Chapter 4
The role of countries

This section is composed of reports on MDT implementation in five countries selected with the intention of showing the types of constraints encountered and the results achieved in different contexts.

4.1 Implementation of WHO MDT in Brazil

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Serious reservations about the introduction of WHO MDT

The recommendation of the WHO Study Group to introduce MDT for the treatment of leprosy met with considerable resistance in Brazil. The National Department for Dermatological Disease (DNDS) advanced a number of arguments against the adoption of WHO MDT by Brazil (1) including:

- significant risk of side-effects;
- efficacy not proven;
- lack of evidence to confirm:
  - speedier attainment of smear-negative results,
  - reduction of disease incidence, not achieved by dapsone monotherapy
  - reduced resistance to dapsone,
  - reduction of relapse caused by bacterial persistence;
- stigmatizing changes in skin pigmentation caused by clofazimine;
- costs and availability.

In 1983, the Ministry of Health set up an advisory committee of experts on alternative treatments in order to evaluate and coordinate the introduction of the new treatment for leprosy (2). The committee’s first task was to review existing proposals for local treatments in Brazil (Amazonas, Amapá, and Rio de Janeiro) by interviewing the officials responsible for the studies, which had been under way since 1982 (2).

At a meeting held later in the same year, with financial support and technical assistance from WHO and the Pan American Health Organization (PAHO), Brazil confirmed its decision not to introduce WHO MDT before a detailed analysis of the results from the ongoing studies was available. Information about two additional projects with alternative treatments for leprosy, one in Pará and the other in the Federal District (3), was also provided at the meeting.

In June 1984, the committee defined its operational strategy, designated an expert for each alternative treatment study, and drew up a schedule for a site visit. The committee’s key recommendations were as follows:

- Clinical trials with proper controls should be carried out by national centres to verify the efficacy of the WHO MDT regimens.
- These studies should compare WHO MDT with new drugs or with drugs already shown to be effective but not fully tested.
The projects already under way (in Manaus, Macapá, Federal District, and Curupaiti hospital in Rio de Janeiro) should be continued with the following revisions:
- use of ethionamide or protionamide as alternative drugs;
- classification of cases as MB or PB without using the Mitsuda reaction;
- longer duration of treatment;
- ascertaining the acceptance by patients of skin discoloration caused by clofazimine.

An agency should be established by Ministry of Health/DNDS to coordinate the recommended measures.

Nationwide introduction of the regimens recommended by WHO was unacceptable, because of the risk of poor results (similar to those achieved when thioacetazone treatment for tuberculosis was introduced in Brazil).

There should be no direct links between local or state services and international organizations without the approval of the Government of Brazil.

The main features of these studies were:
- Because of their overall objectives, they did not systematically comply with the criteria laid down by the committee of experts.
- With one exception, they were financed from abroad, and provided with human and financial resources, including local coordinators.
- A total of only 531 MB and PB patients (male and female, children and adults) were included in the studies.

**Treatment regimens tested**

The studies with WHO MDT did not adhere to the WHO guidelines – the treatment was not supervised, and clofazimine was administered only to patients with primary dapsone resistance. Lepromatous, borderline, and indeterminate patients were examined twice yearly, when they received their drugs for self-administration, and tuberculoid patients once a year (4, 5). The DNDS treatment regimens for adults (over 15 years of age) were as follows (6):

- **Regimen I** – indication, lepromatous or borderline patients never treated before
  - Phase 1: Daily for 3 months – rifampicin 600 mg + dapsone 100 mg
  - Phase 2: Daily from 3 months and for up to 5 years after the disease became inactive – dapsone 100 mg
- **Regimen II** – indication, tuberculoid and indeterminate patients never treated before
  - Daily for 18 months after the disease became inactive – dapsone 100 mg

It was estimated that 32% of new cases and 20% of former lepromatous and borderline cases would require thalidomide to manage likely ENL reactions and that 11% of new cases would develop type 2 reactions requiring prednisolone.

DNDS set up an advisory committee on alternative treatment to monitor the ongoing studies and provide technical coordination.
Factors that convinced the experts to adopt the WHO MDT regimen

At the end of 1984, Brazil had 217,317 registered active cases of leprosy (prevalence of 16.3 per 10,000 inhabitants); 53% of registered patients had abandoned treatment. The average duration of treatment of patients was over 11 years. Almost 40% (85,557) of registered cases had been detected in the previous 5 years (1980–1985). Prevalence varied widely between states, from 0.2 to 129 per 10,000 population; similarly, case detection rates varied from 2 to 82.3 per 100,000.

An evaluation carried out in 1985 highlighted serious operational problems that needed to be addressed, including the lack of standardized laboratory diagnostic procedures, and deficiencies in the knowledge of personnel, as well as staff shortages as a consequence of the low priority assigned to leprosy by the health service. Other problems included a significant dissatisfaction among health professionals, the large number of patients following non-standard treatment regimens (i.e. not strictly recommended by either WHO or DNDS) and the low confidence of patients in the treatment regimens.

The evaluation recommended that the Government of Brazil undertake an immediate restructuring of leprosy services, based on new guidelines (6), in order to control the disease effectively. This decision was supported by broad discussions with specialists from Brazil’s four macro-regions.

Brazil believed that WHO-recommended MDT alone would have no impact on the leprosy situation in Brazil. However, the new treatment regimens would serve as an entry point for the reorganization of all levels of the health services and improve the population’s access to treatment (7, 8). Moreover, the debate about MDT focused attention on the quality of care, notably case holding. The introduction of MDT was considered as an opportunity for the introduction of other changes in the leprosy programme that would significantly increase the coverage and intensity of control measures (9).

The lack of standardization of, and confidence in, the treatment regimens followed at the time was closely related to shortcomings in the strategy adopted to implement them (7). The DNDS was determined not to make the same mistake twice, with potentially graver consequences. Recognizing the value of the new regimens proposed by WHO, DNDS proposed to introduce MDT in a number of pilot units, with the primary objective of evaluating the operational feasibility of the regimens in Brazil’s health services (9).

Adoption of MDT would succeed only if the regimen were introduced gradually, with meticulous planning that included retraining of personnel and development of strategies for integrating the necessary actions into the routine activities of the health services. Continuous monitoring and evaluation of all stages of the project were also essential. A longitudinal supervisory study of leprosy patients was therefore proposed to identify the parameters that would permit evaluation of the feasibility of the WHO-recommended treatment regimens for Brazil’s health services (10, 11). Throughout all phases of the five-year project, supervision and assistance in the pilot areas were integral elements of the systematic evaluation (11).

In January 1986, after the National Scientific Committee, PAHO, WHO, and the American Leprosy Missions (ALM) had approved the guidelines for gradual introduction of MDT, the protocol for MDT WHO in Brazil was developed. It drew heavily on experience at the Curupaiti State Hospital (Rio de Janeiro), the Alfredo da Mata Centre for Tropical Dermatology and Venereal Disease (Manaus-AM), and in the Federal District. The protocol
was introduced, in “pilot demonstration areas”, in 1987. It included a proposal for extensive and specific staff training in order to implement the project, with funding from ALM, and the development and dissemination of the tools (bibliography, forms, agreements, etc.) necessary for the project to become operational (10, 11).

In parallel with the gradual introduction of WHO MDT, DNDS implemented the following measures to reorganize the leprosy programme:

− analysing leprosy trends to identify priority areas;
− promoting increased coverage by the programme;
− training health workers;
− decentralizing administration and control;
− integrating the programme into basic health services;
− organizing the information system;
− carrying out health education activities through a campaign in the mass media;
− establishing formal exchanges between the government and international agencies (PAHO/WHO and NGOs).

Within 6 months of the start of the project, more than 65 health units in 21 states, covering 4% of the total number of cases in Brazil, had introduced the WHO MDT regimen under the coordination of DNDS. Implementation of the new treatment regimens proved easy: 94% of patients complied with treatment and only 0.1% of patients refused clofazimine on the grounds of skin discoloration (12).

Findings from the first national evaluation of WHO MDT, in March 1988, were as follows (13, 14):

- The introduction of WHO MDT promoted the decentralization of basic health services – more than 88 new health facilities adopted the MDT regimen.
- More than 2500 health professionals were trained in five reference centres under DNDS monitoring.
- Treatment compliance was high and clofazimine well accepted.
- The gradual introduction of WHO MDT, in conjunction with the reorganization of health services, was well suited to Brazil’s health services.
- The supervised monthly administration had many advantages:
  - individual patient education;
  - early and appropriate treatment of adverse reactions;
  - prevention and treatment of disabilities;
  - systematic supervision of self-administered drugs;
  - ensuring that rifampicin remained a highly effective drug.

Following the evaluation, the key recommendations were:

- The general guidelines for the extension of MDT should be the same as those that had proved feasible for its introduction.
- The health services should assign priority to leprosy control programmes and gradually encourage them to rely on funds from NGOs.
- Full patient compliance should be sought and guaranteed.
From the operational standpoint, however, the need for monthly supervised administration of the WHO MDT regimen limited the extension of the coverage to basic health facilities. A detailed analysis was needed to identify obstacles that might prevent WHO MDT being extended to as many patients as possible – a major factor in leprosy control (13).

The 1988 evaluation also revealed that the number of cases detected annually had been steadily increasing since 1978 (14). Of the 18 326 cases detected in 1988 (detection rate 13.8/100 000), 45% were lepromatous and borderline; 1659 patients were aged under 15 years (under-15 detection rate 3.34/10 000). Although this increase did not reflect increased transmission, it was noteworthy in view of the low coverage of leprosy services.

Table 4.1 shows the changes in the epidemiological pattern and MDT coverage over seven years (1985–1991) with decentralization and an extensive training programme involving an average of 5600 health professionals each year (MS, 1989, 1990 and 1992b) (15–17):

- Adoption of MDT for new cases rose from 6% in 1986 to 55% in 1991.
- The proportion of patients discharged from the register after being cured rose from 24.3% in 1987 to 59% in 1991.
- WHO MDT coverage increased from 4% in 1986 to 29% in 1991.
- The estimated time for which patients remained registered as clinically active fell from 12.2 years in 1987 to 8.3 years in 1991.
- Between 1987 and 1991, prevalence increased by 9.2%; over the same period, the new case detection rate increased by 29%.

Table 4.1
Changes in epidemiological pattern and operational capacity of the programme over the seven years (1985–1991) of gradual introduction of WHO MDT in Brazil

<table>
<thead>
<tr>
<th>Year</th>
<th>No. of new cases</th>
<th>New cases beginning WHO MDT (%)</th>
<th>No. of registered cases</th>
<th>Time on register (years)</th>
<th>Defaulters (%)</th>
<th>Cured (%)</th>
<th>% patients on register receiving MDT</th>
</tr>
</thead>
<tbody>
<tr>
<td>1985</td>
<td>19 265</td>
<td>–</td>
<td>223 973</td>
<td>11.62</td>
<td>60.00</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>1986</td>
<td>18 400</td>
<td>6.20</td>
<td>234 006</td>
<td>12.71</td>
<td>62.11</td>
<td>–</td>
<td>4.00</td>
</tr>
<tr>
<td>1987</td>
<td>19 685</td>
<td>36.00</td>
<td>239 328</td>
<td>12.15</td>
<td>37.04</td>
<td>24.30</td>
<td>6.00</td>
</tr>
<tr>
<td>1988</td>
<td>26 578</td>
<td>24.00</td>
<td>256 976</td>
<td>9.66</td>
<td>41.39</td>
<td>43.80</td>
<td>8.00</td>
</tr>
<tr>
<td>1989</td>
<td>27 837</td>
<td>29.00</td>
<td>266 578</td>
<td>9.57</td>
<td>25.00</td>
<td>31.30</td>
<td>11.00</td>
</tr>
<tr>
<td>1990</td>
<td>28 482</td>
<td>41.20</td>
<td>278 104</td>
<td>9.76</td>
<td>23.41</td>
<td>37.20</td>
<td>15.00</td>
</tr>
<tr>
<td>1991</td>
<td>30 094</td>
<td>55.44</td>
<td>250 066</td>
<td>8.30</td>
<td>46.64</td>
<td>59.00</td>
<td>29.00</td>
</tr>
</tbody>
</table>

aData from National Programme Coordinating Office reports/Ministry of Health.

In 1991, DNDS adopted WHO MDT as the sole treatment for leprosy patients in Brazil based on its efficacy, acceptance by patients and relative ease of use in health facilities (18).
Adjustment of the norms and guidelines of the leprosy control programme to implement WHO MDT

The introduction of WHO MDT in 1986 in pilot areas of Brazil necessitated many changes to technical norms and also provided an opportunity for a much-needed reorganization of the leprosy services (12, 19). DNDS prepared a manual with the new technical norms and procedures for the diagnosis and treatment of leprosy. In addition, a manual was developed to guide the implementation of WHO MDT, as part of the national plan, and national reference centres were established (20, 21).

Changing the classification of the disease

Operational classification of leprosy depended largely on the results of the Mitsuda test. Indeterminate Mitsuda-negative cases were considered to be MB. Brazil also made extensive use of smear examinations to classify patients as MB or PB by detection of acid-fast bacilli.

After 1994, tuberculoid and indeterminate cases were classified as PB, regardless of Mitsuda results, and lepromatous and borderline cases were considered as MB; this facilitated expansion of the treatment (22). Although the DNDS recommended Madrid classification (22), some states introduced elements of the Ridley–Jopling classification (23) into their training programmes, thus changing the proportion of the MB forms.

Changing the criteria for ending treatment

The average duration of treatment in Brazil was about 11 years. Lepromatous and borderline patients remained under treatment for more than 10 years after becoming clinically inactive and under observation for an undetermined period. Indeterminate cases (Mitsuda-negative) were prescribed 5 years’ treatment after becoming clinically inactive. Treatment of tuberculoid and indeterminate (Mitsuda-positive) cases was continued for 18 months after clinical inactivity; cases were not kept under observation after treatment. The difficulties of declaring patients cured were accentuated during this phase, when the proportion discharged as cured was lowest and leprosy prevalence consequently rose.

With the introduction of WHO MDT, the average duration of treatment decreased, although patients were discharged from treatment only after a completely negative smear examination: some patients received more than 48 doses of WHO MDT.

In 1992, fixed-duration treatment was adopted and smear examination was no longer a requirement for declaring patients cured (22, 24, 25). Patients were considered cured after 6 doses of treatment for PB taken within 9 months and 24 doses of treatment for MB taken within 36 months (22, 26).

Brazil officially reduced the duration of MDT for MB cases from 24 to 12 months in the year 2000 and adopted rifampicin–ofloxacin–minocycline (ROM) for single-lesion PB cases at centres authorized by the Ministry of Health (26).
Changes in the epidemiological situation, impact, side-effects, relapses, and cure

A pilot study had already shown that there were fewer reactions with WHO MDT (27). However, the significance of this reduction in MB patients treated with the WHO MDT regimen was confirmed only in a study comparing it with the regimen previously administered in Brazil (28). The statistically significant difference between groups of patients in terms of reactions, both during and after the end of treatment, confirmed the effectiveness of including clofazimine in the WHO MDT regimen to prevent reactions and reduce their severity, principally with regard to ENL (29).

In the same study, there was no significant difference between groups in terms of distribution by clinical form, sex, age, degree of disability, or average bacteriological index. Two cases of relapse (2.87%) were recorded in patients using daily rifampicin (600 mg) + dapsone (100 mg) for 3 months, followed by dapsone (100 mg) for 21 months; no relapses occurred among patients using the WHO MDT regimen (28).

Even with monthly visits to administer supervised doses, which ensures better personal contact between health services staff and patients, it was recommended that prednisolone be used in the field to treat reactions and recent nerve damage. When treatment is administered by physicians, however, there is an alarming trend, particularly in Brazil, towards more frequent use of steroids – even in cases for which they are not required. Moreover, some patients are aware of the anti-inflammatory effect of prednisolone and demand the drug, or purchase it themselves, to control their symptoms – thus creating further problems (30).

The frequency of adverse reactions to the WHO MDT drugs was very low. When such reactions did occur, the standard regimen was simply adjusted, making it possible for the treatment to continue (27, 31 – 34).

The impact of MDT

With the adoption of simplified diagnosis and case management, fixed-duration treatment, increased coverage of MDT services, and reorganization of Brazil’s health information system, the epidemiological profile of leprosy in Brazil has changed dramatically. Over the past 40 years, the number of newly detected cases had increased each year (35). Until the 1990s, Brazil experienced a simultaneous increase in prevalence and detection rates (Figure 4.1). When the DNDS treatment regimen was the norm (1977–1987), prevalence increased by 25% and detection by 65%; during the period of WHO MDT (1991–2001), prevalence rates fell (by 75%) for the first time and the increase in the rate of detection was under 3% (Table 4.2).
Between 1995 and 1997, there was an increase in the number of new cases in all the 26 states and the Federal District; between 1998 and 2001, an increase occurred in only 14 administrative entities.

The rate of new cases presenting with deformities has dropped to 7% during the past 5 years. In absolute numbers, during the period after adoption of MDT (1991–2001) 20 000 patients with at least one physical disability have begun treatment in Brazil’s health services.

With the adoption of WHO MDT, and as a result of the introduction of new norms for declaring patients clinically cured – an issue that was previously controversial among scientists and ignored or even discredited among the public (36) – the proportion of cured patients removed from the register of active cases increased, from 24.3% in 1987 to 86% in 1999 (Figure 4.2).
The significant increase in the number of new MB cases detected after the introduction of MDT resulted more from overestimation of MB on account of the excess number of borderline forms than from genuine high endemicity (35, 37, 38).

As WHO recommends early diagnosis and treatment of all patients with MDT, efforts also need to focus on improving patients’ access to treatment. A study based on the analysis of data from 5 years after the introduction of MDT indicated that the number of patients that remained to be detected could exceed 52% of the number of known cases (39). This suggests that leprosy will not be eliminated from Brazil until MDT coverage is expanded and a concerted effort made to detect new cases. As long ago as the 1950s, there was evidence that dapsone could prevent indeterminate Mitsuda-negative cases from becoming future sources of transmission and thus that the detection and treatment of patients at that stage could eliminate the disease. However, little was achieved in that respect because of the limited coverage of the programme (30).

The increase in detection rates of new leprosy cases in Brazil during the past 10 years is largely the result of improvements in the coverage of MDT services and in the capacity of health services to detect and treat new cases. In addition, as the data-collection system is undergoing transition, analysis of the data from earlier periods may reveal misleading trends.

The current leprosy situation in Brazil indicates that MDT has been significantly more effective in curing and controlling the disease than either dapsone monotherapy or the DNDS regimen.
Lessons learned

The adoption and gradual introduction of WHO MDT:

- enabled the Ministry of Health to develop a method to directly supervise Brazil’s states, which has been backed up by training for more than 180,000 specialists in the past 10 years;
- fostered the development of partnerships, with financial support from international agencies such as PAHO and WHO plus NGOs such as ALM, Fondation Follereau, German Leprosy Relief Association, Amici di Lepra, Damien Foundation, and the Sasakawa Memorial Health Foundation, which have supported both national efforts and individual local projects;
- made a significant contribution to improving the organization of leprosy control programmes;
- extended coverage of public health services for patients.

In addition:

- patient acceptance of monthly doses of rifampicin and clofazimine is good;
- reactions to the WHO MDT regimen are far less frequent than reactions to the earlier regimen;
- to date, the referral centres in Brazil have detected no significant drug resistance;
- the risk of relapse is apparently lower than with the DNDS regimen;
- the number of severe disabilities is gradually declining;
- the significant number of cases cured each year and acceptance of treatment by patients has resulted in a more positive attitude on the part of the community towards leprosy patients.

References


4.2 Implementation of MDT in Burkina Faso

A. Tiendrebeogo, L. Some

Burkina Faso is a west African country lying within the sweep of the Niger River. In 2000, the population numbered 12 000 000 – up from 7 752 000 in 1980. Burkina Faso attained the leprosy elimination threshold of less than one case per 10 000 inhabitants in 1994, largely as a result of the introduction of a control programme based on MDT as recommended by WHO. The path to this goal was not without difficulties, however, given the country’s meagre resources and the scale of the endemic: in 1965, there were 140 000 cases of leprosy and prevalence in some villages exceeded 5%, i.e. 500 cases per 10 000 inhabitants (1). In 1966, Sansarricq et al. showed that the number of cases declined gradually from the south to the north of the country (see Figure 4.3). Nonetheless, the introduction of MDT regimens was made easier by the existence of treatment circuits dating from the time of dapsone monotherapy.

Burkina Faso is a former French colony, previously known as Upper Volta; it formed part of French West Africa where, in 1957, the Médecin-Général, Pierre Richet, head of the Service des Grandes Endémies, launched the mass leprosy control campaign using dapsone monotherapy (2, 3). The health services in each country of French West Africa were subdivided into sectors for the major endemic diseases (leprosy, onchocerciasis, yaws, and trypanosomiasis). Each sector had mobile teams that conducted annual surveys in villages to detect cases of these diseases. Leprosy diagnosis was the responsibility of specialized nurses and leprosy controllers trained at the Marchoux Institute in Bamako, Mali. Once detected, leprosy cases were treated with dapsone monotherapy; dapsone tablets were distributed to patients in villages by travelling health workers who made their rounds by bicycle.

During its annual survey, the mobile team performed clinical examinations of the leprosy patients under treatment. It took decisions to end treatment; patients were declared as “under observation without treatment” (UOWT) or “clear” and were required to attend the annual visits to their village by the mobile team. After a period of 2–5 years, patients were declared “dispensed from control” – the word “cured” was not used. Some leprosy patients remained under treatment for the rest of their lives.


The WHO Study Group recommended the adoption of MDT for leprosy in 1981, and Burkina Faso introduced the new regimens in 1983, through a pilot project in Houet province, a region in the south-west of the country that included the villages of Bobo Dioulasso, Banfora, and Orodara (4). The treatment regimen adopted for MB patients initially included ethionamide, but the drug was later withdrawn because of side-effects, particularly digestive effects. Thereafter, treatment continued with the drugs now used in WHO MDT – rifampicin, clofazimine, and dapsone for MB cases, and rifampicin and dapsone for PB cases. The duration of treatment was 24 months for MB and 6 months for PB cases.

This pilot project confirmed the efficacy of the proposed regimens. Between 1983 and 1986, more than 1000 patients were treated. A 1997 survey by the Marchoux Institute found 255 patients who had been treated with the regimen and confirmed that the relapse rate was less than 1 case per 1000 patients per year after more than 10 years of follow-up (5).
In view of the success of this pilot project, the national health authorities proposed to introduce MDT in all the provinces of Burkina Faso. Introduction was preceded by a period of transition (1986–1988) during which the provincial directors of health were informed about the new regimens and the procedures needed to prepare for the introduction of MDT. Leprosy registers were brought up to date by the leprosy nurses. During this period, community information/education on leprosy consisted mainly of World Leprosy Days, which were organized at both national and provincial levels. In addition, the leprosy teams continued with their control rounds to villages, visiting patients under treatment or under observation without treatment and taking the opportunity to examine patients’ contacts and to identify new cases of leprosy. The transitional phase before introduction of MDT made it possible:

− to replace the earlier “lepromatous, borderline, tuberculoid, and indeterminate” classification with the new classification (PB and MB) proposed in WHO’s Guide to leprosy control (6) and based on skin-smear examination;
− to reduce the number of patients included in leprosy registers by excluding the large number who had been cured by dapsone monotherapy but retained on the registers because of complications (reactions and deformities) (see Figures 4.3, 4.4 and 4.6 and Table 4.3).

During the preparatory phase, the Association Française Raoul Follereau (AFRF) provided vehicles and motorbikes to the leprosy teams in the different provinces; the number of teams increased from 25 to 30 between 1983 and 1984. AFRF also subsidized training for leprosy specialists and controllers at the Marchoux Institute in Bamako to ensure that there was a nurse trained in clinical and skin-smear diagnosis of leprosy in each province in the country.

Efforts were also made during this preparatory phase to decentralize state services. The subdivision of the country into 25, and then 30, administrative districts in 1983–1984 made it possible to provide better nationwide health coverage. Each Provincial Health Directorate (PHD) had at least one physician and a pharmacist, plus a specialized health worker or leprosy controller who was to become the leprosy supervisory nurse (LSN) for the MDT programme. The government authorities stressed the importance of good management of public funds, and each PHD was made responsible for managing the resources provided by AFRF for leprosy control activities. World Leprosy Day was celebrated in one of the provinces by the national authorities in the presence of the Head of State, and provided an opportunity to present the province and to invite partner countries to become involved in development activities there.

A number of problems arose as a result of the shortage of transport in the new provinces. On many occasions, the vehicle provided by AFRF specifically for leprosy, with assigned funds for fuel and maintenance, was the only serviceable vehicle available to the PHD – or indeed in the whole province. Use of the vehicle by the PHD, or by provincial authorities for purposes unconnected with health, prompted complaints by the LSN. At times, AFRF funds were used to finance all health activities, giving rise to conflicts with the AFRF representative, whose half-yearly release of funds was conditional on documentary proof of compliance with the expenditure forecasts and budgetary items defined in the International Federation of Anti-Leprosy Associations (ILEP) request for funding. Despite these difficulties, however, it proved possible to organize a control programme in every province. By the end of 1988, the provinces were in a position to adopt the new leprosy treatment regimens recommended by WHO and tested with success in Houet province (see Figure 4.4).
Extension of MDT coverage: 1989–1993

The first step in the extension of MDT coverage to all the provinces was the appointment, in 1989, of a coordinator for the national leprosy and tuberculosis control programme (7). Two training sessions on leprosy programme management were organized for the PHDs and LSNs from the provinces: the first, in 1990, covered 17 provinces, including those involved in the pilot project, and the second, in 1991, the remaining 13 provinces. New programme management tools, including the treatment register and the drug-stock card, were proposed and adopted by all provinces.

After the training sessions, each province drew up a provincial leprosy control plan based on MDT, and organized training on MDT implementation for the head nurses of health centres and travelling health workers. Laboratory technicians from health centres were also trained to carry out skin smears to detect the leprosy bacillus. This “cascade” training strategy was encouraged by WHO, and funding from AFRF made it possible to cover the whole country quickly (8). Dapsone monotherapy was rapidly replaced by MDT regimens – by the end of 1992, all leprosy cases registered in Burkina Faso were receiving WHO MDT (9).

During this period, leprosy case detection was essentially passive; cases were identified at health centres and the diagnosis confirmed by the specialized nurses and leprosy controllers. The opportunity was always taken to identify new patients in the villages visited in the course of control rounds; however, the rounds were no longer carried out regularly, and in any case focused on distributing MDT to patients already registered. Two treatment strategies were followed by each health centre. Patients living less than 5 km from a village with a health facility were treated locally; otherwise, the nurse or itinerant health worker travelled by motorcycle to deliver the drugs to patients. In addition, the monthly administration of rifampicin was carefully supervised by health workers responsible for distribution and strict compliance was expected of patients. If treatment was interrupted for two consecutive months, the treatment had to be started again from scratch.

One of the most tedious aspects of the early part of the programme was the long nights spent in medical centres, filling packets with monthly courses of leprosy drugs. Fortunately, this period lasted only until the remaining stocks of bulk dapsone and clofazimine were used up. Bulk drugs were soon replaced by MDT blister packs from the Novartis (formerly Ciba-Geigy) laboratories, making MDT delivery to patients much easier.

In three years (1990–1992), all 30 provinces of Burkina Faso introduced MDT blister packs, and by the end of 1992, MDT was available from every health and welfare centre (HWC). The existence of complete coverage was confirmed by a joint country/AFRF/OCCGE (Organisation de Coordination et de Coopération pour la lutte contre les Grandes Endémies)/WHO evaluation survey carried out in May 1993 (10). The MDT treatment regimens were much shorter and more effective than dapsone monotherapy; as a result, patient compliance with treatment improved and the number of patients declined rapidly during the period.

One of the first provinces to achieve the elimination threshold (less than 1 case per 10 000 population) distinguished itself by presenting the MDT regimens on World Leprosy Day. Addressing the crowd that gathered for the ceremony, the provincial Director of Health invited the provincial authorities to give the first MDT packs to patients. After the ceremony, a rumour went round the province that the High Commissioner (the senior authority in the
province) had brought a new and highly efficient remedy for leprosy. This prompted numerous leprosy patients to go voluntarily to health centres in the province for screening; thanks to MDT, they were cured.

**Leprosy elimination: 1994–2000**

Achievement of the elimination threshold in one province in 1991 encouraged the other provinces and stimulated healthy competition. Each PHD redoubled its efforts to improve patient compliance with treatment and to reduce the number of patients registered. Inspection rounds by the specialized nurses ceased and were replaced by supervisory visits to HWCs, which served to consolidate and improve the performance of the nurses. For purposes of monitoring, the patient treatment register was produced in duplicate – the original was kept by the health worker responsible for treatment at the HWC and the duplicate by the leprosy supervisory nurse at the provincial level. At the suggestion of one of the provincial directors of health, a monthly report form on leprosy treatment was filled out by the heads of health posts, which made it possible to keep the duplicate treatment register up to date. The most widely used monitoring indicators for assessing the quality of services were regularity (rule: two-thirds of rifampicin doses taken under supervision during a given period of treatment) and compliance (completion of 6 doses of MDT for PB leprosy in a maximum of 9 months or of 24 doses of MDT for MB leprosy in a maximum of 36 months).

These efforts enabled Burkina Faso as a whole to reach the elimination threshold by the end of 1994 – an achievement that was proclaimed when World Leprosy Day was celebrated in 1995. Perversely, however, this achievement led to setbacks that jeopardized the programme’s progress in the provinces.

One setback was a waning of interest in leprosy activities at the national level. As a result, the position of national leprosy programme coordinator was held by three physicians in the space of five years and also remained vacant for long periods. Finally, in February 2000, the leprosy and tuberculosis programmes were separated, and the first leprosy programme coordinator resumed his post in 2001.

The second – and no less significant – setback was a cut in funds for the leprosy programme. There has been no AFRF representative in Burkina Faso since 1993, and the Association has considerably reduced its financial and material support for the provinces. The programme’s vehicles and motorcycles were not replaced, funds for maintenance and fuel shrank to negligible levels, and the supervisory visits had to be abandoned. Training/retraining of staff ended in 1995 and a significant number of supervisory nurse positions (vacant because of retirement, reassignment, or death) remained unfilled. As a result, more than half of the provinces, which now number 45, were without a provincial health worker to supervise and monitor of leprosy control activities (11).

As a final setback, the only information on leprosy provided to the public was that delivered by the celebration of World Leprosy Day, and active case detection came to an end when the leprosy control rounds were discontinued. Although the number of new cases detected was very low and prevalence considerably reduced, many leprosy cases remained hidden in villages. In 1997, a survey in Bazèga province by the national programme team detected three times as many leprosy cases as in previous years, revealing the huge gap between estimated and recorded prevalence. The number of new cases detected annually in the country as a whole, which had been less than 800 in the previous two years, rose to 900 in 1997.
These setbacks shifted the focus away from information and case-detection activities to MDT treatment of registered cases. Consequently, the recorded level of prevalence remained below the elimination threshold. In 1997, a survey by a team from the Marchoux Institute showed estimated prevalence to be 2–3 times higher than the levels recorded in the 10 provinces visited (12). Monitoring of leprosy elimination during the same survey showed up the following problems:

- MDT (drugs and information material) was no longer available in all the health and welfare centres (HWC).
- Capacity for leprosy diagnosis at the HWC was essentially non-existent.
- Fewer than 50% of the nurses at the HWC had been given any training in leprosy case management.
- Activities to prevent or treat disabilities caused by leprosy were non-existent or undertaken only by the few services still handling patients with deformities or reactions.

Analysis of the distribution of leprosy cases in 2000 (see Figure 4.5) shows that the provinces with the highest endemicity are grouped in the northern third of the country, where the operational difficulties that have to be dealt with in implementing MDT are compounded by demographic factors (low population density, remoteness of health facilities, and nomadic populations). In contrast with the epidemiological situation described by Sansarricq et al. in 1966 and published in 1968, there is a gradual decline in the number of cases from the north to the south of the country.

On the basis of this situation analysis, the national leprosy programme coordinator drafted a plan of action to revitalize the programme’s activities. Unfortunately, the plan’s implementation has so far been delayed by the frequent changes of national coordinator and the lack of funds from the programme’s partner NGO. Now that the first coordinator of Burkina Faso’s leprosy programme has returned to the position, it is hoped that steps will be taken to enable the country to consolidate its achievement of the elimination threshold nationwide through the effective elimination of leprosy in all 45 provinces. The fine example of MDT Burkina Faso will be upheld only by a genuine effort to revive the Programme’s activities by means of:

- reorganization of the diagnosis and treatment network;
- training/retraining of staff responsible for diagnosis and treatment in the HWCs;
- assignment of funds to the provinces for the supervision of HWC staff by the provincial or district teams;
- organization of information campaigns and ad-hoc measures in provinces where the disease is still endemic.

References

3. Laviron P Les campagnes de masse et leurs difficultés dans la lutte antilépreuse en Afrique noire [Mass campaigns and their difficulties in leprosy control in Africa south of


The number of cases registered was probably close to the actual number of cases and had not yet been significantly reduced by the mass campaign using dapsone (After Sansaricq H. et al. (71))
Figure 4.4
Leprosy situation in Burkina Faso in 1988, before MDT was extended to all provinces

As a rule, prevalence rates have declined significantly in comparison with 1966, as a result of the leprosy control programmes using first dapsone and then MDT.

(After Declercq et al. Atlas Mondial de la Lèpre
Ecole de Santé publique, Université Catholique de Louvain,
Brussels.)
Figure 4.5
Leprosy situation in the provinces in Burkina Faso at the end of 2000

Leprosy in Burkina Faso, 2000
Prevalence rate in Provinces

Pre rate per 10,000

- 0.00 to 0.99
- 1.00 to 1.99
- 2.00 to 2.99
- 3.00 to 3.99
Table 4.3
Data on the leprosy endemic and leprosy control in Burkina Faso, 1980–2000

<table>
<thead>
<tr>
<th>Year</th>
<th>Population (thousands)</th>
<th>Prevalence</th>
<th>Detection</th>
<th>% New cases</th>
<th>Ratio</th>
<th>% under MDT</th>
</tr>
</thead>
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<td></td>
<td></td>
<td>n</td>
<td>Rate/10 000 pop.</td>
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<td>Rate/100 000 pop.</td>
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<td>3 000</td>
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<td>2 800</td>
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Figure 4.6
Evolution of leprosy prevalence and detection in Burkina Faso between 1980 and 2000

- 1983: Updating of registers
- 1984: MDT in all provinces
- 1993: Elimination at national level
4.3 Implementation of WHO MDT in India 1982–2001

C.K. Rao

Progress

One of the most significant features of MDT in India is the priority it was accorded by, and the attention it received from, influential political leaders and decision-makers. Addressing the World Health Assembly in 1981, Mrs Indira Gandhi, the late Prime Minister of India, called for a global effort to eliminate the scourge of leprosy. Shortly thereafter, a commitment was made at the highest level to eradicate leprosy in India by the year 2000.

The basic WHO strategy for reducing the prevalence of leprosy by detecting cases and curing them with MDT has worked well; MDT proved to be a safe, acceptable, and effective tool that made leprosy a curable disease. By 1991, all 201 highly endemic districts were using MDT, of which 66 (mainly in Bihar, Uttar Pradesh, Madhya Pradesh, and West Bengal) lacked a full leprosy infrastructure. At that time, no efforts were made to get additional support from general health staff in these districts.

Before the introduction of MDT, the estimated number of leprosy cases in India was 3.9 million; this fell to 3.4 million in 1986 and, by the end of September 2001, to 384 000. The prevalence rate has declined from 57 cases/10 000 population in 1983 to the current level of 3.7 cases/10 000. The decline was very rapid during the 3–5 years following MDT introduction but slowed considerably thereafter. Time-limited treatment with MDT of a large number of registered cases from the era of dapsone monotherapy (i.e. before MDT), and subsequent discharge, explained the initial steep decline in prevalence.

The number of new cases detected each year rose steadily with the extension of MDT to more areas, reaching more than 650 000 during the early 1990s, but has fallen to about 500 000 during the past 3–4 years. The increase in case detection during the period 1998–2000 was the result of two nationwide Modified Leprosy Elimination Campaigns (MLEC), which detected more than 450 000 new cases.

The number of new cases detected annually showed an increasing trend over the years because the continual expansion of MDT coverage to previously uncovered areas, leading to increased detection of new cases, and as a result of active search campaigns. Targets for case detection, assigned to states and districts, have contributed significantly to over-diagnosis of new cases, including reregistration of some old cases as “new”. As mentioned, the campaigns have also led to over-diagnosis of cases and this has contributed to the stability of case detection.

The rapid reduction in leprosy prevalence has encouraged India in its work towards the goal of eliminating leprosy as a public health problem by reducing the national prevalence rate to less than 1 case/10 000 by the year 2000. National plans for achievement of this goal were implemented in 1993. Individual states also implemented plans for bringing all districts of moderate and low endemicity under MDT by 1995. All of the country’s 563 districts have now been brought under MDT. However, despite efforts to improve the accessibility of MDT in all areas and for all population groups, the existence of areas/groups not covered by MDT cannot be excluded.
More than 10 million cases of leprosy were cured with MDT between 1982 and 2001. The reduction of state prevalence rates during this period is directly related to pre-MDT prevalence and to MDT coverage and duration. Of the 35 states, 13 have already achieved the goal of less than 1 case/10,000 population; nine states have fewer than 3 cases/10,000 and are expected to reach the goal soon. Special efforts are needed in eight states where the prevalence rate remains between 3 and 5 cases/10,000, particularly Andhra Pradesh, Maharashtra, Tamil Nadu, and Uttar Pradesh, which contribute most to the substantial prevalence. In the remaining five states – Bihar, Chattisgarh, Jharkhand, Orissa, and Madhya Pradesh – prevalence rate currently exceeds 5 cases/10,000. Orissa, with its strong leadership and commitment, should be able to reach the goal, but far more intensive efforts and substantial outside support will be needed if Bihar, Jharkhand, and Chattisgarh are to achieve the goal before the revised target date of 2005.

The visible deformity (grade-2) proportion among new cases in the country has declined from over 13% before 1982 to the current level of 2%. However, deformity rates are higher in some of the low-endemicity states because of an influx of old cases from elsewhere that are detected as new cases.

The effectiveness and popularity of MDT have made it possible to extend leprosy programme services and appropriate IEC (information, education, communication) activities, designed to raise community awareness of leprosy, to all areas of the country irrespective of the level of leprosy prevalence. Moreover, the fact that leprosy can be cured with MDT facilitated the repeal, in 1984, of the inhuman and unjust Leper Act of 1898, allowing leprosy patients to be brought into the mainstream of the society. The establishment of new colonies to house those with leprosy was discontinued in 1982; the number of colonies and, more importantly, the number of patients confined in them have dwindled over the years. Patient interviews by monitors/evaluators have shown that increasing numbers of patients – more than 98% in highly endemic rural areas – live with their families.

Several new partners and many long-term partners, especially international nongovernmental and bilateral organizations, have provided or increased their support for the extension of MDT to more areas.

The advent of MDT has enabled the leprosy programme to be restructured as a public health programme. Certain changes based on feasibility and cost-effectiveness have been made in the implementation of strategies. Leprosy programme managers’ posts at national and state levels has become attractive and competitive – facilitating the selection of the best candidates with a background in public health. However, field-level activities had remained the preserve of vertical, specialized leprosy staff since the introduction of leprosy control in 1955, and this situation continued even after MDT was introduced. Special privileges and cash incentives were provided to attract competent leprosy field staff and professionals, in view of the demand for timely delivery of MDT drugs near the patients’ homes. This system of incentives has delayed by nearly a decade the integration of leprosy programmes into the general health service in an effort to improve the accessibility of MDT services. The reluctance of vertical staff to allow transfer of programme tasks and the unwillingness of general health staff to accept these additional tasks without the privileges/incentives available to leprosy staff hindered the successful implementation of integration plans in 1989 and again in 1994.
As a result of bold decisions taken recently, and in consultation with WHO, at the highest political, administrative, and technical levels, the integration of leprosy control into general health services will be achieved soon. Nevertheless, further strengthening is needed in a number of states to accelerate this process.

Developments

Genesis

The availability of MDT as an effective tool to cure leprosy has enabled the Government of India to accord the highest priority to control of this disease and to allocate substantial funding to the programme. A working committee of eminent scientists, established in 1981, drew up recommendations for the rapid expansion of MDT to all affected areas. The leprosy control programme was renamed the leprosy eradication programme and aimed to treat all leprosy cases with MDT by the year 2000 in order to minimize transmission of the disease. Three very highly endemic districts (prevalence rate 100 cases/10 000) with a population of about 2 million each were brought under MDT in 1983 after careful preparation. The preparation involved ensuring full vertical leprosy infrastructure, detection of 80% of the estimated cases, updating of case records, training of all the staff, the availability of sufficient MDT drugs, and adequate funding.

Extension of MDT

Extension of MDT was based on the district as the implementation unit. By 1989, 45 out of 201 highly endemic (prevalence more than 50 cases/10 000) districts were covered by MDT, and by 1992 all such districts were covered. From 1985, MDT was also supplied to all states on demand for supervised administration to leprosy patients in districts not covered by MDT. Between 1991 and 1995, coverage was extended to the remaining districts, of moderate and low endemicity, so that, by the end of 1995, all 563 districts were under MDT.

Diagnosis and classification

WHO criteria for diagnosis and classification of leprosy cases have been adopted. At the time of introduction of MDT in a district, all cases, especially MB cases previously under dapsone treatment, were considered to be active cases.

Since the introduction of MDT, diagnosis has been based on clinical examination of suspected cases. However, between 1982 and 1995, skin-smear examination was also carried out in all MB cases at the time of diagnosis and at the end of treatment with MDT, but ceased to be mandatory for diagnosis between 1996 and 1998. From the beginning of 1999, skin-smear testing has not been required for diagnosis.

Until 1995, leprosy cases with more than 10 lesions (counting number of skin and nerve lesions involved) were classified as MB. In addition, all cases where skin-smear testing gave positive results were classified as MB, irrespective of the number of skin and nerve lesions. Since 1996, the WHO criterion of six or more skin lesions has been used for MB classification. Single skin lesion (SSL) cases were recorded separately from PB cases from 1998 onwards in view of their increasing proportion among new cases and of the availability of a single-dose regimen for their treatment.
Treatment regimens and duration

The MDT drugs and dosages recommended by WHO were modified as follows.

- The duration of treatment for MB cases differed from that recommended by WHO. At the time of MDT introduction in a district, all prevalent MB cases were given 14 daily supervised doses of three drugs before the WHO-recommended regimen. This additional treatment was based on the recommendation of the Indian leprologists’ committee. It was considered that some of the prevalent MB cases previously on dapsone monotherapy would need longer initial treatment. New cases detected subsequently were given the remaining number of supervised daily doses. For example, cases detected on the eighth day of 14 daily doses were given the remaining seven daily supervised doses, and cases detected on the twelfth day received only two daily supervised doses before the start of the WHO-recommended regimen. MDT drugs for 27 days of self-medication were delivered after the monthly supervised drugs for a minimum of 24 times or until skin-smear negativity. From 1994 onwards, MB cases were treated for 24 months and from 1998 only for 12 months in accordance with the WHO recommendation.

- PB cases received only 6 months of the WHO-recommended regimen from the introduction of MDT in 1982.

- In 2000, accompanied MDT was introduced as a new and flexible approach for leprosy cases who for various reasons are unable to attend the monthly clinics and are at risk of not completing treatment. Such patients are given the remaining monthly blister calendar packs (BCPs) to allow them to complete the full course. This innovation was recommended by WHO to reduce treatment defaulters and promote MDT completion.

Annual follow-up of cured cases

Annual clinical and bacteriological follow-up of all MB cases was undertaken for 5 years after completion of MDT treatment. Cured PB cases were followed clinically once a year for two years. Since 1996 there has been no follow-up of cured cases, either MB or PB.

MDT drugs

Central to the successful cure of leprosy cases is the availability of adequate quantities of good-quality drugs. Loose MDT drugs were delivered to patients between 1982 and 1994. Drugs came from a variety of sources: some were purchased by the programme, and some were supplied by participating NGOs. They were delivered to patients, according to disease classification, at the place and time of first diagnosis and subsequently every 28 days for the prescribed duration of treatment by leprosy staff at drug distribution points near patients’ homes. Each mobile team in a district planned monthly circuits to deliver drugs to all patients – a system that continued until 2000. The number of mobile teams in a district varied with the area, the population, and the number of leprosy cases.

The availability since 1995 of MDT drugs free of charge in BCPs has greatly simplified drug delivery and ensured good quality, better storage, and improved compliance with self-administered daily doses.

There were very few instances of shortages of MDT drugs before 1997, and possibly none since.
Delivery of MDT services

Vertical leprosy staff delivered leprosy services, including MDT, until 1998–1999. Plans to involve general health staff in supporting mobile leprosy treatment units, of which two were established in each of the 79 districts of moderate endemicity and one in every low-endemicity district during 1992–1993, did not come to fruition for want of advocacy and of commitment and motivation among both general health staff and decision-makers. Despite the simplification of diagnosis, classification, treatment regimens, drug delivery, and reporting, leprosy programme activities could not be successfully integrated into general health services: there was opposition from leprosy staff and reluctance among general health staff to assume the responsibilities. Concerted efforts since that time, and advocacy meetings with decision-makers at the highest level since 2000, have facilitated the active participation of general health staff; health centres in particular are taking over important tasks related to MDT services from leprosy staff. The involvement of general health staff in MLEC in 1998 has done much to facilitate the integration of the leprosy programme into general health services. This integration needs to be strengthened and sustained.

All 563 districts are expected to have fully integrated leprosy programme by the end of 2003.

Capacity-building of staff

A large body of vertical leprosy staff was created between 1982 and 1991, especially in the highly endemic districts, as a prerequisite for MDT. The increasing demand for training the new staff in leprosy necessitated the establishment of new training centres and the strengthening of existing centres; eventually, there were 49 such centres, 10 of them run by NGOs. To make the courses relevant, practical, and task-oriented, course content for certain categories of health worker has been simplified and course duration shortened. After the integration of leprosy services into general health services, the leprosy course was further simplified and shortened for general health staff.

With declining demand for training of vertical leprosy staff, some of the training centres ceased functioning or were closed down altogether from 1992 onwards.

Operational guidelines were developed and distributed to all implementing units from 1985 and were updated from time to time to ensure uniformity in planning and implementation and to provide reference material.

Information, education, and communication

Before the advent of MDT, leprosy was shrouded in mystery and fear. The vision and concern of Mahatma Gandhi and of other luminaries who followed him and championed the fight against the diseases, heralded an era in which leprosy became everyone’s concern. Nevertheless, the notion of leprosy as a curable disease came only with the availability of MDT.

Community health education on leprosy, an important component of leprosy control even before MDT, was greatly strengthened between 1982 and 2001 by the advances in communication technology. Starting with traditional tools – word of mouth, posters, print media, and so forth – IEC activities have been strengthened and extended, and sustained by increases in budget allocations. The interest, expertise, and resources of several NGOs and bilateral agencies have also played a significant role. Several independent evaluations of the programmes assessed the level of community awareness and allowed appropriate messages to
be developed for identified target groups. The modified leprosy elimination campaign, implemented in 1998–1999, has greatly contributed to increasing community awareness nationwide by involving electronic media – television and radio – in addition to traditional channels to spread messages about leprosy.

The BBC World Service Trust undertook a well conceived project for 16 months in 1999–2000, interacting with the government-owned television and radio network to relay appropriate messages/programmes that reached more than half the country’s population. Since then, television and radio have continued to disseminate similar material.

Disability prevention and correction

The national cumulative number of leprosy cases cured by MDT has now exceeded 10 million, and the number of disabilities prevented in leprosy patients is estimated to be over 1.5 million; MDT is the biggest contributory factor in the prevention of disability. Some NGOs introduced special activities in a few districts to prevent worsening of deformities through distribution of “physical aids” such as protective footwear and gloves to leprosy patients with deformities but the impact of such measures is unknown. The World Bank, in its financial support to the programme, has earmarked funds for surgical correction of leprosy-related deformities.

Modified leprosy elimination campaigns

The leprosy elimination campaign (LEC) approach conceived by WHO in 1995 to detect hidden leprosy cases in relatively small communities was successfully adapted in India in 1997. Subsequently, a successful modified LEC (MLEC) was launched nationwide during 1998. This involved almost a million general health staff and community volunteers being trained as search workers and then using house visits to detect suspected leprosy cases (which would be confirmed later). To promote self-reporting of leprosy cases, a large-scale community leprosy awareness campaign involving electronic and print media was launched before the 6 days of house visits. More than 450 000 new leprosy cases were detected by the MLEC; most of these were from Bihar, Orissa, and Uttar Pradesh states where the programme had not previously been very effective in detecting new cases. In 12% of new cases there was only a single skin lesion.

MLEC was successfully repeated in 1999–2000 in the highly endemic states of Bihar, Uttar Pradesh, Orissa, Madhya Pradesh, and West Bengal and again in late 2001 in highly endemic districts of these states. While the number of new cases detected was less than half the number detected in the earlier MLEC, over-diagnosis of new cases increased.

Preceded by wide publicity and advocacy by political and community leaders at all levels, MLEC proved a useful tool for detection of new cases and subsequent initiation of MDT.

Incentives to staff, states, and districts

Providing MDT services to the needy was considered to be a demanding and arduous task, since the drugs need to be delivered to the patients on time, every month, near their homes by the vertical leprosy staff. A system of monthly cash incentives to vertical leprosy staff, on a scale linked to staff grade/status, was therefore started after the introduction of MDT and continued until 31 March 2000. Ending this scheme, however, was deemed to be a prerequisite for securing the willing participation of general health centres in leprosy programme tasks. Currently no category of staff involved in leprosy programme is paid incentives of any kind.
A national scheme of awards to the best performing state or district has recently been introduced to create the healthy competition that leads to improved performance.

**District Leprosy Society**

It was observed that the MDT activities were interrupted on occasion because the substantial additional funds provided to the districts brought under MDT and sent through the state government did not reach the districts in time or were sometimes either used for purposes other than MDT/leprosy in the districts or used elsewhere. To overcome these problems, a registered District Leprosy Society was created for each district, with the District Magistrate as its chairperson and the District Leprosy Officer as secretary. MDT funds were sent to the Society directly by the national government, together with guidelines on their use. Subsequent review showed that this system functioned very satisfactorily. Each of the 563 districts in the country now has a District Leprosy Society to manage – and account for – additional MDT funds. The success of this scheme has prompted other national health programmes (for example, AIDS, tuberculosis, blindness prevention) to create their own district societies.

In order to facilitate the decentralization of the programme to the states, similar societies were created at the state level during 2000–2001, with the State Health Secretary as chairperson and State Leprosy officer as secretary, to manage, operate and account for the additional funds needed for MDT activities. The Government of India transfers these funds to the State Leprosy Societies, which, in turn, distribute to the District Societies as needed. This decentralization has made the states fully responsible for proper use of funds and their timely distribution to the districts.

**Independent evaluation of the programme**

The introduction of MDT, greater priority for the programme, and higher fund allocation necessitated a system of periodic independent evaluation of the programme. Between 10 and 12 teams – each with three members, of whom one is a WHO expert – were put together for each independent evaluation. So far, there have been eight independent evaluations of the programme, carried out jointly with WHO; the first was carried out in 1986. The objectives of each evaluation, lasting 10–12 days, were to validate the reported data, assess the competence of staff and the level of community awareness, and identify problems and suggest remedial measures. In the last independent evaluation in March/April 2000, the World Bank was a partner with the Government of India and WHO.

These exercises proved to be useful and cost-effective means of reviewing progress and also, from time to time, of motivating leaders at all levels, strengthening and sustaining their commitment to leprosy elimination.

**International and bilateral agencies**

Several international organizations apart from WHO were partners at different times between 1982 and 2001. UNDP and UNICEF have supported MDT activities in selected highly endemic districts, and the World Bank supported the programme with a “soft” loan up to the end of 2003.

WHO has continued to be a natural partner since the leprosy control programme started in 1955. Introduction of MDT, subsequent expansion to cover the whole country, and the goal of elimination of leprosy were all based on the technical advice of WHO. Over the years, WHO
has not only acted as a catalyst, identifying partners willing to support the programme, but has also enhanced its own resource support: the MDT drugs required for the programme were supplied in BCPs free of charge from 1995 and this will continue until the goal is achieved.

The Swedish International Development Agency (SIDA), Norwegian Agency for Development (NORAD), Danish International Development Agency (DANIDA), and United States Agency for International Development (USAID) have supported the extension of MDT to selected districts for some time, and DANIDA has supported the strengthening of various MDT activities in four states over the past 6 years.

**Nongovernmental organizations**

Nongovernmental organizations (NGOs) have long played a pioneering role in leprosy control in India, and since the introduction of MDT their number has increased to about 285 – mostly national organizations. A number of international NGOs – including The Leprosy Mission International (TLMI), the Damien Foundation India Trust (DFIT), the German and British Leprosy Relief Associations (GLRA and LEPLA), the Associazione Italiana Amici di Raoul Follereau (AIFO), Swiss Emmaus, and, more recently, Netherlands Leprosy Relief (NLR) and American Leprosy Missions (ALM) – have played a considerable role in extending MDT to more areas, supporting staff training, promoting community awareness, providing rehabilitation and disability correction, and strengthening and monitoring of the programmes. Some of them have also funded the activities of national NGOs. Since 1984, the Government of India has also supported the national NGOs, reviewing their contributions and providing cash assistance. The resources, commitment, and expertise of a large network of NGOs, working with the programme as partners, have helped to augment leprosy elimination efforts.

In recognition of the contributions made by these organizations, the programme has organized annual meetings with representatives of participating NGOs since 1985 to allow them to share their progress, plans, and problems, to promote coordination among themselves and with the government, and to ensure the implementation of all activities in accordance with the national guidelines.

**Monitoring and supervision**

**District consultant leprologists**

In 1982 the programme found it necessary to provide technical support and guidance to the districts brought under MDT. This was achieved by identifying consultant leprologists and assigning one to each district for about 5 days a month on a part-time basis. Duties included validation of diagnosis, classification, treatment regularity, and management of problem patients. Salary and travel costs were borne by the organization supporting additional MDT costs for the assigned district – in most districts, this was the Government of India. After 1990, it became impossible to provide consultant leprologists to all 201 districts that had been brought under MDT; it was no longer easy to find either the required number of experienced and willing consultant leprologists or the funds required to hire them. However, since 1998, NGOs and WHO have created full-time zonal/district support teams to assist and guide high-prevalence districts in highly endemic states.
National Leprosy Eradication Programme consultants/leprosy coordinators

During the early years of MDT, states faced administrative, operational, and financial problems in extending MDT to more areas. The national programme headquarters did not have sufficient human resources to monitor the progress through field visits or to provide timely assistance to the states. At the request of the programme, WHO has assisted since 1985 with the services of 13 full-time national public health experts as NLEP consultants to cover all states. Each was assigned one or more states on the basis of leprosy prevalence and of such factors as size, population, geographical contiguity etc. WHO supported the salaries and other costs until 2000. WHO replaced these positions in 2001 with state/zonal leprosy coordinators, assigned to problem states/zones to monitor, guide, and support leprosy elimination efforts.

Sample survey-cum-assessment units

In 1986, the programme created 22 sample survey-cum-assessment units (SSAUs) in highly endemic states to validate the reported data; more were established later. However, SSAUs were not able to achieve the intended objectives. The less experienced and less committed staff of SSAUs could not win the confidence of their colleagues in the districts and at higher levels. District data were often found to be more accurate than data generated by SSAUs. Moreover, the mobile nature of SSAU duties meant that experienced staff were often reluctant to take up positions in these units. The net effect is that SSAUs have gradually become non-functional, and a number of them have been abolished.

Information system

A very comprehensive and elaborate card for patients under MDT was started in 1982. It was later abridged, retaining only the core data for use by general health staff. The report format has been similarly simplified over the years to enable the health centre to report on progress to the district, but it is possible that not all the reporting units use the same reporting format.

National Leprosy Eradication Commission

The Chairman and Secretary of the National Leprosy Eradication Commission were the union Health Minister and union Health Secretary. Several union ministers of related departments – Planning, Finance, Information and Broadcasting, Education, Social Welfare – and a number of Chief Ministers of states, by rotation, were the members. The Government has established the Commission to translate the recommendations of the working group formed in 1981 and to review and formulate the policies of the leprosy programme. The Commission functioned between 1984 and 1989; it was able to minimize delays in decision-making for rapid expansion of MDT and provided significant support to the programme.

National Leprosy Eradication Board

With the Health Secretary as Chairman and the Deputy Director-General (Leprosy) as Secretary, the National Leprosy Eradication Board was created in 1984 to implement the policies of the Commission, minimizing bureaucracy, providing an opportunity to review progress, and taking decisions at its twice-yearly meetings to strengthen the programme. Members of the Board were Union Secretaries from related departments – Planning, Finance, Education, Social Welfare, Information and Broadcasting, etc. All the decisions taken at meetings of the Board implied acceptance by all the concerned departments. Huge financial resources needed for the programme and support from other departments became available within a few months of decisions taken by the Board. Like the Commission, the Board functioned between 1984 and 1989.
From 1984 to 1991 the leprosy programme was reviewed through annual reports by both the Prime Minister’s office and the Planning Commission (which allocates funds to all programmes). The programme was adjudged to be one of the best of the health programmes, thanks to the effectiveness of MDT and its implementation, and these favourable reviews gave rise to extensive support and funds from interested parties; several NGOs and bilateral agencies became partners and supported the programmes as a result of these positive reviews.

**Conclusion**

Clearly, MDT is the “jewel in the crown” of the Indian leprosy programme and, over a period of some 20 years, emerged the winner in the battle against the disease. Cutting-edge technology and financial support to the Government of India and its leprosy programme have been provided by WHO; in turn, WHO has learned lessons from its Indian experiences. In fact, WHO, the various international and national NGOs, and the Government of India have gained much by sharing their knowledge, experiences, and resources in the course of the inexorable march towards the goal of leprosy elimination – and the Indian leprosy programme has derived enormous benefits from this synergism, allowing it to fight effectively and relentlessly against this once dreaded disease. It is to be hoped that the programme will continue to receive this much-needed support from all its partners until the goal is achieved.

**Experiences and anecdotes**

1. Considerable time and skill were needed to convince the father of a child with PB leprosy that 6 months’ MDT treatment would cure the condition. Familiar only with the very protracted treatment with dapsone, the father nursed the misconception that the doctor treating the child was unhappy or angry with the child and/or that the government was short of funds. *(Dr V. Ekambaram)*

2. Only long interaction with a PB patient under MDT convinced him that 6 months’ treatment was sufficient to achieve cure (although skin patches did not disappear). The patient thought that the doctor wanted to divert the drugs meant for treating him beyond 6 months in order to treat his relative a for longer period. The patient was finally convinced of the effectiveness of MDT treatment when the skin patches disappeared some months after the end of his 6-month treatment. *(Dr V. Ekambaram)*

3. One MB patient who had received dapsone treatment for nearly 5 years before MDT was surprised to find the treatment duration reduced to 24 months and eventually to 12 months, after which an MB patient could be declared cured. He joked with programme staff that the day was coming when it would suffice just to show the patient the MDT drugs before declaring him cured. *(Dr V. Ekambaram)*

4. Default in completing 14 daily supervised MDT drugs before WHO recommended regimen was, surprisingly, very rare. New innovations associated with MDT drug delivery, such as timely delivery of drugs near patients’ houses, supervised drug intake, and pre-clinic monthly contacts at patients’ homes to remind them of or educate them about regular drug collections, convinced patients that the new drugs were as effective in curing the disease as they had been told. *(Dr K.V. Desikan)*
5. In one district, MDT was restricted to MB patients only in 1982, but was extended to all leprosy patients from 1983. *(Dr K.V. Desikan)*

6. Some community leaders/NGO representatives were of the opinion that statistics were overshadowing human considerations when they observed the high priority being given to MDT delivery compared with the minimal attention being paid to the care of leprosy-disabled patients. *(Dr K.V. Desikan)*

7. The highest priority was accorded to leprosy programme following a special meeting in 1981 between the late Prime Minister Indira Gandhi and several leprologists, at which she expressed her wish for plans to be developed for eradicating leprosy from India by the year 2000. *(Dr Claire Vellut)*

8. During the initial period of MDT introduction in a district, 21 daily, supervised MDT drugs were given to lepromatous leprosy patients after hospitalization. Subsequently, MDT drugs for 14 daily supervised doses were delivered to or near the homes of MB leprosy patients. Later still, only the WHO recommended regimens were followed. *(Dr Claire Vellut)*

9. Several new initiatives associated with MDT – such as delivery of drugs near patients’ homes by teams led by a medical officer, and monthly contacts before and during MDT delivery – convinced patients and the general public that something new, progressive, and effective was available to cure leprosy patients. The new regimen was acceptable and popular, and it reduced the social stigma attached to leprosy. *(Dr Claire Vellut)*

10. Daily movements of vehicles, from 06:00 to 17:00, delivering MDT drugs to leprosy patients in villages created considerable awareness of the leprosy programme in the community and among the local administrators. District magistrates made repeated public declarations that the leprosy programme was the only programme working in the villages; they offered significant support to the programme. *(Dr D. Anandraj)*

11. Leprosy workers used their bicycles to carry disabled active leprosy patients receiving MDT to and from drug distribution points to ensure monthly, supervised MDT drugs. These strict precautions, not even trusting leprosy workers to deliver monthly supervised MDT, seem surprising now, when “accompanied MDT” is accepted as a flexible and standard means of delivering MDT. *(Dr D. Anandraj)*

12. A number of female leprosy patients with reversible claw hand had been abandoned by their husbands but were accepted back after MDT and physiotherapy had corrected the problem. A tailor who also had reversible claw hand was able to continue his work after correction with MDT and physiotherapy. Through patients such as these, and their relatives, MDT grew in popularity. *(Dr D. Anandraj)*

13. A team representing SIDA visited a particular district to support MDT implementation. After a meeting with villagers, the team wanted to see some of the local leprosy patients – several who were sitting with other villagers came forward. The team members were surprised to find the leprosy patients mixing freely with the other villagers, and realized that the social stigma attached to leprosy patients was much less than they had imagined. *(Dr B. Kameswara Rao)*
14. The commitment of leprosy staff to regular delivery of MDT drugs and leprosy patients to compliance with treatment regimens was generally very high during the early years of MDT. Even in conditions of heavy and continuous rain, supervisors often found that staff and patients attended drug distribution points punctually. *(Dr B. Kameswara Rao)*

15. The commitment of staff, patients, and community alike, and the high priority given to the programme by decision-makers, made it particularly pleasurable to be associated with the leprosy programme. *(Dr B. Kameswara Rao)*

16. Red coloration of urine following MDT was mistaken for blood in the urine as a side-effect of the treatment and provoked the leprosy patient concerned into assaulting a medical officer. Considerable time and effort on the part of supervisors was needed to convince the patient that the red colour was not blood in the urine but only a harmless side-effect of rifampicin, one of the three constituent drugs of MDT. *(Dr T.P. Patro)*

17. During supervised intake of MDT at a drug distribution point, one patient was given the three drugs but later spit out the dapsone tablet when the team members were not watching. A supervisor who observed this questioned the patient as to why he spat out the dapsone but swallowed the rifampicin and clofazimine; the patient said that he had had problems whenever he took dapsone in the past (before MDT). Once the supervisor had explained about the safety of dapsone when taken with the other two drugs, the patient agreed to try taking all the drugs. He subsequently completed the full treatment course without any problem. *(Dr T.P. Patro)*

18. A lecturer in a college and a prosperous farmer from a village manhandled a leprosy worker who told them in public (without preparing them) that they had leprosy and should take MDT. However they completed the treatment after the supervisor contacted them at their home and explained that with the availability of MDT, the disease is fully curable and leprosy is milder and less infectious than many other diseases. They later became big promoters of leprosy programme activity, especially MDT. *(Dr T.P. Patro)*

19. A specialist from a medical college discouraged a patient with MB leprosy from taking the drugs provided by the programme, telling him they were cheap and of inferior quality. The specialist then prescribed the same drugs that the patient had purchased for some time. During defaulter retrieval, the patient was finally convinced that the drugs provided by the programme were the same as those he was purchasing on prescription and that he was spending his money unnecessarily. He completed the full course with the drugs provided by the programme. *(Dr T.P. Patro)*

20. A mother of a newborn baby had MB leprosy with ENL reaction and was banished from the house by her husband once he learned of her disease. Her condition improved dramatically with MDT and other drugs; the husband was subsequently persuaded by senior programme staff that she was fully cured of the disease and took his wife and baby back. *(Dr T.P. Patro)*

21. The extent of community awareness of leprosy can be judged from changes in attitude over a period of nearly two decades. In the early days, MDT drugs were distributed outside the village to avoid the anger of the community; later they were distributed to leprosy patients within the village and now they are distributed at the health centres. *(Dr T.P. Patro)*
22. The regimen of 14 daily supervised doses, followed in the early years of MDT, had to be abandoned in one particular unit in a district, because the unit was short-staffed. The patients were given the WHO-recommended regimen only until smear-negativity. Senior officials took a poor view of this and much explanation was needed to justify what had been done. However, the difficulty should be viewed in the light of the present 12-month regimen for cure. (Dr T. Prabhakar Rao)

23. In the absence of guidelines on continuing treatment during pregnancy, there was considerable anxiety among an expert group at a leprosy research and training centre when an MB patient under MDT became pregnant. A bold decision was taken to continue the treatment but to monitor the patient continuously for adverse outcome. There was great relief when a healthy baby was born and the mother suffered no untoward reaction. After the birth, the patient continued to take MDT until she reached smear-negativity. (Dr P. Vijaya Kumaran)

24. A leprosy worker who delivered MDT drugs to a close relative of the patient, when the patient was away from home, was reprimanded and faced disciplinary action. At that time, no one had thought of “accompanied MDT”. (Dr P. Vijaya Kumaran)

25. One MB leprosy patient had to be given a special allowance as well as his MDT drugs to meet the increased appetite he claimed to have developed during treatment and thus to ensure that he completed the full course. (Dr P. Vijaya Kumaran)

26. An elderly MB patient treated with MDT for 5 years questioned the need for 5 years of treatment to achieve cure when he had recently observed some of his family members being told that they were cured after 12 months of MDT. (Dr P. Vijaya Kumaran)

27. The drugs needed for MDT were purchased mainly by the Government until WHO started to supply them. During 1986, a private firm submitted a quotation for supplying clofazimine at very low cost to the procuring agency (outside the health ministry) for the programme. It was learned unofficially that the product supplied by this firm was of substandard quality but that the mandatory quality test report, required before the order was placed, had been falsified. An alternative, and cheaper, source of good-quality clofazimine was essential if the risk of jeopardizing the programme was to be avoided. An urgent request for clofazimine was therefore made to WHO’s Regional Office for South-East Asia; after consultation with WHO in Geneva, it was agreed within 10 days that clofazimine worth US$ 500 000 would be supplied free of charge. The original purchase order for clofazimine from the local firm was then cancelled. The speed of WHO’s response and the willingness to absorb a substantial and unplanned expense were greatly appreciated by senior government decision-makers in the government and convinced them of the high priority accorded by WHO to the Indian leprosy programme. It was also a salutary lesson for private firms of the importance of supplying a product of assured quality in response to a purchase order from the procuring agency. Thereafter, the procuring agency ensured that purchase orders were placed only with firms manufacturing clofazimine of standard quality. (Dr C.K. Rao)
28. The first MLEC in India in 1998 detected some 450 000 new leprosy cases in the country. Of these, 150 000 were in the state of Bihar; this state was not only the largest contributor to numbers of cases but also had the largest new case-detection rate. This undermined the credibility of earlier reports, from several levels of supervisors and from many external evaluators, of satisfactory case-detection efforts in Bihar. (Dr C.K. Rao)

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