

REPORT ON SIXTH MEETING OF THE
WHO TECHNICAL ADVISORY GROUP ON
ELIMINATION OF LEPROSY

Geneva, 9 and 10 February 2004



World Health Organization

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**Report on sixth meeting of the
Who Technical Advisory Group on Elimination of Leprosy
Geneva, 9 and 10 February 2004**

1. Introduction

The sixth meeting of the WHO Technical Advisory Group on Elimination of Leprosy (TAG) was held in Geneva, Switzerland, on 9 and 10 February 2004. Professor W.C.S. Smith was unanimously elected as Chairperson for the two-year period 2004–2005, and thanked the outgoing members, Dr M. Becx-Bleumink and Dr A.O. Awe, for their contributions. Professor Smith welcomed four new members of the TAG: Drs H. Assé (Cote d'Ivoire), S. Jianping (China), K. Katoch (India), and P. Saunderson (USA). Dr P. Krishnamurthy of the Damien Foundation India Trust attended the meeting as a special invitee. National leprosy programme managers from Brazil, India, Nepal and the United Republic Tanzania also participated in the meeting, but the Technical Commission of the International Federation of Anti-Leprosy Associations (ILEP) was unable to send its representative.

In his opening remarks, Professor Smith thanked the outgoing Chairperson, Dr Becx-Bleumink, for her outstanding leadership during her two-year tenure. Many remarkable milestones had been attained during this period, not only in bringing more endemic countries closer to achieving elimination but also in the further simplification of technical issues in order to facilitate the full integration of leprosy control activities within the local health services. Professor Smith reminded the TAG that, in spite of remarkable progress, many challenges still remained; to meet these remaining challenges, he stressed that the TAG should continue to act as the independent body of experts providing appropriate advice to WHO's leprosy programme.

2. Report on fifth meeting of TAG

The report on the fifth meeting of the TAG, held in Yangon, Myanmar, on 9 and 10 February 2003, was circulated widely. The Medico-Social Commission of ILEP – now renamed the ILEP Technical Commission – welcomed the report and provided comments that were discussed by members of TAG.

- The Commission strongly endorsed the moves being made towards integration, but felt that the comment that Brazil and India were lagging behind in their progress towards integration was too sweeping. The TAG stressed that the statement was made in the light of the situation prevailing at the time and welcomed any new information that suggested a more favourable rate of progress.
- The Commission welcomed the emphasis on improving the quality and coverage of detection. However, it disputed the assertion that “a limited number of new cases will continue to occur in the coming years”, and the TAG agreed that, in the absence of reliable tools, it is difficult to measure trends in the incidence of leprosy. The TAG noted that the data on global case detection showed a reduction of almost 20% during 2002 compared with 2001. The available information suggests that this downward trend is likely to have continued during 2003.

- TAG appreciated the suggestion that ILEP would undertake studies on uniform MDT (U-MDT) with modified protocols, possibly using a control group. The results could be shared and compared with the current WHO-sponsored studies.
- The Commission called for guidelines on updating leprosy registers to be made available to national programmes. Several countries and regions, and particularly WHO's Regional Office for Africa, have developed such guidelines.
- Concern over the increasing use of accompanied multidrug therapy (A-MDT) was expressed by the Commission. However, a presentation made later in the TAG meeting reviewed a study from India, comparing A-MDT with routine (monthly) MDT delivery. The results demonstrate that, with adequate counselling and appropriate support, treatment adherence can be better with A-MDT than with routine MDT delivery. More programmes should document their experiences with A-MDT.
- The Commission agreed that "there is no role for maintaining outdated active surveys which are costly, unreliable and more importantly perpetuate the negative image of leprosy in the community".
- The Commission agreed with the TAG recommendation that leprosy elimination campaigns (LECs) should focus on selected areas only and use carefully identified LEC components.
- The Commission welcomed the statement that "WHO does not propose to change the definition of elimination or give any new target date for elimination".

The report on the fifth meeting of the TAG was approved by the members.

3. Current global situation

Since 1985, global prevalence has declined by about 90% and more than 13 million patients¹ have been cured with WHO-recommended MDT. The strategy has been applied with full political and professional commitment in all endemic countries, resulting in the attainment of the global target of less than one case per 10 000 population by the end of 2000. It has also helped to focus special attention on countries with a high disease burden. To date, of the 122 countries where leprosy was considered to be a public health problem² in 1985, only 10 still have to reach the elimination goal. They are: Angola, Brazil, Central African Republic, Congo, India, Liberia, Madagascar, Mozambique, Nepal and United Republic of Tanzania. Taken together, these 10 countries contributed 86% of the global prevalence at the beginning of 2003 and 88.5% of new cases detected during 2002.

The available information shows that about 621 000 new cases were detected during 2002, which is almost 20% less than the number detected during 2001. It is thought that this downward trend will have continued during 2003, although this will not be confirmed until later in 2004.

In spite of the progress being made, it is clear that in many programmes the registered prevalence is artificially inflated because of non-adherence to the treatment guidelines and a

¹ This figure is the cumulative number of leprosy patients who were declared as cured, after treatment with MDT, since its introduction into the global programme in 1982. It does not include patients cured with dapsone or any other antileprosy therapy.

² The elimination of leprosy as a public health problem is defined as the reduction of leprosy prevalence at a given point in time to less than one case per 10 000 population, at the national level.

reluctance to remove from the treatment registers individuals who are cured or who are long-term defaulters. Similarly, the number of new cases detected includes a significant proportion of wrongly diagnosed cases and old cured cases re-registered as new cases, particularly in programmes that depend largely on active surveys as the preferred method of case detection. There is an urgent need for all programmes to update treatment registers regularly and improve the quality of diagnosis of new cases of leprosy.

The leprosy control activities in all endemic countries are progressively moving towards integration within the general health services. Integration is considered to be the key element in ensuring the long-term sustainability of free and easy access to MDT services³ to all affected communities. However, implementation of this process remains slow in several highly endemic countries.

4. Country presentations: remaining challenges for achieving elimination

The national programme managers from four top endemic countries – Brazil, India, Nepal and United Republic of Tanzania – participated in the meeting. They made brief presentations on the main challenges faced by their programmes in working towards elimination targets at the national level and their plans for the coming years.

4.1 Brazil

Brazil is one of the world's most highly endemic countries for leprosy. The reported prevalence rate, which includes a significant proportion of long-term defaulters and patients given extended treatment with MDT, was more than 4 per 10 000 population in 2003. However, applying the WHO definitions of prevalence and treatment duration, the corrected rate was 2.46 per 10 000 population. The new case-detection rate for the year 2003 was 2.32 per 10 000 population. Three of the five regions – North, North-East and South-East – contributed 80% of new cases detected during 2003. Since 1985, the new case-detection rate has shown an increasing trend, possibly reflecting improved coverage and large-scale introduction of MDT. By contrast, prevalence declined from 16.4 per 10 000 population in 1985 to 4.1 per 10 000 population in 2003.

During 2003, the programme undertook several activities to accelerate the pace of elimination, principally mass information campaigns and the leprosy elimination monitoring (LEM) exercise. The mass information campaigns were specially targeted to increase community awareness of the disease and the availability of an effective treatment in the 14 most endemic states.

Leprosy elimination monitoring – 2003

The objectives of the LEM exercise were:

- to evaluate leprosy elimination activities in all 27 states (including the Federal District of Brasília);
- to evaluate the status of integration of MDT services within Family Health Care Units (FCHUs);

³ MDT services include diagnosis, treatment with MDT, patient and family counselling, community education and referral for complications.

- to identify potential obstacles to the successful implementation of key activities; and
- to make recommendations for improvement.

Monitors visited 183 municipalities, covering all 27 states, examined more than 25 000 patients records and interviewed about 1000 patients.

Main findings

- The reported prevalence was significantly higher (about double) than that observed by the monitors, who used WHO definitions for defaulters and duration of treatment with MDT.
- In 16 out of 27 states, the prevalence:detection ratio (P:D ratio) exceeded one, indicating an extended duration of treatment with MDT and a significant irregularity in treatment adherence and default.
- Out of 2189 FHCUs visited, MDT was available in only 485 (22.2%); MDT coverage ranged from 0% in the South region to 41.2% in the North-East region. The FHCU is considered to be the most peripheral health facility within the general health services. These observations thus indicate very limited success with integration and underscore the urgent need to strengthen this element of leprosy control activities.

The TAG stressed that all programmes for external reporting and country comparisons should follow WHO guidelines for definitions regarding diagnosis, treatment, cure and defaulters, and for reporting the point prevalence rate.

4.2 India

India has made remarkable progress in reducing the leprosy prevalence from 25.9 per 10 000 in 1991 to 3.23 per 10 000 in 2003. Over this period the annual new case-detection rate fluctuated between 5 and 6 per 10 000 population, with a peak of 8.9 per 10 000 in 1999. During 2003, despite intense case-detection activities through LECs, the programme recorded its lowest new case-detection rate (4.4 per 10 000), which represents a reduction of more than 25% from the 2002 rate.

Main challenges and proposed actions

- At the beginning of 2004, 212 of 590 districts have reached the elimination target, while the prevalence rate in 118 districts remains above 5 per 10 000 population.
- The process of integration, both structural and functional, needs to be accelerated.
- The simplified information system and regular updating of registers should be fully implemented.
- Mechanisms should be built into the programme for improving the quality of diagnosis of new cases of leprosy and preventing the re-registration of previously treated cases as new cases.
- MDT supply and stock management should be improved at all levels.
- Special action is needed for urban areas, migratory groups and communities that are difficult to access.

- Innovative approaches need to be sought to improve community awareness and participation.
- An integrated strategy for prevention of disabilities and rehabilitation needs to be developed.

The Indian programme remains determined to overcome these challenges and reach the target of elimination by the end of 2005.

4.3 Nepal

The leprosy control programme in Nepal introduced MDT in 1982. In 1987 the programme was integrated within the general basic health services, and by 1996 coverage with MDT had reached 100%. At the beginning of 2004, leprosy prevalence stands at 2.98 per 10 000 population and is still more than one case per 10 000 population in 44 districts (out of 75), mainly situated in the plains regions bordering India.

Main challenges

- The political situation in the country continues to give rise to insecurity and internal displacement of some sections of the population.
- Nepal has established a good health infrastructure but has limited resources and is affected by political instability.
- Community awareness needs to be increased as new cases are still reporting late with grade-2 deformities.
- The programme has expanded MDT services to the most peripheral levels, but restricted mobility, particularly at the sub-health post level, has made it difficult to carry out monitoring and supervision activities.
- Wrong diagnosis, re-registration and defaulting have been significantly reduced but continue to be a problem, particularly among the patients who attend referral clinics run by international NGOs.

Proposed solutions

- To strengthen monitoring at the peripheral level, a focal person at the health post will be identified. This person will be responsible for coordination and management at the local level and will report to the district team.
- Mass media and local initiatives should be used to increase community awareness and participation.
- The use of A-MDT should be increased to improve treatment completion and reduce the defaulter rate.
- To solve the problem of defaulting/irregular patients, a mechanism of cross-referral notification from INGO referral clinics to the nearest health facility has been introduced in the programme.

4.4 United Republic of Tanzania

The Tanzanian National Tuberculosis and Leprosy Programme was launched in 1977; it is integrated into the existing primary health care system, with all health providers responsible for early case detection and appropriate treatment. A limited number of specialized staff are available to provide technical guidance, monitoring and supervision at national, regional and district levels. The Programme introduced WHO-recommended MDT as recently as 1996–1997. Before this, from 1983 to 1996, the Programme used Isoprodian®-based antileprosy treatment.

Registered prevalence declined continuously from about 27 000 in 1985 to 2500 in 1998, thus reaching the target of elimination at the national level. However, the annual number of new cases detected remained between 3000 and 4000 up to 1998, with high proportion of grade-2 disability and multibacillary (MB) cases. This static situation clearly indicated that a substantial number of cases remained undetected and that the delay in diagnosis was considerable. During 1999 and 2002, therefore, the programme conducted two LECs and, from 1999, the annual number of new cases detected increased significantly, to between 6000 and 7000. In some regions, new case detection increased three- to four-fold compared with previous years. At the beginning of 2003 prevalence was about 7000 (two per 10 000 population). In addition, the programme conducted two exercises – updating of leprosy registers and LEM – to identify the major challenges and initiate remedial actions.

Major challenges

- A significant number of cases in the community remain undetected.
- Community awareness is low, leading to delays in diagnosis.
- General health workers need training and supervisory support to improve diagnosis and case management and the timely removal of cured patients from registers.
- Special action will be needed to improve access to MDT services for nomadic populations, refugees and difficult-to-access areas.
- Currently, MDT services are available in less than 50% of existing health facilities.

Main areas for action

- The process of integration and making MDT services available in all health facilities will need capacity building and the transfer of responsibilities to local health workers.
- Updating of treatment registers should become part of routine monitoring and supervision.
- Areas suspected of having a large number of undetected cases should be identified for focused campaigns. Special campaigns should be carried out to increase community awareness of leprosy, its curability and the availability of free treatment (MDT).
- Particular attention needs to be paid to providing MDT services for special population groups, such as nomadic groups, refugees and those living in difficult-to-access areas.

5. Follow-up of TDR/SWG recommendations

The TDR Scientific Working Group on Leprosy Research (TDR/SWG) met at WHO headquarters, Geneva, in November 2002. A detailed presentation on the major issues identified, as well as recommendations of the SWG, had already been reported during the fifth meeting of the TAG in Yangon, Myanmar, on 9 and 10 February 2003.

The SWG had achieved a clear consensus on the major possibilities for leprosy research based on the expressed needs of endemic countries and the current research opportunities. The next steps proposed were to translate the major priorities into detailed programmes and research protocols in the four identified areas: transmission, diagnostics, nerve damage and integration. Two workshops – on research in nerve damage and reactions in leprosy and leprosy transmission and on diagnosis – were held during 2003. It is planned to hold a workshop on integration and implementation research in Brazil in March 2004.

6. Preliminary results of the study comparing outcomes of 12-month MDT and 24-month MDT in MB patients

Since the recommendation made by the seventh meeting of the WHO Expert Committee on Leprosy in 1998, most national programmes have introduced the 12-month MDT regimen for all MB leprosy patients. Data on the absolute number of relapses, collected annually from national programmes and provided to WHO, do not indicate an increased risk of relapse in MB patients treated with the 12-month MDT regimen.

The National School of Public Health and Leprosy Laboratory, Oswaldo Cruz Foundation, Rio de Janeiro, Brazil, undertook a longitudinal study designed to compare the outcomes of 12- and 24-month MDT for smear-positive MB leprosy patients.

Group 1 was made up of 128 smear-positive MB patients and Group 2 of 85 smear-positive MB patients. The preliminary results were available for a total of 48 months from the time of intake into the study. The outcomes measured were: reduction in bacteriological index (BI), frequency of reactions, and occurrence of new disabilities.

Preliminary conclusions of the study

- The two treatment regimens resulted in a similar BI reduction rate during and after completion of treatment.
- There was no difference between the two groups in the occurrence of lepra-reactions. Patients in both groups with a BI of 1.5 or more were at higher risk of developing lepra-reactions.
- The proportion of patients with grade-2 disability remained the same in both the groups.
- Follow-up of patients needs to continue in order to provide more information both on outcomes and on relapses (if any).

So far, this study has shown a favourable outcome for MB leprosy patients treated with 12-month MDT. The TAG stressed the importance of countries continuing to accumulate data from their programmes on relapse in this group of patients.

7. Uniform-MDT study: progress report

The multicentre study on uniform-MDT (U-MDT) is being coordinated by the National Institute of Epidemiology in Chennai, India. The preparatory planning, training workshops and logistics, including the supply of special U-MDT patient packs for the study sites, have already been completed. The study was launched in September 2003, with the participation of four districts in India and three districts in China. The intake period is for two years, during which about 2500 PB and 2500 MB patients will be recruited for the study. More countries are likely to join the study during 2004. The ILEP Technical Commission (previously the Medico-Social Commission) has expressed interest in supporting similar studies with some modifications to the protocol. The TAG welcomed this offer of collaboration and the sharing of findings of the U-MDT study undertaken under the sponsorship of WHO and ILEP. It recommended that all participating centres make extra efforts to complete the recruitment of patients on time.

8. Results of operational study comparing accompanied MDT and routine MDT

The TAG had strongly recommended that A-MDT would give better access to MDT for patients in general and, in particular, for those unable to visit the health centre regularly for a variety of reasons. Patients choosing A-MDT as their treatment option should be fully informed about the disease and its treatment, including the importance of reporting promptly to the health centre in the case of complications, and at the end of treatment.

The Damien Foundation India Trust carried out an operational study in Madhepura district, Bihar State, comparing treatment adherence with A-MDT and with routinely followed MDT delivery. Madhepura district has a population of 1.5 million and detects an average of about 3500 new cases annually. The problems listed were: high rates of irregularity and defaulting, difficult terrain, low literacy rate and migratory population. The district has only eight health facilities – seven primary health centres and one urban hospital – far below the norm in other areas. The health facilities were randomly divided into two groups of four: one group was the study group (A-MDT), and the other was the control group (routine MDT).

The district conducted an LEC just before the study, during which a large number of new cases were detected. All confirmed new cases of leprosy were recruited into the study.

Patients in the study group (A-MDT) were given a full course of drugs at the start of treatment – six PB blister-packs for PB cases and 12 MB blister-packs for MB cases. Patients in the control group (routine MDT) collected drugs every month from the nearest health facility. Treatment adherence, for both the monthly pulse dose and daily doses, was measured by inspecting the blister packs during a home visit at the end of the treatment period. Patients in both groups received counselling according to a standardized format, and were requested to retain all used blister-packs until completion of the study.

A total of 462 PB patients (168 given A-MDT and 294 given routine MDT) and 125 MB patients (58 A-MDT and 67 routine MDT) were recruited into the study.

8.1 Results for PB leprosy

Treatment adherence for monthly pulse doses, i.e. taking all six monthly pulse doses, was 80% for the A-MDT group of patients but only 54% for the routine MDT group. Considering only those blister-packs that were actually collected, treatment adherence for daily doses (defined

as taking two-thirds of the doses) was 99% for the A-MDT group and 94% for the routine MDT group.

8.2 Results for MB leprosy

Treatment adherence for monthly pulse doses, i.e. taking all 12 monthly pulse doses, was 79% for the A-MDT group of patients but only 42% for the routine MDT group. Considering only those blister-packs that were actually collected, treatment adherence for daily doses (defined as taking two-thirds of the doses) was 84% for the A-MDT group and 79% for the routine MDT group.

In the routine MDT group, the main reasons for missing treatment were distance from the health facility, MDT drugs out of stock at the health facility, and closed health facility. For the A-MDT group, on the other hand, the main reasons were loss of drugs and damaged drugs. Three patients (one A-MDT and two routine MDT) reported to the health facility with complications.

The TAG congratulated the Damien Foundation Trust India for conducting an excellent study under field conditions. The results demonstrate that, with adequate counselling and appropriate support, treatment adherence with A-MDT can be better than with routine MDT. It is recommended that this study be published as soon as possible, as the results could have implications for other disease control programmes. The TAG urged that similar documentation of experiences be undertaken in other programme settings.

9. Progress with ongoing multicentre clinical trial for the treatment of PB leprosy patients with single dose of rifampicin, ofloxacin and minocycline (ROM)

A multicentre clinical trial is being coordinated by the National Institute of Epidemiology, Chennai, India, with the objective of comparing the efficacy of a combination of rifampicin, ofloxacin and minocycline (ROM), administered as a single dose, with the standard 6-month PB MDT regimen for the treatment of skin-smear-negative PB leprosy cases. The trial consists of two parts – an open study for single-lesion PB cases and a double-blind study for PB cases with 2–5 skin lesions.

A total of 2788 previously untreated PB leprosy patients (1262 single-lesion patients and 1526 with 2–5 skin lesions) from five different centres in India have been recruited into the trial. The study is now in its fourth year with excellent follow-up (more than 99% coverage at the end of 42 months) of patients recruited in the trial. Follow-up will continue for another year and detailed results will be available in early 2005.

10. Leprosy elimination monitoring: experiences from Nepal

The leprosy control programme in Nepal conducted an LEM exercise in July and August 2003 in order to assess the current situation and prepare plans of action to reach the elimination target during the period 2004–2005. The objectives of the exercise were: validation of reported information on prevalence and detection; assessment of the current status of integration within the general health services; assessment of the quality of MDT services and cure rates; and evaluation of the adequacy of MDT supply and other logistics. The exercise also attempted to gather information on the level of awareness about leprosy in the community.

More than 80% of the leprosy burden is contributed by 20 districts in the plains region. Ten endemic districts were randomly selected for the LEM exercise and eight health facilities in each, including one referral facility run by an international NGO, were subjected to detailed assessment. In addition, about 1200 community members were interviewed regarding their knowledge about leprosy and its curability.

10.1 Main findings

- Major discrepancies were found in the reported and actual prevalence.
- Prevalence and detection show a declining trend over the past five years. The proportion of female patients among new cases detected has increased in recent years. More than 75% of new cases detected during the past five years have been in the age group 15–59 years; only 10–20% of them have been children.
- Some districts reported a very high proportion of new cases presenting with grade-2 deformities.
- The proportion of new cases with single skin lesions was high in areas where active surveys were used for case detection.
- The average delay in diagnosis ranged from 14 months to 30 months.
- Patients had to travel 1–6 kilometres to reach the nearest government health facility, but 8–42 kilometres to reaching a referral facility run by NGOs.
- All health facilities provided patient-friendly MDT delivery, allowing more than one month's supply or providing the full course as A-MDT.
- The cure rate for cohorts of both MB and PB patients was low, particularly among those collecting treatment from the referral facilities run by NGOs.
- Most health facilities had inadequate (less than four months) stocks of MDT available. The same was true of other essential materials, such as patient cards, guidelines and manuals, and information, education and communication (IEC) materials.
- The level of community awareness about leprosy, its curability and availability of MDT free of cost at the health facility was low.

10.2 Main recommendations

- There is an urgent need to strengthen monitoring and supervision activities. However, this will also require improvement in the security situation currently prevailing in the country.
- All health workers involved in diagnosis and management of leprosy will need job-oriented training in order to improve the specificity of diagnosis, avoid the reregistration of old cases, improve treatment adherence and ensure the timely removal of cured individuals from the treatment registers.
- Referral health facilities run by NGOs are less accessible than others and should therefore, while continuing to provide special care for patients with complications, advise other patients to report to the nearest government-run health facility for continuation of treatment.

- In spite of the security situation, all attempts should be made to provide adequate stocks of MDT and other essential materials to peripheral health facilities. In such situations, the use of A-MDT will greatly reduce irregularity and default.
- Efforts must be made to increase community awareness of leprosy, its curability and the availability of effective MDT, free of charge, from the nearest health facility. In the current security situation, radio is the preferred medium for this, because of its wide availability and coverage.
- The programme should focus more attention on, and use more of its human and other resources for, improving the situation in the 20 most highly endemic districts, which together contributed more than 80% of leprosy burden in the country during 2004–2005.

The TAG reiterated the relevance of LEM exercises for monitoring leprosy control activities and objectively assessing the strengths and weaknesses of the programme in order to implement corrective actions.

11. Validation of diagnosis of newly-detected cases: results from India

During the fifth meeting of the TAG, it was agreed that stable, or even increasing, detection in some countries or areas is a matter of major concern. The elimination of leprosy, though defined as a reduction of prevalence below a particular level, depends to a large extent on a reduction of the occurrence of new cases. It is therefore important to validate case detection figures, both through a review of registers and by assessment of the recently-detected patients themselves, at least on a sample basis. The expected outcomes of such an exercise are a more accurate picture of disease occurrence in a given area, and health workers who can correctly diagnose a new case of leprosy.

In collaboration with WHO and the National Institute of Health and Family Welfare, New Delhi, the Indian national programme conducted an independent study during 2003. The objective of the study was to assess the accuracy of diagnosis and classification of newly detected cases of leprosy, the re-registration of old treated cases, and the proportion of non-existent cases, if any.

A Core Group was formed, comprising experts from all major partners supporting the Indian leprosy programme, including several ILEP members, and developed standard protocols for the validation of leprosy diagnosis and classification into MB and PB categories. The Core Group also identified a number of local experts as validators and conducted workshops to ensure that standard methods and procedures would be followed during the actual field work.

One district from each of the 12 most highly endemic states was randomly selected. Each provided a list of recently detected new cases to the validation teams (within one month for PB and two months for MB). Each validation team consisted of two experts, who independently assessed each listed patient for the correctness of diagnosis and classification and ascertained whether a patient had any previous history of antileprosy treatment. Thus there were two sets of records for each patient examined; these were sent to the National Institute of Health and Family Welfare, for independent analysis.

11.1 Main findings

- A total of 2541 recently-detected patients were included in the study.
- Only 1503 patients (about 60%) were available for examination by both validators. Agreement between the validators was 87%.
- Some 9.4% of diagnosed cases were not, in fact, cases of leprosy. For individual states, this proportion ranged from 1.1% in Bihar to 21.1% in Madhya Pradesh. For PB leprosy the range was from 0.9% in Jharkhand to 25.0% in Madhya Pradesh, and for MB leprosy from 2.0% in Chattisgarh to 18.9% in Madhya Pradesh. The proportion of wrongly-diagnosed cases was significantly higher for PB than for MB cases.
- About 13.5% of newly-registered cases had been previously registered and treated. This proportion was lowest in Andhra Pradesh (3.0%) and highest in Karnataka (49.5%). For PB leprosy the range was from 0.7% in Jharkhand and 30.2% in Karnataka, and for MB leprosy from 4.4% in Andhra Pradesh to 64.8% in Karnataka. The proportion of reregistered patients was significantly higher for MB than for PB cases.
- The proportion of wrong classification was 11.2% overall; for MB cases the proportion was 18.3%, compared with 4.2% for PB cases.
- The proportion of non-existent cases was high in Delhi (31.3%), Bihar (14.5%) and Uttar Pradesh (7.7%), but none were found in the states of Andhra Pradesh, Maharashtra and West Bengal. Non-existent cases are defined as patients who were on the list prepared by the local health facility, but who could not be found at the given address and whose existence was unknown to community/neighbours in the area. In short, these were either fictitious cases or individuals who gave a misleading address.

In summary, combined over-reporting of new cases – including wrong diagnosis, re-registration and non-existent patients – accounted for at least 25% of new cases.

11.2 Main recommendations

- All health workers involved in the diagnosis of leprosy should apply standard definitions and examination procedures for clinical diagnosis and classification of a new case of leprosy.
- All health workers involved in the diagnosis of leprosy should systematically ask the patient, at the time of diagnosis, about any history of previous antileprosy treatment taken by the patient, in order to avoid their re-registration as a new case.
- Each district should set up a simple, in-built system for the routine validation of newly-detected cases, at least on a sample basis.
- On-the-job training should be carried out, particularly in areas where there is a high proportion of wrong diagnosis, wrong classification or re-registration.
- Any individual wrongly labelled as a case of leprosy should be given appropriate counselling and his or her name should be removed from the leprosy treatment register.

- The treatment of any patient found to have been wrongly classified as PB or MB should be adjusted appropriately (shortened or extended). The treatment register and the patient's card should be updated accordingly.
- Non-existent patients should be removed from the leprosy treatment register.

Members of the TAG expressed their appreciation of the Indian national programme for undertaking this important study. The lessons learned from the study are important for leprosy control programme in every endemic country. All programmes must make serious efforts to improve the quality of leprosy diagnosis.

12. Report on the informal consultation on post-elimination strategy (Manila, Philippines, November 2003)

Within the TAG, discussion on development of a post-elimination strategy continues but is still far from complete. The essential framework will be developed in consultation with concerned countries, experts, partners and WHO regional offices.

An informal consultation on the subject was organized in November 2003 by the WHO Regional Office for the Western Pacific, Manila, Philippines. Its main objective was to identify the key elements of, and steps in developing, a comprehensive post-elimination strategy for Member States in the Region, almost all of which have achieved the target of eliminating leprosy as a public health problem. However, the disease remains a public health problem in a few island countries/areas and in highly endemic pockets in several other countries.

The participants agreed that the key strategy for leprosy control will remain early detection of new cases in the community and their prompt treatment with MDT. The challenge will be to sustain leprosy control activities and reduce the disease burden further by fully integrating MDT services within the existing general health services. Appropriate referral services will still be needed for management of complications and training of health workers. For monitoring purposes, the principal indicator will be new case detection (including quality of diagnosis) and its trend.

The WHO Regional Offices for South-East Asia and the Western Pacific are jointly planning a further meeting of selected Member States of the two Regions during the latter part of 2004.

13. Antileprosy vaccine trials in India: review and next steps

A multi-arm prophylactic trial of antileprosy vaccines was initiated in south India in January 1991. From a population of about 300 000, 171 400 individuals were recruited to take part in the trial, based on voluntary informed written consent. The trial had five arms – BCG alone, BCG + HKML, *M. w.*, ICRC, and placebo. The intake survey was completed between January 1991 and July 1993, and three re-surveys have been completed since then. Preliminary findings from the third re-survey conducted between August 1999 and December 2002 were presented to the TAG.

Preliminary findings: third re-survey

- Overall vaccine efficacy reached 67% for BCG + HKML, 51% for ICRC, 41% for *M. w.* and 22% for BCG alone.
- Vaccine efficacy for contacts was: BCG + HKML 88%, *M. w.* 87%, BCG 11% and ICRC 11%.
- Interestingly, the placebo group showed a significant decline in leprosy incidence during the three re-surveys – from 23.6 per 10 000 during the first re-survey, to 12.8 per 10 000 during the second and 6.1 per 10 000 during the third.

The TAG noted that further studies of the use of booster doses of BCG in schoolchildren and BCG use in household contacts are in progress in Brazil.

The implications of these new results for the role of antileprosy vaccines in leprosy control should be reviewed in the context of other findings on mycobacterial vaccines.

14. Developing a framework for a strategy to sustain elimination: 2006–2010

It is clear that, by the end of 2005, leprosy will be considered to be a rare disease in most countries where it was a public health problem in 1985. For various reasons, the defined target of reducing the prevalence rate to below one case per 10 000 population may not be achieved by the end of 2005 in some countries – but should be reached within just a few years more.

Given such a scenario, it is important that efforts be made to sustain such achievements, to reduce the disease burden still further, and to make MDT services easily accessible to communities in which new cases of leprosy will continue to be detected. There will be no advantage in continuing to use elimination as an indicator or in defining another numerical target or timeframe for the period beyond 2005: the most important indicator for monitoring the leprosy situation will be the declining trend in new case detection.

The key issue will be to integrate all essential components of leprosy control, including the referral facilities, within the existing primary health care system or another relevant programme. This will need careful planning and probably different approaches within a single country, depending on the local leprosy burden and the availability of an appropriate health infrastructure or programme for integration.

The main concern, at least in some large vertical programmes, will be the reallocation of existing personnel, in order to provide technical support, monitoring and supervision. It will be important to build up the capacity of both vertical workers and general health workers to take on new responsibilities.

The TAG recommended that a clear strategy with a new focus be developed by the WHO secretariat for the next five years (2006–2010) in order to sustain the achievements of the elimination strategy to date and to reduce the disease burden further at national and sub-national level. This will involve extensive discussions with WHO's Member States and regional offices; the strategy should be developed in time for presentation to the next TAG meeting.

15. Conclusions and recommendations

1. Although much progress has been made towards the elimination of leprosy as a public health problem, major challenges remain in several highly endemic countries, which will need close attention during the coming years. In addition, other countries still have highly endemic pockets at province/district levels; they should identify these areas and take special action to analyse the circumstances and implement appropriate control measures.
2. For external reporting, monitoring of progress and international comparisons, countries should follow the WHO guidelines for definitions of diagnosis, treatment, cure and defaulters, and for reporting of the point prevalence rate.
3. Wherever possible, programmes are recommended to analyse new case detection trends by age, sex and type of leprosy in selected populations for review by the TAG. WHO can advise countries on appropriate methods for doing this.
4. The Indian national programme has conducted an impressive study on the validation of new case detection. The lessons learned from this study are important for all endemic countries, which are urged to conduct similar studies, with a detailed analysis and presentation of findings. Efforts must be made to reduce wrong diagnoses and the reregistration of old cases as new cases.
5. The WHO leprosy programme should continue to collaborate in developing an appropriate research agenda, including operational research, with TDR.
6. The TAG welcomes the favourable results obtained so far in the Brazilian study comparing 12-month and 24-month MDT for MB patients, and recommends that countries continue to accumulate data on the outcome of 12-month MDT for MB patients.
7. The TAG congratulated the Damien Foundation, India, for an excellent study comparing accompanied MDT with routine MDT under field conditions. The results demonstrate that, with adequate counselling and appropriate support, treatment adherence with A-MDT can be better than with routine MDT. The TAG re-endorsed the use of A-MDT and urged that similar documentation of experiences be undertaken in other programme settings.
8. The TAG reviewed the recent findings of the third re-survey in the south India leprosy vaccine trial. Further studies of the use of booster doses of BCG in schoolchildren and BCG use in household contacts are in progress in Brazil. The implications of these new results for the role of antileprosy vaccines in leprosy control should be reviewed in the context of other findings on mycobacterial vaccines.
9. The TAG reiterated the relevance of LEM exercises for monitoring various aspects of leprosy control activities, and encourages all endemic countries to conduct such exercises.
10. Evidence to date from national reporting and from well conducted cohort studies indicate that relapse after MDT is rare. However, it is important that monitoring of relapse continue, that studies of resistance (particularly to rifampicin) in relapses are undertaken, and that the use of molecular genetic methods to distinguish relapse from reinfection is explored.
11. The TAG welcomed the launch of the trial of uniform MDT in China and India, and encourages other centres and agencies, including ILEP, to participate in such trials.

12. The TAG reviewed preliminary findings from trials of rifampicin–ofloxacin–minocycline for treatment of PB cases with single skin lesions and with up to five skin lesions, and recommends one additional year of follow-up with a full analysis of findings.
13. The TAG discussed in detail the objectives and activities necessary to sustain leprosy programmes after 2006. Feedback from countries that have already achieved the elimination target indicate that leprosy programmes are being sustained within existing health services. Further documentation of the experiences of such countries would be valuable for developing future strategies, which should be based on integration of all leprosy activities within existing primary health care health services. The continued free donation of high-quality MDT drugs by Novartis is an essential component of these strategies. Monitoring of new case detection at national and sub-national levels is also essential.
14. The TAG recommended that a clear strategy with a new focus be developed by the WHO secretariat for the next five years (2006–2010) in order to sustain the achievements of the elimination strategy to date and to reduce the disease burden further at national and sub-national level. Such a strategy may be the subject of a World Health Assembly resolution in 2005 or 2006.

WHO Technical Advisory Group on Elimination of Leprosy

Terms of Reference

The WHO Technical Advisory Group on Elimination of Leprosy is composed of nine experts who are independent of WHO and of the other partners in the Global Alliance. Members are chosen for their expertise in leprosy and programme management with particular reference to public health, epidemiology, community mobilization and advocacy, operational research, and disability prevention. They form a strong team with a good technical balance and geographical representation.

The members of this advisory body are selected and appointed by WHO and meet once a year. The period of membership is two years, with the possibility of extension. The Technical Advisory Group's deliberations are open to representatives of partners as observers to encourage open debate.

The terms of reference are:

- To review and monitor implementation of the intensified strategy for elimination of leprosy.
- To advise WHO on new strategies and approaches if necessary.
- To review progress towards elimination.
- To give technical advice and guidance on efforts towards elimination of leprosy.
- To identify gaps and obstacles that may deter smooth operations and find solutions in order to facilitate implementation of planned activities in the field.

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**Sixth meeting of WHO Technical Advisory Group on Elimination of Leprosy
Geneva, 9 and 10 February 2004**

Agenda

Monday, 9 February 2004

- 09:00–09:30 Welcome (*Dr H. Endo*)
Introduction of new members (Dr K. Katoch, Dr P. Saunderson,
Dr Shen Jianping and Professor H. Asse)
Nomination of Chairperson (Professor Cairns Smith)
Opening remarks (*Chairperson – Professor Cairns Smith*)
- 09:30–10:00 Approval of report on fifth TAG meeting, Yangon, February 2003
Response to report on fifth TAG meeting by ILEP/MSC (*Dr P. Saunderson*)
- 10:00–10:30 Current global leprosy situation (*Dr D. Daumerie*)
- 11:00–11:30 Follow-up of TDR Scientific Working Group on Leprosy Research,
Geneva, November 2002 (*Dr A. Kroeger*)
- 11:30–12:00 Leprosy elimination campaigns: impact of IEC activities
- 12:00–12:30 12-month MDT regimen vs 24-month MDT regimen for MB leprosy:
preliminary results (*Dr E.N. Sarno*)
- 14:00–14:30 Uniform MDT – progress report (*Dr M.D. Gupte*)
- 14:30–15:00 Experiences with accompanied-MDT study (*Dr P. Krishnamurthy*)
- 15:00–15:30 ROM study for PB leprosy cases: review and next steps (*Dr M.D. Gupte*)
- 16:00–16:30 Leprosy elimination monitoring exercise in Nepal, 2003 (*Dr Bimla Ojha*)
- 16:30–17:00 Validation of diagnosis of newly-detected cases: results from India
(*Dr G.P. Dhillon*)
- 17:00–17:30 Report on informal consultation on post-elimination strategy:
Manila, November 2003 (*Dr S. Barua*)

Tuesday, 10 February 2004

- 09:00–10:30 Remaining challenges for achieving elimination

Brazil (*Dr Gerson Pereira*)
India (*Dr G.P. Dhillon*)
- 11:00–12:00 Nepal (*Dr Bimla Ojha*)
United Republic of Tanzania (*Dr B. Njako*)

- 12:00–12:30 Vaccine trial: review and next steps (*Dr M.D. Gupte*)
- 14:00–17:00 Developing a framework for a strategy to sustain elimination: 2006–2010
Moderator: *Professor Cairns Smith*
Introduction: *Dr M. Becx-Bleumink*
- 17:00–17:30 Conclusions and recommendations

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**Sixth meeting of WHO Technical Advisory Group on Elimination of Leprosy
Geneva, 9 and 10 February 2004**

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* Invited but unable to attend