to diagnose relapse; and (v) to help differentiate relapse from reactions.

Therefore, the programme should make efforts to develop and upgrade skin-smear services. However, skin-smear is not an absolute prerequisite for initiating an MDT programme since in most cases it is possible to distinguish MB and PB leprosy on clinical grounds. When the classification is in doubt, the patient should be treated as an MB case. However, the proportion of such doubtful cases should be within reasonable limits.

Sites for smear: A minimum of three sites should be taken including one ear lobe and two representative active skin lesions. In PB cases, if there is only a single lesion, then two smears may be taken from its active edge at sites diametrically opposite to each other. Slides should be used only once. As far as possible, the skin-smears should be taken by a limited number of specially trained personnel. To prevent transmission of AIDS and Hepatitis B infection during skin-smear taking, the precautions mentioned in "A Guide to Leprosy Control", 2nd Edition, WHO, Geneva, 1988, should be followed.

The reporting of skin-smear should be done in a standard quantitative manner using the widely acceptable Ridley's scale. Quality control and continuous supervision and monitoring of skin-smear service should be organized with the help of available reference laboratories.

Morphological index is not recommended for use in leprosy control programmes.

Biopsy: The taking of biopsies should not replace reliable skin-smear services.

Lepromin test: Although useful for the classification of leprosy patients, it is not considered a useful tool in field programmes.

(d) Treatment

Available information based on experience in the field so far has clearly demonstrated the safety and effectiveness (in treatment response and extremely low relapse rates) of MDT in both PB and MB leprosy.

Duration of treatment - MB: Several programmes have opted for limiting MDT to MB patients to 24 months - the minimum period recommended by the 1981 WHO Study Group on Leprosy. It is possible that the minimum period of 24 months will meet the need of most situations and that treatment up to smear-negativity may not be necessary particularly if there are resource constraints. It is therefore recommended that MDT programmes should consider wider application than hitherto of fixed duration treatment of 24 months of MDT for MB cases.

Duration of treatment - PB: In most MDT programmes the implementation of the fixed six months treatment for PB leprosy has been found to be quite satisfactory in terms of clinical response and very low rate of relapse after completion of treatment. However, a few programmes have reported problems in relation to: (a) persistence of clinical lesions in a significant proportion of patients at the end of six months and, (b) appearance of new lesions after completion of treatment in a significant proportion of patients which can be interpreted as relapse or reversal reaction. Patients and health workers in these programmes are reportedly unhappy about stopping treatment at six months. These programmes have therefore tried to cope with the situation through: (i) extending PB treatment to 9 months or even 12 months, and (ii) administering MB treatment for PB patients who have multiple lesions (more than 5 lesions or more than 10 lesions) even if smear negative.

Although there is no clear evidence to support the above policies, it is conceivable that a small subgroup of PB patients, particularly those with multiple lesions, behave more like MB patients in spite of negative smears. In this connection, it is important

to classify patients as MB and PB very carefully, particularly those with multiple lesions and already dapsone treated. When in doubt, the tendency should be to lean towards MB. Patients should be clearly educated at the beginning and at the end of six months about what to expect from the treatment and be appropriately reassured.

Drug supply: The programme should have an effective system of procurement and distribution of anti-leprosy drugs to all levels, including the most peripheral treatment delivery points.

There should be an adequate stock of drugs at all levels to meet the requirements for a period of preferably six months and for a reasonable period at the national level, while ensuring that the drugs are used within their shelf-life.

Compliance: PB patients should continue to receive 6 doses of MDT to be taken within nine months.

MB patients should receive 24 monthly doses to be taken within 36 months. Thereafter the treatment may be stopped. During any period of one year, MB patients should receive at least $^{2}/_{3}$ of the doses to be considered regular, while the period of continuous absence should not exceed four months. Those patients considered 'irregular' should be given another full course of MDT.

It is a general observation that patient compliance with clinic attendance for MDT collection is satisfactory in most countries. Good quality services have contributed to this. Defaulters could be further minimised by adequate education and motivation of patients at the commencement of MDT and during the monthly attendance for supervised treatment. The services should be provided as near to the patients as feasible.

The development of cross-notification of patients who have migrated could be explored. In special situations, patients may be compensated for travel costs to improve compliance.

Supervised treatment: In principle, the monthly dose of MDT should be given under supervision by the responsible health worker. However, in difficult situations, the provision of supervised treatment may be delegated to a reliable local person, e.g., a teacher or church leader or the patients could be provided with a supply of drugs for more than one month at a time.

Side-effects from MDT: Experiences gained in the implementation of MDT in the field over the last eight years have shown negligible side-effects. Therefore MDT should be given to all leprosy patients in need of treatment except: (i) patients with a known history of hypersensitivity to sulfonamides and/or rifampicins; (ii) patients presenting with jaundice. Treatment should be restarted as soon as they recover. However, during MDT, the patient should be periodically monitored for side-effects and should be referred to appropriate referral centres if side-effects occur.

(e) Complications

Lepra reactions and management: The recommendations on this subject made by the WHO Sixth Expert Committee on Leprosy, Technical Report Series (TRS) 768, 1988, are endorsed. However, more emphasis should be placed on the early recognition and reporting of lepra reactions and effective and prompt treatment to prevent disabilities. As an important method of disability prevention, there should be awareness among health workers about early diagnosis of leprosy reactions and knowledge to manage these reactions under field conditions. The inclusion of this topic in the guidelines is important. In the absence of accessible referral facilities, the management of reactions including neuritis could be entrusted to trained peripheral health workers.

Prevention and management of disabilities: Effective treatment of early diagnosed cases are the key to the prevention of deformity. However, leprosy is equated with deformity by the patient and the community. It is true that if sufficient attention and treatment is not provided to patients who have signs of nerve involvement with potential for new deformities, then the whole treatment is at risk of being discredited. Therefore all MDT programmes should try to include a component on the prevention and management of disabilities.

(f) Compliance monitoring

Compliance in the intake of MDT is of the utmost importance for the success of the leprosy control programme. All leprosy patients on MDT should be cured by ensuring that all the drugs as prescribed are taken. In order to achieve the above, several factors are involved:

Health services compliance which: (i) ensure an uninterrupted and regular supply of drugs; (ii) ensure intake of the monthly supervised dose within the existing delivery system and also ensures an effective retrieval system for irregularly attending patients, and (iii) in addition, monitors, wherever possible, the daily unsupervised intake of drugs.

(g) Programme supervision

Regular and continuous supervision is crucial to improve and maintain the quality of services by guiding, educating and motivating health workers.

(h) Post-treatment surveillance

The recommendations of the WHO Sixth Expert Committee on Leprosy are endorsed. However, it should be noted that post-treatment surveillance can be carried out through passive surveillance procedures depending upon the patient's problems. The patients should receive appropriate education and advised at the cessation of treatment to report back as soon as they have a problem. The possible problems in relation to hands, feet, eyes, skin and nerves must be clearly told to the patient at cessation of treatment as well as at his visits during surveillance. This kind of passive surveillance should be maintained at least for two years for PB cases and for five years for MB cases after cessation of MDT. Vertical leprosy control programmes should involve the primary health care staff during the follow-up of MDT.

(i) Urban areas

The problems in urban areas are special, therefore the strategies for implementation of MDT in urban areas should be in conformity with the problems and speciality, e.g., active participation of the medical professionals and utilization of schools.

7.2 Evaluation of leprosy control programmes using MDT

7.2.1 The main goals of leprosy control programmes are to interrupt the transmission of infection by detecting cases as early as possible and treating them in order to achieve complete cure. A leprosy control programme also aims to prevent the development or occurrence of deformities and disabilities, either before or during treatment. Therefore, the most relevant indicators are those which reflect the programme with regard to effectiveness and efficiency in terms of detection and management of leprosy cases. The indicators mentioned in TRS 716, 1985, while generally useful, are far too many and need rationalization to make them more appropriate for application in routine programmes. Hence, to reduce workload at peripheral as well as managerial levels, only a few indicators which are most useful and practical to the programme should be considered.

Three groups of indicators are proposed as tools for evaluation: (1) required indicators; (2) optional indicators for advanced programmes, both to be collected through routine reports and, (3) indicators obtained through special studies.

7.2.2 Required indicators

(a) Prevalence: The current definition of leprosy case as "a person who is clinically and/or bacteriologically diagnosed to be having leprosy and requiring chemotherapy" is appropriate. Prevalence rate in general is useful in estimating workloads, drug requirements and other activities and inputs of the programme. The prevalence rate should be defined as "the number of registered cases at the end of the year divided by population in which the cases occur". The prevalence rate should be specified into multibacillary (MB) and paucibacillary (PB).

(b) Case detection: It is not feasible to calculate accurately the true incidence rate. In view of this difficulty, the most appropriate indicator remains the detection rate as a crude tool for epidemiological and operational evaluation. The detection rate, in combination with the prevalence rate, is useful for the estimation of workloads, drug requirements and other activities and inputs of the programme. The case detection rate should be defined as the number of new cases detected during a given period (generally a year) divided by the population at risk. The detection rate should be specified for multibacillary (MB) and paucibacillary (PB) leprosy.

(c) Proportion of patients with disability Grade II among newly detected cases

The proportion of patients reflects the effectiveness of the programme in terms of early case finding, community awareness of the disease, as well as the level of health worker's diagnostic ability - especially with regard to early nerve damage. This indicator should be defined as the number of newly detected cases with disability Grade I divided by the total of new cases detected during the year.

(d) MDT coverage

All programmes should aim at treating all known cases with MDT. This indicator reflects the effectiveness of the programme with regard to the provision of adequate treatment.

The MDT coverage should be defined as the proportion of patients on MDT amongst all those registered for chemotherapy. This could be derived separately for MB and PB cases.

(e) MDT completion

In principle, all patients starting MDT treatment should complete their regimen within the prescribed duration. The MDT completion should be defined as the proportion of patients who have completed their MDT treatment amongst those expected to complete their treatment. This could be derived separately for MB and PB cases. In arriving at this rate it was considered that cohort analysis should be used and completion of treatment be defined as those, in the case of PB cases, who take 6 doses within a period of 9 months and for MB cases as those who take 24 doses within a period of 36 months.

7.2.3 Optional indicators

The optional indicators proposed are as follows:-

(a) Proportion of children (aged 0-14 years) amongst newly detected cases - refer to the WHO TRS No. 716.

(b) Case detection by mode of detection - refer to the WHO TRS No. 716.

This indicator may be useful for programmes which carry out active case-finding in order to identify the efficiency of the various methods.

(c) Incidence of new disabilities and deformities amongst registered cases - refer to the WHO TRS No. 716.

This indicator reflects the effectiveness of health education and patient care activities aiming at disability prevention.

(d) Proportion of registered cases subjected to skin-smear - refer to the WHO TRS, No. 716.

This indicator intends to measure the proportion of patients smeared according to the guidelines of the control programme. However, without adequate quality control the use of this indicator is useless.

7.2.4 Indicators obtained through special studies

Some of the indicators mentioned in TRS No. 716 are important but not, however, feasible for routine reporting in leprosy control programmes. These indicators include:

(a) Relapse rate: refer to the WHO TRS No. 716. This indicator needs a clear definition and can be only useful when analysed for treatment cohorts.

(b) Estimated prevalence: refer to the WHO TRS No. 716.

7.2.5 Simplified annual report format

POPULATION _____

	NEW CASES		PREVALENCE		MDT COVERAGE
	DETECTION	DISABLED	MDT	OTHER	
PB	a	c	e	g	$\frac{e}{e+g}$
MB	b	d	f	h	$\frac{f}{f+h}$
Total	a + b	c + d	m = e+f	o = g+h	$\frac{m}{m+o}$
			m + o		

	COMPLETION OF MDT TREATMENT	COHORT
PB		1 year
MB		3 years

Prevalence = m + o

Prevalence rate = $\frac{m+o}{\text{population}}$

Number of new cases = a + b

Case detection rate = $\frac{a+b}{\text{population}}$

Proportion of disabled among newly detected cases = $\frac{c+d}{a+b}$

7.3 Training and health systems research

7.3.1 The subject of training was discussed at length. There was consensus about the importance of training as a key element in leprosy control programmes. It was agreed that more inputs should go into training. Training should be task-oriented at every level and it should be geared to meet the need of the particular programme. The training requirements of the different categories of health personnel at different levels of health delivery for both integrated and vertical programmes was looked into.

7.3.2 Training needs at peripheral level

At the peripheral level, the worker should be able to detect leprosy cases and refer to higher level where diagnosis could be confirmed. To undertake these responsibilities he should have the appropriate training to enable him to:-

(a) know early signs of leprosy;
(b) health educate the community;
(c) follow-up leprosy patients and undertake responsibility for defaulter retrieval;
(d) examine contacts/patients and refer suspected cases;
(e) identify major complications of leprosy and refer;
(f) maintain a register of patients referred.

7.3.3 Training needs at intermediate level

At the second level (health clinic/dispensary, health station, etc.) the worker should be trained so that he can:

(a) confirm diagnosis clinically;

(b) classify patients clinically;

(c) initiate treatment;

(d) identify complications at an early stage and refer to a higher level;

(e) detect side-effects of drugs;

(f) register patients and keep accurate records;

(g) supervise and support lower level;

7.3.4 Training needs at referral level

At the district level (district hospital/health clinic) the medical officer/leprosy supervisor should be given enough training to be able to:

(a) diagnose and classify leprosy patients;

(b) detect and treat complications;

(c) review cases during treatment and surveillance;

(d) release from chemotherapy and control;

(e) undertake responsibility for training and supervision of low level workers in the district;

(f) liaise with the central ministry of health and coordinate the work of the nongovernmental agencies engaged in leprosy work in the area;

(g) plan, supervise, monitor and evaluate programme activities in the district;

(h) organize and supervise skin-smear taking and examination.

In vertical programmes, the training components are more or less the same except that some additional training should be provided because the responsibilities of the peripheral worker include active case-finding, surveillance, smear-taking, charting and recording and giving basic physiotherapy to patients.

7.3.5 Training of other health workers involved in MDT

The responsible laboratory worker (microscopist, laboratory assistant, smear technician) should have the appropriate training to enable him to take a slit-smear, stain and read. In integrated programmes, basic physiotherapy and health education should be integrated into the training curriculum. In vertical programmes, there are physiotherapy and laboratory technicians and health educators that need specialist training.

7.3.6 Training in medical schools and paramedical training institutions

To ensure involvement of medical and paramedical health workers in the expansion of MDT, leprosy training should be included in the curricula of those schools. Appropriate training material, including training modules, should be developed. Help could be sought from specialist leprosy training centres, WHO, voluntary organizations, etc.

7.3.7 Short orientation programmes

Being aware of the important role of some target groups, efforts should be made to organize orientation programmes (varying from a few hours to three days) for the general practitioners, nurses, teachers and other groups that could have valuable input in the control programme.

7.3.8 Training of trainers

The need for training of trainers was identified. It was agreed that competent trainers should be identified at national level (in universities, health institutes, etc.) so as to improve the quality of training.

7.3.9 Training and orientation of programme managers

At the central level the person responsible for the programme should have, besides leprosy knowledge, sufficient management training to enable him to manage the programme. The optimum training period for each category of health personnel should be determined in the light of the specific needs.

7.3.10 Health systems research

The subject of health systems research was also discussed. The group felt that there were many operational problems that require research to maximize the programme input and output and to ensure programme efficiency. Hence the following examples for research were identified:

(a) patient compliance;

(b) clinical versus laboratory diagnosis and classification;

(c) optimal way of minimizing over and under diagnosis of leprosy by comparing different approaches/cost implications;

(d) alternative methods of delivery of MDT, particularly in difficult areas/situations;

(e) cost-effectiveness of MDT implementation through vertical versus integrated programme/pilot studies prior to start of MDT;

(f) study of optimum manpower needs with regard to disease endemicity, accessibility and case-load.

8. MAJOR CONCLUSIONS AND RECOMMENDATIONS

1. Experience of implementation of MDT over the past eight years has shown that it is safe and effective and that some of the stringent prerequisites originally needed to start MDT programmes may not be absolutely necessary. This opens the possibility of starting MDT, even in areas with relatively limited health development and human resources.

2. Starting of MDT programmes should not be delayed by waiting for perfect conditions to be established. For instance, it should be possible to start MDT even before establishing reliable skin smear services, although such services should be established or upgraded as soon as possible.

3. There is no need to change the recommendations of the 1982 Study Group on the duration of treatment for MB and PB leprosy. However, taking into consideration resource limitations, programmes should consider wider application than hitherto considered of fixed duration treatment of 24 months of MDT for MB patients. With regard to PB treatment, it is conceivable that a small proportion of currently classified PB patients behave more as MB patients. This brings to attention the need to classify leprosy cases very carefully, taking into consideration both clinical and bacteriological findings.

4. It is more important that a wider coverage of MDT is achieved, even in areas with not so well developed health infrastructure. This could be achieved by making use of community health workers and community leaders for administering treatment.

5. Compliance of patients to MDT depends, to a large extent, on availability of good services including uninterrupted supply of drugs, facilities for treatment of complications etc. Patient education and education of the community are also vital for reaching high levels of treatment compliance.

6. Periodic evaluation of MDT programmes are important and every effort should be made to evaluate through the application of a limited number of simple and essential indicators.

7. Task-oriented training is the key to successful implementation of MDT. Training should include all categories of workers, including managers. Training should be periodically monitored and evaluated.

8. Several operational problems in implementing MDT - some of local nature and others global - exist. These should be sought through well-organized health systems research.

CONSULTATION ON TECHNICAL AND OPERATIONAL
ASPECTS OF MULTIDRUG THERAPY (MDT) IN LEPROSY

Male, Maldives, 11-15 June 1990

LIST OF PARTICIPANTS

Dr (Mrs) M. BECX, Plasweg 15, 768 AKL, Soest, The Netherlands.

Dr (Mrs) Ngeri S. BENEBO, National Tuberculosis and Leprosy Control Programme, Federal Ministry of Health, Ikoyi, Lagos, Nigeria.

Dr P. CHAROON, Leprosy Division, Soi Bamrasnaradoon Hospital, Tiwanond Road, Moo 4 Tambon Talaad Kwuan, Maung District, Nonthaburi 11000, Thailand.

Dr T.J. CHIANG, Marie Adelaide Leprosy Centre, AM-21 off Frere Road, P.O. Box 8666, Karachi 74 400, Pakistan.

Dr P. FEENSTRA, Royal Tropical Institute, 135 Wibautstraat, 1097 Amsterdam, The Netherlands.

Professor J. GROSSET, Faculté de Médecine, Pitié Salpêtrière, 91 Boulevard de l'Hôpital, 75634 Paris Cedex 13, France.

Dr HAIDAR ABUAHMED MOHAMED, Faculty of Medicine, University of Khartoum, P.O. Box 102, Khartoum, Sudan.

Dr LI, Huan Ying, Leprosy Unit, Beijing Tropical Medicine Research Institute, 95 Yun An Lu, Beijing, People's Republic of China.

Dr D. LOBO, Gremaltes Referral Hospital and Leprosy Centre, 5 Gajapathy Street, Shenoynagar, Madras 600 030, India.

Dr B. MITTAL, Directorate General of Health Services, Ministry of Health & Family Welfare, Nirman Bhavan, New Delhi 110 011, India.

Dr L.-B. MPUTU, Bureau National de Lutte contre la Lèpre, B.P. 4741, Kinshasa, Zaire.

Dr P.A. OREGE, Director, Alupe Leprosy and Skin Diseases Research Centre, P.O. Box 3, Busia, Kenya.

*Dr B. RAJA RAO, District Leprosy Officer, Eluru, W. Godabury Dist., Andhra Pradesh, India.

Dr C.K. RAO, New Delhi, India.

---

* Invited but unable to attend

Mr Tadele TEDLA, National Leprosy Control Project, Ministry of Health, P.O. Box 5033, Addis Ababa, Ethiopia.

Dr U TIN MYINT, Deputy Director (Leprosy), Yangon, Myanmar

Dr C. VIARDO, J.N. Rodriguez Memorial Hospital, Tala, Calrocan City 11402, Philippines.

Dr Y. YUASA, Executive and Medical Director, Sasakawa Memorial Health Foundation, The Sasakawa Memorial Hall, 3-12-12 Mita, Minato-ku, Tokyo 108, Japan.

Dr A.M. ZULUETA RODRIGUEZ, Instituto de Biomedicina, Apartado Postal 4043, San Jose, Caracas 1010A, Venezuela.

Secretariat

Dr A.S. ABDULLAH, Medical Officer, Leprosy, WHO Regional for South-East Asia (SEARO)
Mrs J. BELL, Leprosy Unit, WHO, HQ
Dr D. DAUMERIE, WHO Short-Term Consultant, Africa
Dr L. LOPEZ BRAVO, Leprosy Unit, WHO, HQ
Dr S.K. NOORDEEN, Chief, Leprosy Unit, WHO, HQ
