STATUS OF TUBERCULOSIS
IN THE 22 HIGH-BURDEN COUNTRIES

AND

GLOBAL CONSTRAINTS TO TB CONTROL

Global Tuberculosis Programme
World Health Organization
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GTB staff at headquarters, regional and country level prepared these documents as background for the discussions of the Ad-hoc Committee on the Global Epidemic during the meeting in London on 17-19 March 1998.

The content of the documents represents the views of WHO/GTB staff on the current status of TB control and the estimated tuberculosis incidence in the respective countries, and on the major problems and possible solutions to accelerate tuberculosis control and reduce human suffering and death due to TB.
STATUS OF TUBERCULOSIS
IN THE 22 HIGH-BURDEN COUNTRIES
**STATUS of TUBERCULOSIS IN THE 22 HIGH-BURDEN COUNTRIES**

The table below gives an overview of tuberculosis in the top 22 high-burden countries in terms of incidence and deaths.

<table>
<thead>
<tr>
<th>Rank</th>
<th>Country</th>
<th>Population millions</th>
<th># of TB cases</th>
<th>Incidence rate per 100,000</th>
<th>as % of all TB cases globally</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>India</td>
<td>944</td>
<td>2,078,000</td>
<td>220</td>
<td>28.4</td>
</tr>
<tr>
<td>2</td>
<td>China</td>
<td>1,232</td>
<td>1,047,000</td>
<td>85</td>
<td>14.3</td>
</tr>
<tr>
<td>3</td>
<td>Indonesia</td>
<td>201</td>
<td>443,000</td>
<td>220</td>
<td>6.0</td>
</tr>
<tr>
<td>4</td>
<td>Bangladesh</td>
<td>120</td>
<td>266,000</td>
<td>220</td>
<td>3.6</td>
</tr>
<tr>
<td>5</td>
<td>Nigeria</td>
<td>115</td>
<td>258,000</td>
<td>222</td>
<td>3.5</td>
</tr>
<tr>
<td>6</td>
<td>Pakistan</td>
<td>139</td>
<td>210,000</td>
<td>150</td>
<td>2.9</td>
</tr>
<tr>
<td>7</td>
<td>Philippines</td>
<td>69</td>
<td>194,000</td>
<td>280</td>
<td>2.6</td>
</tr>
<tr>
<td>8</td>
<td>DR Congo</td>
<td>46</td>
<td>156,000</td>
<td>333</td>
<td>2.1</td>
</tr>
<tr>
<td>9</td>
<td>Russian Fed.</td>
<td>148</td>
<td>147,000</td>
<td>99</td>
<td>2.0</td>
</tr>
<tr>
<td>10</td>
<td>Brazil</td>
<td>161</td>
<td>129,000</td>
<td>80</td>
<td>1.8</td>
</tr>
<tr>
<td>11</td>
<td>Viet Nam</td>
<td>75</td>
<td>125,000</td>
<td>166</td>
<td>1.7</td>
</tr>
<tr>
<td>12</td>
<td>South Africa</td>
<td>42</td>
<td>106,000</td>
<td>250</td>
<td>1.4</td>
</tr>
<tr>
<td>13</td>
<td>Thailand</td>
<td>58</td>
<td>101,000</td>
<td>173</td>
<td>1.4</td>
</tr>
<tr>
<td>14</td>
<td>Ethiopia</td>
<td>58</td>
<td>90,000</td>
<td>155</td>
<td>1.2</td>
</tr>
<tr>
<td>15</td>
<td>Myanmar</td>
<td>45</td>
<td>87,000</td>
<td>189</td>
<td>1.2</td>
</tr>
<tr>
<td>16</td>
<td>Uganda</td>
<td>20</td>
<td>61,000</td>
<td>300</td>
<td>0.8</td>
</tr>
<tr>
<td>17</td>
<td>Peru</td>
<td>23</td>
<td>60,000</td>
<td>250</td>
<td>0.8</td>
</tr>
<tr>
<td>18</td>
<td>Iran</td>
<td>69</td>
<td>58,000</td>
<td>83</td>
<td>0.8</td>
</tr>
<tr>
<td>19</td>
<td>Afghanistan</td>
<td>20</td>
<td>58,000</td>
<td>278</td>
<td>0.8</td>
</tr>
<tr>
<td>20</td>
<td>Tanzania</td>
<td>30</td>
<td>58,000</td>
<td>187</td>
<td>0.8</td>
</tr>
<tr>
<td>21</td>
<td>Sudan</td>
<td>27</td>
<td>57,000</td>
<td>211</td>
<td>0.8</td>
</tr>
<tr>
<td>22</td>
<td>Mexico</td>
<td>92</td>
<td>56,000</td>
<td>60</td>
<td>0.8</td>
</tr>
</tbody>
</table>

| Total |             | 3,734 | 5,840,000 | 80                      |

The following fact sheets begin with a more detailed quantitative status report for each country. The first two boxes in the top row compare the estimated and reported (taken to equal detected) numbers of TB cases of all forms, both infectious (sputum smear-positive, ss+) and non-infectious. Boxes 3 and 4 do the same for infectious cases only. The remaining three boxes indicate the fractions of infectious cases reported from DOTS areas (the ‘DOTS detection rate’), from non-DOTS areas, and in total (the ‘case detection rate’).

Data in the second row show the outcomes of treatment in DOTS and non-DOTS areas of each country. Treatment success is measured as the percentage of registered cases which were demonstrably cured (a positive smear became negative), plus those which completed the recommended course of treatment. Treatment success rates have not been calculated for non-DOTS areas because the data are not reliable.

**Patients which were not successfully treated either defaulted (interrupted treatment), failed (positive smear did not convert to negative), died (of TB or another cause), or transferred to another reporting unit. Data are missing from many boxes, either because they have not been provided, or because they have been provided in some incompatible format. Full definitions of all these terms are given on pages 7-9 of the report entitled “Global Tuberculosis Control – WHO Report 1998.”**
TB in AFGHANISTAN

TB cases, 1996 vs Infectious cases (SS+)*, 1996

<table>
<thead>
<tr>
<th>Estimated # of TB cases</th>
<th>Officially reported # of TB cases</th>
<th>Estimated # SS+</th>
<th>Officially reported # SS+</th>
<th>% of SS+ cases detected by DOTS**</th>
<th>% of SS+ cases detected by Non-DOTS</th>
<th>% of SS+ cases detected</th>
</tr>
</thead>
<tbody>
<tr>
<td>58000</td>
<td></td>
<td>26000</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* SS+ = Sputum smear positive  ** DOTS detection rate

Treatment outcomes, 1995

<table>
<thead>
<tr>
<th>Registered cases (new SS+)</th>
<th>Cured</th>
<th>Completed treatment</th>
<th>Defaulted</th>
<th>Failed</th>
<th>Died</th>
<th>Transfered out</th>
<th>% not evaluated</th>
</tr>
</thead>
<tbody>
<tr>
<td>DOTS</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non-DOTS</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Note: In non-DOTS areas there was no reporting on treatment outcomes.

ANALYSIS

The estimated incidence rate of TB is alarmingly high in Afghanistan. Yet, there is no national TB programme (NTP) in place. Previous NTP activities were heavily damaged due to long-standing civil strife. Virtually no information is available on case notifications or treatment outcome at national level.

TB control takes place in very limited areas with the support of WHO, international agencies and other non-governmental organizations (NGOs). The DOTS strategy was implemented only in one area (Kabul) in 1997 by an NGO. At the end of 1997, there were 31 sites in the country that provided TB treatment services to the community. However, most of them suffer from shortage of funds, anti-TB drugs and equipment for health facilities. The “government” health workers are still present in the field, but they are paid only nominal salaries on an irregular basis.

Status Report on the Elements of DOTS

Political commitment: There is no TB control programme in the country. The theoretical NTP focal point, namely the National TB Institute in Kabul, operates in isolation and provides services such as TB diagnosis and treatment to a limited population in Kabul. There are no standardized guidelines for TB control in Afghanistan.

There is little information available with which to evaluate case detection activities. Laboratories with functioning binocular microscopes exist in the majority of the health facilities at regional and provincial levels. TB case notifications are not regularly reported from the field.

The treatment regimen is not standardized in the majority of the country. WHO recommended treatment regimens are used in a few areas, but even in these, there is no direct observation of treatment and drugs are generally prescribed on weekly basis in the initial phase of treatment.

The drug supply is hampered by shortages of anti-TB drugs due to insufficient funds, lack of buffer stock and difficulties in transportation.
The recording and reporting system is poor in Afghanistan. WHO-recommended recording and reporting forms are not widely used and case-notification reports and treatment outcome reports are not submitted regularly from the field. One main reason for the poor recording and reporting system is lack of proper supervision to correct mistakes in the forms. Shortage of recording and reporting forms is also a problem.

Research and Other Issues

There are no data regarding research efforts in the country.

Risks and Constraints

One important and unavoidable risk to TB control is the on-going armed conflict. Although most of the areas of Afghanistan are now under the control of one authority, there is always the possibility that strife will be re-ignited on a wider scale and damage health services. Of immediate concern is the weak TB control activities at all levels. There is no standardization in TB control and the DOTS strategy is not implemented except for one site in Kabul. Short-course chemotherapy is used without supervision, and anti-TB drugs are available in the local market. If this situation continues, the incidence of tuberculosis and multidrug-resistant TB will increase and could further damage TB control efforts in the future.

Activities to Address Constraints

In early 1998, WHO sent a mission of TB consultants to explore the most appropriate ways to rehabilitate TB control activities in Afghanistan. Through extensive discussions with the concerned staff at all levels and observations in some areas, it was concluded that a phase-in of the DOTS strategy in stable areas of Afghanistan may be feasible.

The objective is to start several DOTS demonstration projects in 1998 and achieve 20 percent population coverage by the end of 1999. This would need meticulous preparation and monitoring and funding. Standardized TB control guidelines, selection of demonstration project sites, secure and effective procurement of anti-TB drugs and training of health personnel will be needed.
TB in BANGLADESH

TB cases, 1996

<table>
<thead>
<tr>
<th>Estimated # of TB cases</th>
<th>Officially reported # of TB cases</th>
<th>Estimated # SS+</th>
<th>Officially reported # SS+</th>
<th>% of SS+ cases detected by DOTS**</th>
<th>% of SS+ cases detected by Non-DOTS</th>
<th>% of SS+ cases detected</th>
</tr>
</thead>
<tbody>
<tr>
<td>264000</td>
<td>63471</td>
<td>119000</td>
<td>29674</td>
<td>16.5</td>
<td>8.5</td>
<td>25.0</td>
</tr>
</tbody>
</table>

* SS+ = Sputum smear positive  
* DOTS detection rate

Treatment outcomes, 1995

<table>
<thead>
<tr>
<th>Registered cases (new SS+)</th>
<th>Cured</th>
<th>Completed treatment</th>
<th>Defaulted</th>
<th>Failed</th>
<th>Died</th>
<th>Transferred out</th>
<th>% not evaluated</th>
</tr>
</thead>
<tbody>
<tr>
<td>DOTS</td>
<td>10867</td>
<td>66.4%</td>
<td>4.9%</td>
<td>10.1%</td>
<td>1.5%</td>
<td>4.9%</td>
<td>2.7%</td>
</tr>
<tr>
<td>Treatment success</td>
<td></td>
<td>71.3%</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Note: In non-DOTS areas there was no reporting of treatment outcomes.

ANALYSIS

The National TB Control Programme (NTP) in Bangladesh is a sub-component of the Fourth Population and Health Project (FPHP) and is integrated with the leprosy programme. It is financed by the Government of Bangladesh (GoB), the International Development Agency/World Bank (IDA) and the Government of The Netherlands.

The revised NTP in Bangladesh was established in 1991 following a World Bank feasibility study performed in 1990. At that time, TB activities were mainly carried out in TB clinics and hospitals with a cure rate of approximately 40 percent.

The DOTS strategy was adopted in 1992 and the revised NTP field implementation began in November 1993 in four pilot thanas (sub-districts). At present, DOTS is implemented in areas covering 65 percent of the population. There are plans to cover the remaining thanas and to start implementation in the metropolitan areas by June 1998. A new national five-year health plan financed by IDA/World Bank and other donors is expected to start after June 1998 as the Fifth Health and Population Programme (HAPP-5).

In Bangladesh, the Ministry of Health and Family Welfare is divided into two wings: health and family planning. The NTP is in the health wing and under the Directorate General of Health Services. TB control is provided through the thana health complex, a health center covering about 300,000 population. Multi-purpose staff provides TB services to outpatients and in the community. Staff from donor programmes also support the NTP at thana, district, divisional and national levels. Specialized TB facilities within the NTP include 44 clinics, four hospitals and eight segregation hospitals.

Status Report on the Elements of DOTS

Strong political commitment has been a determinant in implementing the revised NTP. The programme, including leprosy, is one of the largest within the FPHP, with a budget of $17.2 million. This has ensured that sufficient staff, drugs and supplies were made available throughout the country.

Case detection is by direct microscopy of three sputum samples from each symptomatic patient with a chronic cough. The laboratory network is functioning reasonably, but requires
strengthening through supervision and quality control. There is a need to develop a National Reference Laboratory for culture and susceptibility testing.

**Treatment** is for eight months for sputum smear-positive patients and twelve months for smear-negative patients. All new patients have isoniazid and thiacetazone in the continuation phase. Rifampicin intake is directly observed. Cohort analysis of new smear-positive patients shows very high sputum conversion rate at two to three months and a cure/completion rate of over 75% in the project period.

The **drug supply** is adequate and has been ensured through the district stores or the non-governmental organizations (NGOs) operating in the area.

The **recording and reporting system** is well maintained.

**Research and Other Issues**

The Bangladesh Rural Advancement Committee (BRAC), in collaboration with ICDDR-B, has conducted **operational research** to evaluate the effectiveness of its DOTS programme areas. The TB Research Institute of Japan (RIT) has been involved in the assessment of urban TB programmes. No data on drug resistance is available to GTB.

Collaboration with NGOs is intrinsic to the NTP in Bangladesh. Six main NGOs are operating within the NTP and cover 35 percent of the area. The collaboration between the GoB and NGOs is based on a Memorandum of Understanding whereby NTP implementation is coordinated and ensured within national standards.

**Risks and Constraints**

The FPHP is phasing out next June. The new national five-year health plan (HAPP-5) is under discussion between GoB and the donors. It considers the reunification of the Ministry of Health & Family Welfare into one wing and the prioritization of health delivery into a package of essential services, without specific resources for categorical disease control programmes such as TB. This may result in lack of funds for TB drugs, for supervision and management of the programme and to maintain contractual services with NGOs implementing the DOTS strategy, and in failure of the programme.

The current case detection rate of sputum smear-positive patients is low (around 30%) and therefore the programme is not achieving its potential to reduce TB transmission.

**Activities to Address Constraints**

The GoB has already identified major policy strategies to improve the health care delivery system. Health reform and the Programme Implementation Plan for the HAPP-5 are now under discussion by GoB, with advice from WHO. An upcoming World Bank appraisal mission in Bangladesh is expected to finalize the HAPP-5 with the GoB and the donors. The success of TB programme implementation in HAPP-4 will be discussed, and should result in earmarking of HAPP-5 resources for the essential elements of DOTS.

After maintaining satisfactory cure/treatment completion rates during its expansion, the NTP is now working to improve case detection. New strategies are also considered under the "Behavior Change Communication" component of the HAPP-5. New partnerships are being explored with the Asian Development Bank (ADB) and other organizations committed to providing primary health care services in the four largest cities of Bangladesh.
TB in BRAZIL

TB cases, 1996

<table>
<thead>
<tr>
<th>Estimated # of TB cases</th>
<th>Officially reported # of TB cases</th>
<th>Estimated # SS+</th>
<th>Officially reported # SS+</th>
<th>% of SS+ cases detected by DOTS**</th>
<th>% of SS+ cases detected by Non-DOTS</th>
<th>% of SS+ cases detected</th>
</tr>
</thead>
<tbody>
<tr>
<td>129000</td>
<td>87254</td>
<td>58000</td>
<td>44501</td>
<td>0.0</td>
<td>76.7</td>
<td>76.7</td>
</tr>
</tbody>
</table>

* SS+ = Sputum smear positive

**DOTS detection rate

Treatment outcomes, 1995

<table>
<thead>
<tr>
<th>Registered cases (new SS+)</th>
<th>Cured</th>
<th>Completed treatment</th>
<th>Defaulted</th>
<th>Failed</th>
<th>Died</th>
<th>Transferred out</th>
<th>% not evaluated</th>
</tr>
</thead>
<tbody>
<tr>
<td>DOTS</td>
<td>-</td>
<td>-%</td>
<td>-%</td>
<td>-%</td>
<td>-%</td>
<td>-%</td>
<td>-%</td>
</tr>
<tr>
<td>Treatment Success</td>
<td>-%</td>
<td>-%</td>
<td>-%</td>
<td>-%</td>
<td>-%</td>
<td>-%</td>
<td>-%</td>
</tr>
</tbody>
</table>

Non-DOTS

<table>
<thead>
<tr>
<th>Registered cases (new SS+)</th>
<th>Cured</th>
<th>Completed treatment</th>
<th>Defaulted</th>
<th>Failed</th>
<th>Died</th>
<th>Transferred out</th>
<th>% not evaluated</th>
</tr>
</thead>
<tbody>
<tr>
<td>11413*</td>
<td>67.7%</td>
<td>-%</td>
<td>12.7%</td>
<td>2.4%</td>
<td>2.9%</td>
<td>2.6%</td>
<td>11.2%</td>
</tr>
</tbody>
</table>

* Cohort analysis of treatment outcome is performed only in cases registered during one month in each quarter.

Note: In non-DOTS areas, the reported treatment outcomes are not based on a WHO standard cohort analysis.

ANALYSIS

The Brazil TB programme was evaluated by the Government of Brazil (GoB) and the Pan American Health Organization (PAHO)/World Health Organization (WHO) in 1994. As a consequence, the GoB adopted some of the key elements of the DOTS strategy (case detection strategy, registration and reporting system), revised the treatment guidelines and decided to pilot direct observation of treatment. The country has had short-course chemotherapy at national level for twenty years, always using a daily self-administered regimen, using rifampicin and isoniazid in fixed drug combination.

Insufficient political commitment and programme monitoring, and health sector reform have led to unsatisfactory treatment outcomes and a reduction in the proportion of health facilities providing TB case detection and treatment. Use of fixed combinations of drugs and referral of patients for treatment by private practitioners to the public system, where TB drugs are available regularly, are probable factors for determining low levels of drug resistance.

After a period of deterioration - which culminated in 1990-92 with the elimination of the federal TB unit and the interruption of drug supplies - the TB programme is slowly recovering. The programme has advisory, supervision and monitoring functions at national and state levels: macro-regional units comprising several states complement supervision and monitoring from the national level. The responsibility of service delivery is now with the municipal governments. The decentralization of health to about 5,000 municipalities and the transfer of the state delivery services were carried out without adequate follow-up and training on TB programme organization. This resulted in poor monitoring, further deterioration of the laboratory network for smear examination and reduced access of the population to TB case detection and treatment. There is an active training programme at national level, but this has not resulted in compliance with the national policies at field level, except for treatment regimens.
Status Report on the Elements of DOTS

Political commitment has increased gradually since 1995. The federal government has maintained central drug procurement and provided financial resources of approximately US $20 million per year, but has not established a specific budget for TB. A new programme manager and a new director of the national TB Institute were designated in 1997. The central unit is understaffed.

Case detection is through smear microscopy in patients with respiratory symptoms attending health facilities. Irregular supplies and poor access to microscopy services, which often do not depend on the same administrative jurisdiction as the health facility, hamper this activity. The laboratory network for tuberculosis is poorly organized in most states.

Treatment is six months with a daily, self-administered regimen. Only three drugs are used in the initial phase in new patients. There is a high level of treatment default. Pilot areas with directly observed treatment are just starting implementation.

Drug supply is so far regular and sufficient, with national procurement. However, the essential drug purchasing office at national level has been deactivated and there is high risk of interruption of drug supplies.

Recording and reporting guidelines accord with WHO recommendations, but implementation of the revised forms and registers was not accompanied by adequate training and supervision. The laboratory books have not been implemented; information produced is not adequate for programme monitoring.

Research and Other Issues

Research includes studies on the prevalence of drug resistance (with WHO support) which showed less than expected levels, and studies of cost-effectiveness of treatment delivery strategies. The National TB Institute and the Q-TROP programme carry out limited operational research. The impact of HIV on TB has been assessed by studies in Rio de Janeiro. Clinical trials of twice-weekly treatment were completed in Sao Paulo.

Risks and Constraints

Changes in the health structure of Brazil have major implications for TB control. Effective decentralization to municipalities requires intensive training. Many municipal governments do not yet have the capacity to implement the TB control programme or give sufficient priority to the problem. Instead of increasing the number of health facilities providing TB diagnosis, the transfer of state facilities has resulted in centralization of TB patients in specialized services, less accessible to patients for monitoring of treatment.

Decentralization of drug purchases substantially increases the cost and the risk of poor quality. The laboratory services and the large hospitals serve multiple health facilities outside their jurisdiction, and there is poor co-ordination and communication.

Activities to Address Constraints

At present, the Government is reorganizing the central TB Unit, implementing a three-year emergency plan to assist municipalities with the highest incidence, and starting implementation of the full DOTS strategy on a pilot basis. WHO and PAHO provide technical support to define priorities, provide appropriate advice and monitor outcomes. A large loan for health from the World Bank and Inter-American Development Bank, now in preparation, may include some components of the TB programme.
TB in CHINA

TB cases, 1996

<table>
<thead>
<tr>
<th>Estimated # of TB cases</th>
<th>Officially reported # of TB cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>1047000</td>
<td>469358</td>
</tr>
</tbody>
</table>

Infectious cases (SS+)*, 1996

<table>
<thead>
<tr>
<th>Estimated # SS+</th>
<th>Officially reported # SS+</th>
<th>% of SS+ cases detected by DOTS**</th>
<th>% of SS+ cases detected by Non-DOTS</th>
<th>% of SS+ cases detected</th>
</tr>
</thead>
<tbody>
<tr>
<td>471000</td>
<td>168270</td>
<td>25.2</td>
<td>6.5</td>
<td>35.7</td>
</tr>
</tbody>
</table>

* SS+ = Sputum smear positive  ** DOTS detection rate

Treatment outcomes, 1995

<table>
<thead>
<tr>
<th>Registered cases (new SS+)</th>
<th>Cured</th>
<th>Completed treatment</th>
<th>Defaulted</th>
<th>Failed</th>
<th>Died</th>
<th>Transferred out</th>
<th>% not evaluated</th>
</tr>
</thead>
<tbody>
<tr>
<td>DOTS</td>
<td>99628</td>
<td>94.5%</td>
<td>1.4%</td>
<td>0.8%</td>
<td>1.0%</td>
<td>1.5%</td>
<td>0.3%</td>
</tr>
<tr>
<td>Treatment success</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>95.8%</td>
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Non-DOTS

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th>7.5%</th>
</tr>
</thead>
<tbody>
<tr>
<td>31885</td>
<td></td>
<td>85.1%</td>
<td>3.3%</td>
<td>0.6%</td>
<td>2.2%</td>
<td>1.3%</td>
<td></td>
</tr>
</tbody>
</table>

Note: In non-DOTS areas, the reported treatment outcomes are not based on a WHO standard cohort analysis.

ANALYSIS

Pilot projects in Beijing incorporating the key elements of DOTS were already established during the 1980s and were achieving significant success in reducing the prevalence of TB compared with the rest of the country. In 1991, a new pilot project in six counties in the Hebei province demonstrated the feasibility of the DOTS strategy in rural China.

In 1992, the strategy began expansion to the 13 provinces included in a World Bank-supported project (Infectious and Endemic Disease Control Project–IEDCP). By the end of 1996, 1149 counties (95 percent) were implementing DOTS covering a population of 560 million. In the remaining provinces, the Ministry of Health-supported project (MOHP) was covering 274 counties. In the IEDCP, half a million patients with infectious TB have been cured. Another significant result of the project has been the reduction of the proportion of cases that failed due to previously inadequate treatment.

Before the introduction of DOTS, and in the provinces and counties not included in the IEDCP, TB was mainly treated in hospitals or institutions without a well-defined strategy. In non-DOTS areas, tuberculosis prevalence remains high.

There is neither one overall TB programme in China, nor a sufficiently staffed central TB unit. The country is divided in three areas: one which implements the full DOTS strategy (IEDCP); one which implements a modified strategy; and the remaining administrative areas which implement the old policy.

Status Report on the Elements of DOTS

Overall, China has not made a political commitment to introduce DOTS in the whole country nor to maintain DOTS activities in the provinces and counties currently implementing them once the World Bank funding is finished. In the IEDCP provinces, the government committed local funds to help with TB until the end of the World Bank supported project. These funds permit TB patients to be treated for free. In the rest of the country, there are not sufficient funds for priority health programmes, including TB, and TB patients have to pay for all services and drugs.

The case detection rate of new infectious patients has been improving since early 1997 when the Government made TB a reportable disease and requested all health units to refer TB
patients to the Endemic Disease Department. Outside the DOTS project, microscopy services are poorly organized, quality control is usually not implemented and case finding of new cases is significantly lower than in the DOTS project. In DOTS project, microscopy services have been strengthened, including quality control.

The IEDCP has applied a standardized six-month treatment regimen with each dose directly administered to the patient every other day by village health workers. In the experimental Ministry of Health project areas, the initial phase of the regimen is given daily and direct observation of the treatment is provided to only half the patients. Outside these areas, the regimens are usually unstandardized and are self-administered by patients.

In the IEDCP, drug supply is centralized and procured by international bidding. No significant drug shortage has been reported. As a result of the large quantities of drugs ordered, prices were very low. Drugs are supplied in blister packs, which contain one week's supply. This packing has been reported to be useful in simplifying drug distribution. Outside the DOTS and Ministry projects, drugs are bought locally by single institutions, quality is often poor and prices are higher.

IEDCP implements the full WHO-recommended reporting system. In addition, due to World Bank requirements, the monitoring system includes a management report allowing a complete monitoring of the project outcome indicators. Outside the project, the reporting system is insufficient to evaluate even the most basic indicators of treatment outcome.

Research and Other Issues

There is a WHO collaborating center on TB treatment, which has been used to introduce a scientific approach to assess treatment regimens and has contributed to the introduction of standardized regimens. The IEDCP has established a committee to review operational research proposals with the participation of scientists working in fields and institutions other than TB. This experience has not fully achieved the initial objectives of improving the quality of operational research conducted, but has been able to address and complete about ten studies. The role of the private sector in TB control has yet to be addressed in China.

Risks and Constraints

The IEDCP achievements have led to a broad consensus and endorsement of the technical components of the DOTS strategy in China. Remaining issues are how to sustain and expand the approach through a national tuberculosis programme using DOTS for the whole country. There are key financial issues to be resolved, such as the feasibility of charging patients. A recent review of TB control in China concluded that in poor areas, an estimated 50 percent of patients default due to financial difficulty, causing a high percentage of relapse cases. Other financial issues are how the central drug procurement may be maintained and expanded nationwide.

Activities to Address Constraints

WHO and the World Bank should promote a high-level consultation meeting with the Government, including the Ministry of Finance, State Planning Commission and Provincial Governments to address the sustainability and expansion. In collaboration with WHO, MOH should develop a finalized proposal outlining the plan for establishing a coherent National Tuberculosis Programme to be presented at this high-level meeting.
TB in DEMOCRATIC REPUBLIC of CONGO

TB cases, 1996

<table>
<thead>
<tr>
<th>Estimated # of TB cases</th>
<th>Officially reported # of TB cases</th>
<th>Estimate d # SS+</th>
<th>Officially reported # SS+</th>
<th>% of SS+ cases detected by DOTS**</th>
<th>% of SS+ cases detected by Non-DOTS</th>
<th>% of SS+ cases detected</th>
</tr>
</thead>
<tbody>
<tr>
<td>156000</td>
<td>45999</td>
<td>70000</td>
<td>24125</td>
<td>34.4</td>
<td>0.0</td>
<td>34.4</td>
</tr>
</tbody>
</table>

* SS+ = Sputum smear positive  ** DOTS detection rate

Treatment outcomes, 1995

<table>
<thead>
<tr>
<th>Registered cases (new SS+)</th>
<th>Cured</th>
<th>Completed treatment</th>
<th>Defaulted</th>
<th>Failed</th>
<th>Died</th>
<th>Transferred out</th>
<th>% not evaluated</th>
</tr>
</thead>
<tbody>
<tr>
<td>DOTS</td>
<td>8052*</td>
<td>63.9%</td>
<td>15.9%</td>
<td>8.3%</td>
<td>1.5%</td>
<td>5.5%</td>
<td>6.0%</td>
</tr>
<tr>
<td>Treatment success</td>
<td></td>
<td>79.8%</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Cohort analysis is based on a selected group of patients

Note: In non-DOTS areas there was no reporting of treatment outcomes.

ANALYSIS

In 1981, the Ministry of Health (MOH) implemented a National Tuberculosis Programme (NTP) as part of primary health care services. The NTP operates under the leadership of the Bureau National de la Tuberculose (BNT), and has been supported by several non-governmental organizations (NGOs), mainly the Damien Foundation and Ligue Anti-tuberculose.

Between 1985 and 1994, political instability, increasing poverty, migration to urban areas, an influx of refugees from Rwanda and Burundi, internally displaced people, an increase in the AIDS epidemic, and reduction of governmental budget and external assistance have resulted in an increase in TB.

In 1994, the NTP covered only 47 percent of 306 districts. In October 1994, the BNT decided to adopt the DOTS strategy. The new regimen (eight months for both new and retreatment cases) was implemented in 39 districts in 1996 and progressively expanded. Today, only 11 districts (five percent of the total) are not covered by the NTP.

Despite socio-political instability, the programme has been able to expand DOTS because of several factors: integration of activities in general health services; stability and motivation of managerial and supervisory staff at central and intermediate levels; and strong financial and managerial support given by NGOs.

Status Report on the Elements of DOTS

Political commitment is evidenced by the stability of the TB management team (BNT), and the coordination insured by the MOH. Unfortunately, the government’s budget for TB control is very low.

Case detection and diagnosis have shown considerable improvement, and notified incidence has increased. Quality of diagnosis is good, with 76 percent of pulmonary cases confirmed by smear examination. The improvement is more obvious in Kinshasa, where 10 percent of the population is living and 30 percent of TB cases are detected. A specific system of quality control for laboratories has been developed in Kinshasa.
With the implementation of the new revised programme, eight-month short-course chemotherapy treatment regimens are applied to all TB patients (new and re-treatment cases). Treatment is observed during the initial phase for new cases and for the entire duration of treatment for retreatment cases.

The drug supply is carefully managed by the NTP with the assistance of the Damien Foundation. All NGOs and groups working with the DOTS strategy have access to the drug supply, which is centrally procured. TB drugs are available free to patients, or with a small symbolic participation (US $1-$3).

The recording and reporting system is functional and used in all the regions, whether they are covered by the NTP or not.

Research and Other Issues

A special co-ordination team has been created to promote the participation of the private sector in the NTP.

Two major research projects have been implemented. The KINUE project studies the coordination of TB activities in Kinshasa between public health services and church health services, through quality control of laboratories and TB drug procurement. A second project examines public/private TB activities in Kinshasa in order to improve the results of TB case management.

Risks and Constraints

The major constraints are poor funding of the NTP by the MOH, poverty, lack of recent information on HIV prevalence and of drug resistance among TB patients, transportation (roads) problems, and communication difficulties.

Activities to Address Constraints

The Bureau National de la Tuberculose (BNT) and WHO are working to obtain long-term support from additional external sponsors. The NTP is working to increase the number of management teams at intermediate level (regional and sub-regional) from 20 to 35 and integrate TB activities at district level in the 306 health areas ("zones de santé").
TB in ETHIOPIA

TB cases, 1996

<table>
<thead>
<tr>
<th>Estimated # of TB cases</th>
<th>Officially reported # of TB cases</th>
<th>Estimated # SS+</th>
<th>Officially reported # SS+</th>
<th>% of SS+ cases detected by DOTS**</th>
<th>% of SS+ cases detected by Non-DOTS</th>
<th>% of SS+ cases detected</th>
</tr>
</thead>
<tbody>
<tr>
<td>90000</td>
<td>171033</td>
<td>41000</td>
<td>9225</td>
<td>22.7</td>
<td>0.0</td>
<td>22.7</td>
</tr>
</tbody>
</table>

* SS+ = Sputum smear positive  
* *DOTS detection rate

Treatment outcomes, 1995

<table>
<thead>
<tr>
<th>Registered cases (new SS+)</th>
<th>Cured</th>
<th>Defaulted</th>
<th>Failed</th>
<th>Died</th>
<th>Transferred out</th>
<th>% not evaluated</th>
</tr>
</thead>
<tbody>
<tr>
<td>DOTS</td>
<td>5042</td>
<td>57.7%</td>
<td>2.0%</td>
<td>14.1%</td>
<td>1.4%</td>
<td>6.4%</td>
</tr>
<tr>
<td>Non-DOTS</td>
<td>-</td>
<td>-%</td>
<td>-%</td>
<td>-%</td>
<td>-%</td>
<td>-%</td>
</tr>
</tbody>
</table>

Treatment success: 59.7%

Note: In non-DOTS areas there was no reporting on treatment outcomes.

ANALYSIS

With the exception of areas where DOTS has been adopted, TB services are poorly organized. Case detection largely depends on clinical and X-ray findings. Health institutions with very small budgets supply TB drugs, but the supply is inadequate and irregular. There is no information on treatment outcomes, and a significant number of patients abscond. A large difference between the estimated TB incidence (World Bank report) and the number of notified cases can be attributed to underestimation of the incidence, duplication of notifications or over-diagnosis of TB based on clinical and radiological data, without bacteriological confirmation.

A five-year Project Development Plan (PDP) was formulated in 1995 based on recommendations from a joint review of the TB programme by the Government of Ethiopia and WHO. An agreement was signed in December 1996 between the Ministry of Health (MOH), WHO and KNCV to achieve 75 percent DOTS coverage in a five-year period. A major achievement in this strongly decentralized country was consensus on the National Tuberculosis and Leprosy Control Programme (NTLCP) strategy, which has been accepted by all regions and has been set out in a national TB and leprosy manual published in August 1997.

Ethiopia is administratively divided into 11 Regions. Each Regional State is composed of administrative Zones (60 in total), sub-divided into 521 Woredas (districts). Currently the programme is establishing a functional infrastructure with a strong Central Office at the MoH with managerial teams at the regional levels. Staffing at all levels is still inadequate. Five out of 11 regions have a leprosy and TB coordinator (RTLC). District Health Offices have been established in most Woredas.

Status Report on the Elements of DOTS

There is clear political commitment from the Ministry of Health as well as from the Regional Health Bureaus to implement the DOTS strategy. The Central Office of the NTLCP at the Ministry of Health consists of three experts, but will be strengthened with two additional medical officers.

Passive case detection and diagnosis in the DOTS demonstration areas is based on sputum microscopy and meets WHO recommendations. Treatment is free of charge and directly observed treatment is delivered in selected demonstration areas, mainly on an ambulatory basis in hospitals and health centers and in selected
Health stations. Treatment regimens recommended in the new national norms follow WHO guidelines. In only two zones are treatment outcomes satisfactory.

The drug supply required for the areas implementing DOTS is provided through KNCV. The Italian Co-operation, which has supported the TB control programmes of Arssi and Bale Zones in Oromiya Region since 1992, continues to supply drugs and materials to these zones. Drugs and laboratory supplies are distributed through the standard Ministry of Health system, with buffer stocks at central, regional and zone levels.

A new recording and reporting system, based on WHO recommendations, will be introduced countrywide during 1998. The system is based on the district TB register and will be computerized at the central level.

Research and Other Issues

Some research has been conducted to examine the impact of HIV on TB.

Private health care establishments are exclusively located in urban centers. Their role in TB is mainly confined to diagnosis and referral to government institutions. Several NGOs are active in supporting the NTLCP. The major NGO is the GLRA. MSF, Norwegian Church Aid and ALERT also provide support.

Risks and Constraints

General constraints include shortage of skilled manpower at regional, zone, district and health facility levels; lack of transportation; low coverage of the health services; and time-consuming administrative procedures.

The combination of the TB and leprosy components is not well-established. The leprosy component is not well integrated into the general health services, mainly due to reluctance of workers from vertical programmes. There is inadequate supervision at all levels and an inadequate microscopy network.

The current health system is inadequate and covers only 40 percent of the population. HIV has a substantial impact on the TB problem and the programme's performance.

Activities to Address Constraints

During 1998, the programme will consolidate its activities primarily in the DOTS areas. The emphasis will be on improving quality and increasing the proportion of patients under observed treatment by increasing the number of health facilities applying the strategy. Plans have been made to fully integrate the leprosy component into the general health services during 1998/1999. New national guidelines, with a simplified recording and reporting system, will be introduced throughout the country.

Quality control of microscopy will also start in 1998 in three regions. A laboratory manual is currently being developed. Several regions have started to train junior laboratory technicians to cope with the shortage of laboratory personnel.

WHO and KNCV continue to provide technical assistance through a WHO TB and leprosy advisor and short-term consultants. Co-ordination meetings with donor agencies and NGOs will be organized to promote a uniform national programme. Despite the many constraints, a promising factor is the high quality and motivation of the usually young peripheral health workers working at health facilities and their eagerness to be involved in the TB control programme.
TB in INDIA

TB cases, 1996

<table>
<thead>
<tr>
<th>Estimated # of TB cases</th>
<th>Officially reported # of TB cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>2078000</td>
<td>1300935</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Estimated # SS+</th>
<th>Officially reported # SS+</th>
<th>% of SS+ cases detected by DOTS*</th>
<th>% of SS+ cases detected by Non-DOTS</th>
<th>% of SS+ cases detected</th>
</tr>
</thead>
<tbody>
<tr>
<td>935000</td>
<td>291205</td>
<td>0.7</td>
<td>30.5</td>
<td>31.1</td>
</tr>
</tbody>
</table>

* SS+ = Sputum smear positive  
* DOTS detection rate

Infectious cases (SS+)*, 1996

Treatment outcomes, 1995

<table>
<thead>
<tr>
<th>Registered cases (new SS+)</th>
<th>Cured</th>
<th>Completed treatment</th>
<th>Defaulted</th>
<th>Failed</th>
<th>Died</th>
<th>Transferred out</th>
<th>% not evaluated</th>
</tr>
</thead>
<tbody>
<tr>
<td>DOTS</td>
<td>2089</td>
<td>75.5%</td>
<td>3.3%</td>
<td>7.6%</td>
<td>3.4%</td>
<td>3.4%</td>
<td>6.9%</td>
</tr>
<tr>
<td>Non-DOTS</td>
<td>262633</td>
<td>78.8%</td>
<td>24.7%</td>
<td>-%</td>
<td>-%</td>
<td>-%</td>
<td>-%</td>
</tr>
</tbody>
</table>

Note: In non-DOTS areas, the reported treatment outcomes are not based on a WHO standard cohort analysis.

ANALYSIS

The Government of India (GoI) and WHO conducted a joint review of the TB control programme in September 1992. Problems identified in the 1992 review include managerial weakness at the central level, poor diagnosis based mainly on x-rays instead of sputum smear microscopy, poor treatment results, an irregular and insufficient drug supply, and no programme performance monitoring. In addition, the dominant role of the private sector - with a multitude of treatment procedures and very poor outcomes - resulted in the frequent transfer of patients between the private and public sectors.

The GoI implemented the DOTS strategy in demonstration areas in 1993 in preparation for a proposed TB control project with World Bank support. The project, approved in 1997, includes implementing the strategy in 102 districts with a total population of 271 million and strengthening the remaining districts for future expansion. The current 20 pilot areas cover a population of 18.3 million. The rest of the country has self-administered short-course chemotherapy or 12 months conventional treatment, with irregular drug supply, poor outcomes and lack of cohort analysis. The results achieved in the demonstration areas indicate the feasibility of implementing the Indian Revised National Tuberculosis Programme in both urban and rural settings.

The revised programme is ready for expansion to 39 districts (130 million population), except for serious delays in the procurement of drugs and equipment by the Ministry of Health, which may result in suspension of the World Bank loan.

Status Report on the Elements of DOTS

The government has shown increased political commitment to TB control by implementing a national plan and raising the annual TB control budget from US $3 million to about US $20 million. The World Bank loan of US $142 million is being used for the preparations for expansion. However, service delivery in the revised programme based on the DOTS strategy is being delayed due to a single key issue: the capacity to procure drugs and supplies.

Case detection and diagnosis have shown improvement in the pilot areas due to the use of three smears for diagnosis and a stricter interpretation of x-rays. In recent years, the number of staff has increased at the central level, and state and district staff are being trained in using DOTS.
National guidelines, policies and training modules have been developed. Sub-district supervisory teams have been created. The treatment regimen is six months for new sputum smear-positive cases. All treatment is directly observed each time in the initial phase and once per week in the continuation phase. Drugs used are in blister packs and in packages containing the full treatment for a patient. The drug supply has been sufficient for the demonstration areas through Government supply and assistance from donors such as the Swedish International Development Cooperation Agency (SIDA), World Bank, Department for International Development (DFID) and the Danish International Development Agency (DANIDA), but only on an emergency basis. In the rest of the country, the supply is still insufficient, and drugs are not yet available for the expansion of the programme. The recording and reporting system is functional and improving in the pilot areas.

Research and Other Issues

Research is performed at national institutes and academic institutions such as the Tuberculosis Research Center (TRC), which conducted drug resistance surveillance. The National Tuberculosis Institute (NITI) conducts annual risk of infection studies. Operational research supported by WHO, DFID, the Indian Council of Medical Research (ICMR) and TRC has investigated the role of the private practitioner in TB case management. Other studies have investigated the health-seeking behavior of TB patients, the economic benefits of DOTS in India, and the involvement of the private sector in TB control.

The private sector has a major role in TB case detection. Due to lack of confidence in the public health services (irregularity of drug supplies and difficult access in terms of distance and hours of operation), more than half of the TB patients are initially treated by the private practitioner. These patients must buy their own drugs in private pharmacies. This results in movement between the two sectors, with treatment discontinuity, mono-therapy, drug resistance, high case fatality, and production of chronic cases. National, international and local non-governmental organizations (NGOs) provide TB services, but in general have small geographic coverage and do not follow WHO recommendations. DANIDA and DFID have committed resources to support implementation of the revised strategy in one state each (respectively part of Orissa and all of Andhra Pradesh), in co-ordination with GoI.

Risks and Constraints

Because of delays in implementing the revised TB control strategy, the momentum and interest in the TB programme could be jeopardized. The inability to ensure timely, quality drug procurement, and to streamline administrative procedures could seriously undermine all Government efforts to control tuberculosis. In addition, strengthening of the managerial and supervisory capacity at central and district level has been slow, and it may not be sufficient to ensure programme quality during expansion.

Activities to Address Constraints

DFID and DANIDA have offered support for drugs to maintain the pilot projects and possibly start expansion of the revised strategy. WHO and the World Bank are monitoring the situation and providing advice on this key issue, as well as monitoring the preparation for expansion. WHO is supporting activities through its staff at regional level headquarters, and is funding national programme officers until GoI can find a mechanism to hire additional staff with its own resources.
TB in INDONESIA

TB cases, 1996

<table>
<thead>
<tr>
<th>Estimated # of TB cases</th>
<th>Officially reported # of TB cases</th>
<th>Estimated # SS+</th>
<th>Officially reported # SS+</th>
<th>% of SS+ cases detected by DOTS**</th>
<th>% of SS+ cases detected by Non-DOTS</th>
<th>% of SS+ cases detected</th>
</tr>
</thead>
<tbody>
<tr>
<td>443000</td>
<td>24547</td>
<td>199000</td>
<td>11790</td>
<td>5.9</td>
<td>0.0</td>
<td>5.9</td>
</tr>
</tbody>
</table>

* SS+ = Sputum smear positive  
* DOTS detection rate

Treatment outcomes, 1995

<table>
<thead>
<tr>
<th>Registered cases (new SS+)</th>
<th>Completed treatment</th>
<th>Defaulted</th>
<th>Failed</th>
<th>Died</th>
<th>Transferred out</th>
<th>% not evaluated</th>
</tr>
</thead>
<tbody>
<tr>
<td>DOTS</td>
<td>3018</td>
<td>73.1%</td>
<td>17.6%</td>
<td>6.0%</td>
<td>0.4%</td>
<td>1.9%</td>
</tr>
<tr>
<td>Treatment success</td>
<td>90.7%</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Non-DOTS: -

Note: In non-DOTS areas there was no reporting of treatment outcomes.

ANALYSIS

The National Tuberculosis Programme (NTP) was established in Indonesia in 1969 under the Directorate of the Communicable Disease and Environmental Health in the Ministry of Health. Prior to the adoption of DOTS, the TB programme covered approximately 50 percent of the 7,000 health centers, with cure rates of 60 percent.

Based on recommendations from a 1994 WHO review of the programme, the government declared TB an urgent public health problem, and adopted the DOTS strategy. A five-year plan for phased implementation was developed. In 1995, national training and demonstration areas were implemented in one district in the East Java and Jambi provinces. The Sulawesi project, started in 1993 with support from the Royal Netherlands Tuberculosis Association (KNCV), expanded in the same year to cover a population of 3.8 million.

The DOTS strategy has gradually expanded since 1995 and now covers 23 percent of the population, although only three provinces have 100 percent coverage.

Tuberculosis is a major public health problem in Indonesia and kills more of the population than any other infectious disease. Tuberculosis cases are diagnosed in hospitals, specialized health services, health centers and in the private sector. Most sectors have different reporting systems and the private sector does not report TB cases at all. There is no population-based information on new and old TB cases, TB/HIV co-infection prevalence or drug resistance.

Status Report on the Elements of DOTS

Political commitment is increasing. The National Steering Committee for Tuberculosis was established in 1996 and advises the Minister of Health. The committee has determined that also sputum-smear negative TB cases will be treated within the NTP free of charge and that the private sector will receive free TB drugs. The government budget for TB has increased annually and the drug budget has been sufficient.

Case detection is based on smear microscopy in DOTS areas. Binocular microscopes are being provided to health centers. The Center for Laboratories at the provincial level deals with basic and refresher laboratory training and with quality control of slides. The laboratory at the Persahabatan Hospital in Jakarta is a WHO Collaborating Center. This laboratory has the capacity
for drug resistance surveillance for the NTP. The quality control of TB slides functions irregularly, mainly due to insufficient budget.

**Treatment** is directly observed once a week in a health center. On the remaining days a treatment observer, often a family member, has the responsibility to supervise the treatment during the first two months.

The **drug supply** is the responsibility of the Drug and Food Control Directorate. The TB programme drugs are free to patients and are produced in Indonesia and packed for individual patients in blister packs called combi-packs. Routine information on TB drug utilization and stocks is not maintained.

A new **recording and reporting system** has been introduced, but it still functions poorly in spite of staff training. Reports are not complete and are often delayed for several quarters. Software was developed to computerize the information.

**Research and Other Issues**

WHO has provided **technical assistance** to the NTP over the last years in the form of missions, short-term consultants, national consultants and, since August 1996, a long-term staff member. The Australian Government has financed a WHO medical officer for TB. WHO provided technical support to conduct a study on the impact of HIV infection on TB, to write an economic analysis of TB control, and to develop software for the TB database.

The Asian Development Bank project on communicable diseases will shortly start supporting 21 districts in six provinces. The ongoing World Bank Health Project 4 (HP4) also has a small TB component, mainly for quality assurance. An ASEAN Tuberculosis Initiative is under preparation.

The Indonesian TB Association (PFTI) is actively involved in TB control in several provinces. This **NGO** is the only one officially recognized by the government. The Netherlands Tuberculosis Association (KNCV), the Rio Tinto Foundation, Caritas, the Freeport Co. and the Dutch Leprosy Association also collaborate in TB control.

**Risks and Constraints**

The management of the programme needs improvement, and the coordination between the different health directorates involved in TB control isinsufficient. The Central Unit of the TB programme (TB sub directorate) in the MOH is weak, understaffed and ill equipped. Increasing staff is difficult because of a zero growth target for staff within the MOH.

Supervisory activities are limited because of the lack of manpower and budget at different levels. Reports are incomplete and delayed for more than a year in some cases. The smear microscopy results are not reliable and quality control of smear microscopy is irregular.

There is a danger of drug expiry or shortage in some districts because reporting of cases is not accurate and drugs are distributed without knowing existing stocks at district level. The present economic crisis may have a further negative impact on the funding of the TB programme, undermining the progress achieved.

**Activities to Address Constraints**

There has been very little action at Government level to solve the problems indicated above. Because the government TB budget is inadequate, the WHO country budget for TB has increased from US $366,500 to US $577,000.
TB in IRAN

TB cases, 1996

<table>
<thead>
<tr>
<th>Estimated # of TB cases</th>
<th>Officially reported # of TB cases</th>
<th>Estimated # SS+</th>
<th>Officially reported # SS+</th>
<th>% of SS+ cases detected by DOTS**</th>
<th>% of SS+ cases detected by Non-DOTS</th>
<th>% of SS+ cases detected</th>
</tr>
</thead>
<tbody>
<tr>
<td>58000</td>
<td>14189</td>
<td>26000</td>
<td>5373</td>
<td>0.0</td>
<td>20.6</td>
<td>20.6</td>
</tr>
</tbody>
</table>

* SS+ = Sputum smear positive
* DOTS detection rate

Treatment outcomes, 1995

<table>
<thead>
<tr>
<th>Registered cases (new SS+)</th>
<th>Cured</th>
<th>Completed treatment</th>
<th>Defaulted</th>
<th>Failed</th>
<th>Died</th>
<th>Transferred out</th>
<th>% not evaluated</th>
</tr>
</thead>
<tbody>
<tr>
<td>DOTS</td>
<td>-</td>
<td>-%</td>
<td>-%</td>
<td>-%</td>
<td>-%</td>
<td>-%</td>
<td>-%</td>
</tr>
</tbody>
</table>

Treatment success: -%

| Non-DOTS | - | -% | -% | -% | -% | -% | -% |

Note: In non-DOTS areas there was no reporting on treatment outcomes.

ANALYSIS

Iran adopted the DOTS strategy in 1993 and started demonstration projects in two districts, but has shown only limited progress and no data on case detection of smear positive cases or treatment outcomes for those projects are available for 1995-6. Despite the availability of a well-established primary health care (PHC) network throughout the country, and sufficient human and financial resources in the Ministry of Health and Medical Education (MOHME), current DOTS coverage is only five percent.

The central unit of the NTP in the MOHME has overall responsibility for TB control. The central unit is supported by the National TB Board, which is represented by TB specialists, the PHC network, academic societies and other concerned authorities. At provincial and district levels, multi-purpose medical officers are designated as TB coordinators. At the peripheral level, health centers with trained village health workers are distributed throughout the country.

Status Report on the Elements of DOTS

Political commitment is present in Iran. High-level decision-makers, including the Minister of Health and Medical Education, have agreed that there is the need to rehabilitate the NTP, and have provided necessary financial support to the programme. However, there is a lack of leadership and management capacity at national level and there are no supporting medical officers at the central unit.

Case detection and diagnosis are primarily based on sputum smear microscopy. Binocular microscopes are available at all district health centers. There is no designated national reference laboratory for TB control. As a result, nation-wide systematic quality control for smear microscopy has not taken place. Two laboratories in Tehran City do culture and drug-sensitivity tests.

Treatment is with WHO-recommended regimens (six months for new smear-positive cases), but with daily self-administration throughout the treatment period. In the DOTS projects, patients' daily intake of anti-TB drugs is supervised by health workers in the health centers or by family members of patients. In other places, anti-TB drugs are generally given to patients on a monthly basis.

The drug supply and supply of laboratory materials are well managed by the MOHME, and are regular and sufficient.
The recording and reporting system in the DOTS project areas is in line with WHO recommendations, but data for 1995-96 has not been reported to GTB. In the rest of the country, the WHO-recommended system is not fully implemented, particularly the report on treatment outcomes (cohort analysis). Supervision from the central level to provincial and peripheral levels is weak because of insufficient human resources at the national level. The NTP manager could not regularly visit the provincial DOTS projects.

Research and Other Issues

Research on anti-TB drug resistance will take place in collaboration with the WHO project on global anti-TB drug resistance surveillance. Coordination among all the concerned authorities in Iran is needed for the successful launch of the survey.

Coordination between the private sector, NGOs and other health care providers is important. In Iran, medical schools are fully involved in the government health services, and the private sector, which is rapidly growing, is partially under the control of the government. However, more coordination between these sectors is needed to fully involve them in TB control.

Risks and Constraints

The main concern is the weak managerial and technical capacity at the central unit of the NTP. This has resulted in the failure to expand DOTS projects in the country. Lack of provincial and district TB coordinators with explicit knowledge and skills on the DOTS strategy is also a problem. The programme has failed to effectively utilize the well-established primary health care network. Anti-TB drugs are available at private pharmacies.

Activities to Address Constraints

WHO Eastern Mediterranean Regional Office (EMRO) and the MOHME are planning to conduct an in-depth NTP review in mid-1998. The review will evaluate NTP policies and procedures, particularly the activities of the on-going DOTS projects, and propose organizational, administrative and technical recommendations for the improvement of the programme. A practical plan of action for the expansion of the DOTS projects will be prepared to help Iran meet global targets.
TB in MEXICO

TB cases, 1996

<table>
<thead>
<tr>
<th>Estimated # of TB cases</th>
<th>Officially reported # of TB cases</th>
<th>Estimated # SS+</th>
<th>Officially reported # SS+</th>
<th>% of SS+ cases detected by DOTS**</th>
<th>% of SS+ cases detected by Non-DOTS</th>
<th>% of SS+ cases detected</th>
</tr>
</thead>
<tbody>
<tr>
<td>56000</td>
<td>10852</td>
<td>25000</td>
<td>8495</td>
<td>0.0</td>
<td>33.9</td>
<td>33.9</td>
</tr>
</tbody>
</table>

* SS+ = Sputum smear positive

** DOTS detection rate

Treatment outcomes, 1995

<table>
<thead>
<tr>
<th>Registered cases (new SS+)</th>
<th>Cured</th>
<th>Completed treatment</th>
<th>Defaulted</th>
<th>Failed</th>
<th>Died</th>
<th>Transferred out</th>
<th>% not evaluated</th>
</tr>
</thead>
<tbody>
<tr>
<td>DOTS</td>
<td>0</td>
<td>%</td>
<td>%</td>
<td>%</td>
<td>%</td>
<td>%</td>
<td>%</td>
</tr>
</tbody>
</table>

Treatment success: %

| Non-DOTS | 9220 | 68.7% | 6.0% | 12.3% | 3.1% | 4.4% | 4.2% | 1.3% |

Note: In non-DOTS areas, the reported treatment outcomes are not based on a WHO standard cohort analysis.

ANALYSIS

In the 1970s and 1980s, Mexico experienced a steady decline in the TB epidemic. By the early 1990s, however, this declining trend slowed because of factors such as HIV-infection and a rapid migratory movement from rural to urban areas.

In collaboration with the Pan American Health Organization (PAHO), the Ministry of Health conducted a comprehensive programme review in June 1995. The review showed that only a small proportion of patients received their medication under direct observation. In addition, a low level of case detection and poor inter-institutional coordination created barriers to TB patient care in the public system. In late 1995, the Ministry of Health, the Social Security Institute and other health agencies represented in the Tuberculosis Coordinating Inter-institutional Group devised a plan to implement DOTS beginning in 1996. Tuberculosis control was included in the basic package of services promoted in the 1995 health sector reform plan, whose main objective was to extend services to previously uncovered populations.

Ten demonstration areas tested DOTS during 1996, and were evaluated in 1997 with good results (data for these projects was not included in the 1996 reports). In 1997 the health institutions decided to begin expansion to the whole country and by the end of the year all states had established DOTS projects in at least one of their jurisdictions. Inter-institutional coordination became the central axis of the programme within each DOTS demonstration areas. All the agencies adopted the national guidelines on diagnosis and treatment, and the same procedures for registry of cases.

Status Report on the Elements of DOTS

There is strong political commitment and financial support from the government.

There is an extensive laboratory network to perform bacteriological diagnosis. In all institutions, the principal case detection method is sputum microscopy among patients with respiratory symptoms attending primary health care services. In all cases, three sputum samples are requested at 24-hour intervals. The transport of smear specimens in urban areas and of the smear-fixed slides from peripheral health units to the laboratory is well organized. A microscopy quality control system has been established in almost all demonstration areas.

Directly observed treatment is standardized across all health units of all agencies and meets with WHO recommendations. Only fixed drug combinations (with the exception of
ethambutol) are used. The bacteriological sputum examinations for treatment control are made once a month.

Regular and uninterrupted supplies of drugs are available for free treatment of all notified cases. For the first time in 1997, the data from all agencies on tuberculosis cases and treatment outcomes by cohorts of patients were consolidated for all DOTS areas.

Research and Other Issues

A drug resistance survey in three states is underway by the Ministry of Health, with the support of the Centre for Disease Control, Atlanta, under the Global Project Initiative. Stanford University is supporting studies on transmission of tuberculosis (with RFLP).

In 1997, the Ministry of Health introduced structural changes to adapt to the decentralization and programme integration policies of health reform. Under the new system, each state is responsible for planning and implementation of TB control and must budget for the purchase of TB drugs. It is still too early to analyze the impact of the decentralization process on TB control and advantages are generally believed to outstrip disadvantages.

Risks and Constraints

There is a risk that decentralized purchase of drugs may be more expensive and carry a higher risk of low quality acquisitions than purchasing drugs at federal level for the whole country.

A common problem is availability of staff sufficiently trained to carry out microscopy examinations, particularly in Ministry of Health laboratories. DOTS implementation resulted in a significant increase in the number of sputum samples for diagnosis and treatment control. Laboratories are working at their maximum capacity. Case detection cannot be intensified if laboratory human resources are not increased.

Although case diagnosis is fully consistent with the national guidelines at primary health care units, the hospitals from Social Security agencies notify a high proportion of bacteriologically negative pulmonary cases and extra-pulmonary cases, especially of renal tuberculosis.

A major challenge is the implementation of the DOTS strategy in very large cities, particularly Mexico City, due to the complexity of health service delivery.

The prevalence of chronic multidrug-resistant patients is a serious problem, a consequence of problems with ineffective treatment of TB in earlier years. There are no national guidelines on clinical and therapeutic management of chronic patients. Second line drugs such as cycloserine and prothionamide are not usually available in the country.

Activities to Address Constraints

The Ministry of Health Tuberculosis Component is organizing workshops for state health officers to produce planning and evaluation guidelines—including purchase of drugs—for the decentralized management of the tuberculosis programme at state level.

The Tuberculosis Component and the Social Security agencies are preparing guidelines on the rationalization of laboratory workload for the diagnosis of TB. Recommendations to states on strengthening the laboratory staff for tuberculosis microscopy are being prepared. The Social Security agencies are preparing guidelines on diagnosis of pulmonary and extrapulmonary tuberculosis for their second and third level institutions. A plan for the dissemination of the guidelines through clinical seminars and clinical quality insurance activities will be prepared.

Preparatory work at federal level for the elaboration of guidelines on case management of chronic tuberculosis patients and procurement of second line drugs is underway.
TB in MYANMAR

TB cases, 1996

<table>
<thead>
<tr>
<th>Estimated # of TB cases</th>
<th>Officially reported # of TB cases</th>
<th>Officially reported # SS*</th>
<th>Estimated # SS*</th>
<th>% of SS+ cases detected by DOTS**</th>
<th>% of SS+ cases detected by Non-DOTS</th>
<th>% of SS+ cases detected</th>
</tr>
</thead>
<tbody>
<tr>
<td>87000</td>
<td>22201</td>
<td>39000</td>
<td>9716</td>
<td>22.5</td>
<td>2.4</td>
<td>24.9</td>
</tr>
</tbody>
</table>

* SS+ = Sputum smear positive  
** DOTS detection rate

Treatment outcomes, 1995

<table>
<thead>
<tr>
<th>Registered cases (new SS+)</th>
<th>Cured</th>
<th>Completed treatment</th>
<th>Defaulted</th>
<th>Failed</th>
<th>Died</th>
<th>Transferred out</th>
<th>% not evaluated</th>
</tr>
</thead>
<tbody>
<tr>
<td>DOTS</td>
<td>6994</td>
<td>54.1%</td>
<td>12.0%</td>
<td>18.4%</td>
<td>3.8%</td>
<td>4.1%</td>
<td>7.7%</td>
</tr>
<tr>
<td>Non-DOTS</td>
<td>877</td>
<td>45.0%</td>
<td>32.5%</td>
<td>15.1%</td>
<td>1.0%</td>
<td>4.4%</td>
<td>1.9%</td>
</tr>
</tbody>
</table>

Treatment success: 66.0%

Note: In non-DOTS areas, the reported treatment outcomes are not based on a WHO standard cohort analysis.

ANALYSIS

Short-course chemotherapy (SCC) was implemented in Myanmar in 1994 and rapidly expanded to cover almost half the population. The government adopted the DOTS strategy in principle in 1995 and revised its manual of procedures based on WHO recommendations. With WHO assistance, a five-year plan for phased expansion of the DOTS strategy was developed in 1996, but is yet to be formally approved by the government. DOTS demonstration projects were initiated in 1996 and expansion followed during 1997 after extensive training.

Myanmar has a good health infrastructure and a large pool of well-educated and motivated health workers. Administratively there are 16 states and divisions, 55 districts and 324 townships with an average population of 130,000 to 140,000. DOTS is implemented at township level. The township hospital serves as the unit of management. Directly observed treatment is also carried out from several rural health centers and by trained community volunteers. Responsibility for monitoring and supervision of TB control activities is assigned to TB coordinators at township and district levels. DOTS will be implemented in only 153 townships in phases, while standard chemotherapy is being provided to 80 townships. There is no national policy in the remaining 91 townships.

Status Report on the Elements of DOTS

Political commitment is lacking and the five-year NTP plan is yet to be approved by the government. Funds for implementing this plan also need to be secured.

Case detection is generally done at township hospitals through sputum-smear microscopy (three direct smears for each suspect). Most of the microscopes are monocular and old, thus affecting the quality of smear examinations.

Treatment regimens are standardized in accordance with WHO guidelines in the DOTS townships. In many of the townships, NGOs and community volunteers have been mobilized to administer directly observed treatment to patients during the intensive phase. Proper coordination of all personnel involved (particularly the volunteers) with the township hospital is necessary to ensure standardization of procedures and successful results.
There is an acute shortage of **drugs**. Changes in policy such as short-course chemotherapy for all smear-positive and only ten percent of seriously ill smear-negative patients, are temporary solutions during the crisis period. The government has not procured a buffer stock of drugs, nor ensured regular and sufficient quantities of drugs for the future.

The **recording and reporting** system is well implemented. The data from the quarterly reports could be strengthened to better analyze the SCC versus non-SCC areas.

**Risks and Constraints**

The government has not demonstrated commitment to the five-year NTP plan for implementing DOTS. Funds have not been secured for TB control and the organizational structure at intermediate level has not been strengthened. If activities are not properly coordinated in the townships and supervised by the intermediate level, the quality of work will deteriorate.

The most pressing concern is the lack of a regular and adequate drug supply. Failure by the government to solve this problem will result in the collapse of the NTP and serious consequences, such as emergence of multidrug resistance in the country.

**Activities to Address Constraints**

Action by the government to solve the drug crisis is not evident. WHO has increased the biennial budget for TB control during 1998-99. Using most of these funds, WHO’s South-East Asia Regional Office (SEARO) will procure SCC drugs sufficient for smear-positive patients and seriously ill smear-negative patients in the SCC townships.

The International Union Against Tuberculosis and Lung Disease (IUATLD) has attempted to obtain donor support to the NTP plan through NGOs. However, channeling of funds through NGOs operating in the townships was not supported by the government. There are currently no plans to monitor TB/HIV sero-prevalence or the emergence of multidrug-resistant TB.
TB in NIGERIA

TB cases, 1996

<table>
<thead>
<tr>
<th>Estimated # of TB cases</th>
<th>Officially reported # of TB cases</th>
<th>Estimated # SS+</th>
<th>Officially reported # SS+</th>
<th>% of SS+ cases detected by DOTS**</th>
<th>% of SS+ cases detected by Non-DOTS</th>
<th>% of SS+ cases detected</th>
</tr>
</thead>
<tbody>
<tr>
<td>255000</td>
<td>24063</td>
<td>115000</td>
<td>15704</td>
<td>13.7</td>
<td>0.0</td>
<td>13.7</td>
</tr>
</tbody>
</table>

* SS+ = Sputum smear positive  
** DOTS detection rate

Treatment outcomes, 1995

<table>
<thead>
<tr>
<th>Registered cases (now SS+)</th>
<th>Cured</th>
<th>Completed treatment</th>
<th>Defaulted</th>
<th>Failed</th>
<th>Died</th>
<th>Transferred out</th>
<th>% not evaluated</th>
</tr>
</thead>
<tbody>
<tr>
<td>DOTS</td>
<td>9476</td>
<td>34.0%</td>
<td>15.1%</td>
<td>9.0%</td>
<td>2.0%</td>
<td>4.7%</td>
<td>1.0%</td>
</tr>
<tr>
<td>Treatment success</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>49.1%</td>
<td></td>
</tr>
</tbody>
</table>

Non-DOTS

Note: In non-DOTS areas there was no reporting of treatment outcomes.

ANALYSIS

Tuberculosis remains a major public health problem in Nigeria. The National Tuberculosis & Leprosy Control Programme (NTLCP) was established by the Federal Ministry of Health in 1989, formally launched in 1991 and implemented in 17 out of 36 States, and the Federal Capital Territory. At that time, the Federal Ministry of Health (MOH) was the sole provider of TB drugs for the whole country—though drug supplies were inadequate and control efforts therefore hampered.

In 1993, the Federal MOH formally adopted the WHO DOTS strategy for TB control. Key activities in the 17 states that received external donor support began in 1994. Thirteen states are supported with anti-TB drugs, laboratory reagents and other logistics by the German Leprosy Relief Association (GLRA), two states by the Damien Foundation, Belgium (DFB) and two by the Netherlands Leprosy Relief Society (NSL).

DOTS implementation is in pilot phase in the majority of states and stagnant in some. The overall impact of the DOTS strategy is limited, implemented in less than half the states in the country and within these covering less than 50 percent of the population. The NTLCP has shown some improvement in case detection and treatment outcome in some of the states with donor support.

The NTLCP was originally established as a vertical programme. Attempts to integrate it into general health services have recently been made. The organizational structure of the NTLCP follows the three-tier governmental administrative system of the country: federal, state and local level. At federal level, a national co-ordinator of the programme, assisted by three medical officers, three environmental health officers, one logistics officer and some support staff, is responsible for the TB control programme. A WHO consultant (for leprosy) is also attached to the programme. At state level, the programme is under the Director of the Department of Disease Control; the day-to-day programme implementation and supervision are carried out by State TB/Lep. Control Officers, supported by the State TB/Lep. Supervisors. At local level, the local government TB/Lep.Supervisor is the backbone of field control activities and is responsible for the day-to-day implementation. In addition to GLRA, DFB and NSL, the Leprosy Mission International (TLMl) and Sasakawa Memorial Health Foundation support specific areas of the country.
Status Report on the Elements of DOTS

Government commitment is weak, hence the reliance on external donors for funding of control activities.

It is the government's mandate to provide microscopy facilities for case detection and anti-TB drug supplies to the entire nation, but these are limited.

WHO-recommended treatment regimens are being used in the NTLCP.

The recommended DOTS recording and reporting system is not fully established, even in the DOTS-states, thus leading to under-reporting in many of them.

Research and Other Issues

Research studies in HIV infection among TB patients in urban settings have shown a range of 4 – 6 percent.

Steps have been taken to involve the community in TB patient care in some states, but this is yet to be institutionalized.

A strong private health sector provides service to a significant proportion of the population, especially in urban centers. Some offer TB treatment services but these have not been integrated into the NTLCP and quality of service is uncertain. Several local and external NGOs operate in the health sector in Nigeria.

External non-governmental organizations (NGOs) that previously supported leprosy control activities have now directed their support to TB control, although their coverage is limited to 17 States.

Risks and Constraints

The main constraints that the NTLCP has faced over the years have been weak government commitment and limited resources available through official channels. As one of the largest countries in Africa and the most populous in the region, Nigeria faces a major public health problem in TB control.

Activities to Address Constraints

Having adopted the DOTS strategy to control TB, the Federal MOH has begun harnessing resources to deal with the problem nationwide. It submitted a request to WHO/AFRO to assist the MOH in reviewing the programme and developing a five-year strategic plan to strengthen the resource mobilization efforts—scheduled to take place in July 1998.

A local NGO—National TB/Leprosy Association (NTBLA)—has been revived and developed a long-term programme of advocacy and resource mobilization to support the NTLCP.
TB in PAKISTAN

TB cases, 1996

<table>
<thead>
<tr>
<th>Estimated # of TB cases</th>
<th>Officially reported # of TB cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>210000</td>
<td>4307</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Estimated # of SS+</th>
<th>Officially reported # SS+</th>
</tr>
</thead>
<tbody>
<tr>
<td>94000</td>
<td>1849</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>% of SS+ cases detected by DOTS**</th>
<th>% of SS+ cases detected by Non-DOTS</th>
<th>% of SS+ cases detected</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.0</td>
<td>0.0</td>
<td>2.0</td>
</tr>
</tbody>
</table>

* SS+ = Sputum smear positive
** DOTS detection rate

Infectious cases (SS+)*, 1996

<table>
<thead>
<tr>
<th>Treatment outcomes, 1995</th>
</tr>
</thead>
<tbody>
<tr>
<td>Registered cases (new SS+)</td>
</tr>
<tr>
<td>---------------------------</td>
</tr>
<tr>
<td>DOTS</td>
</tr>
<tr>
<td>Non-DOTS</td>
</tr>
</tbody>
</table>

Note: In non-DOTS areas, the reported treatment outcomes are not based on a WHO standard cohort analysis.

ANALYSIS

Although Pakistan adopted the DOTS strategy in late 1995 and began implementing pilot projects in 1996, there has been no significant improvement in TB control. The pilot projects have made very limited progress in terms of expansion and cover less than three percent of the total population of Pakistan. The only exception is the DOTS project in the North West Frontier Province (NWFP) where considerable progress was observed in the demonstration districts.

The Federal Directorate for TB control was established in 1965 with the responsibility to define policies and implement/monitor the National Tuberculosis Programme (NTP). A director has not been officially nominated during the last four years to head the NTP. Recently this directorate has been placed under the National Institutes for Health. Following adoption of the DOTS strategy, NTP guidelines were developed and key TB specialists were trained. A few DOTS demonstration projects were initiated in 1996 in NWFP and Karachi City. The other provinces have yet to implement the DOTS strategy.

Overall responsibility for TB control rests with the federal government. The federal (national) TB manager and the Federal TB Board formulate the national strategy on TB control and coordinate its implementation in the provinces. As with all health services in Pakistan, the responsibility for TB control activities rests with the provincial governments, which have their own budgets. At this level, provincial TB coordinators, supported by the provincial TB boards, implement TB control activities. There are five provinces in the country and 102 districts. The district is the basic unit of management for TB control.

Status Report on the Elements of DOTS

The five-year plan of action, prepared in 1995, awaits approval by the government. Lack of political commitment for TB in Pakistan has resulted in delays in DOTS expansion (even in pilot areas), insufficient funding to support the five-year NTP plan, weak technical leadership at the federal and provincial levels, and little overall understanding of the TB situation and TB control in the country.

Case detection and diagnosis have shown improvement in the demonstration districts. However, there are few cases registered in DOTS projects. Apart from the DOTS projects,
diagnosis of TB is still based on x-rays and there are neither national nor provincial reference laboratories on tuberculosis control that conduct quality control of sputum-smear examination.

Treatment in DOTS projects follows WHO-recommended regimens with daily administration throughout the treatment period. Health workers have implemented DOTS on an ambulatory basis during the initial phase of treatment. However, in the rest of the country, treatment regimens are not standardized and anti-TB drugs are used without any supervision.

The drug supply has been sufficient in the DOTS projects of NWFP because of support from the Italian Cooperation for Development. TB programmes in the rest of the country face shortages of anti-TB drugs quite frequently. Anti-TB drugs are also available without prescription and without adequate quality control at private pharmacies.

The recording and reporting system is in line with WHO recommendations and is functioning in DOTS projects. There is no standardized recording and reporting system implemented in other parts of the country.

Research and Other Issues

Research on the immunological response to tuberculosis was carried out by the Aga Khan University. Different options for supervision of treatment are under assessment in the NWFP, supported by the Department for International Development (DfID) and assisted by the Nuffield Institute.

The private sector and NGOs have a large role in providing general health services in Pakistan and have substantial activities in TB control. Yet, there is no coordination among the different partners. The private sector and NGOs do not use the NTP guidelines for TB control. Consequently, there is no standardization of TB case finding or treatment activities in these sectors.

Risks and Constraints

The main concerns are lack of political commitment and weak technical leadership in the NTP, which have delayed the implementation/expansion of DOTS projects considerably. The delay has also affected the momentum and interest in TB control generated at various levels of health services. Failure to quickly address this problem will result in widespread emergence of MDR-TB in the country.

Any support of WHO and external donors will not be effective unless the Pakistan Government translates its commitment into practical action for TB control.

Activities to Address Constraints

Action by the federal government to address TB control is extremely limited.

WHO (GTB/EMRO) has been negotiating with potential donors such as the Islamic Development Bank and the World Bank to raise financial support for the projects.

WHO (EMRO/GTB) is also strengthening TB control capacity at the provincial level and is recruiting national programme officers on TB control who will assist the provincial TB coordinators in implementing and expanding DOTS projects.
TB in PERU

TB cases, 1996

<table>
<thead>
<tr>
<th>Estimated # of TB cases</th>
<th>Officially reported # of TB cases</th>
<th>Estimated # SS+</th>
<th>Officially reported # SS+</th>
<th>% of SS+ cases detected by DOTS*</th>
<th>% of SS+ cases detected by Non-DOTS</th>
<th>% of SS+ cases detected</th>
</tr>
</thead>
<tbody>
<tr>
<td>60000</td>
<td>41739</td>
<td>27000</td>
<td>26800</td>
<td>99.5</td>
<td>0.0</td>
<td>99.5</td>
</tr>
</tbody>
</table>

* SS+ = Sputum smear positive  
* DOTS detection rate

Treatment outcomes, 1995

<table>
<thead>
<tr>
<th>Registered cases (new SS+)</th>
<th>Cured</th>
<th>Completed treatment</th>
<th>Defaulted</th>
<th>Failed</th>
<th>Died</th>
<th>Transferred out</th>
<th>% not evaluated</th>
</tr>
</thead>
<tbody>
<tr>
<td>DOTS</td>
<td>28185</td>
<td>74.6%</td>
<td>8.8%</td>
<td>5.6%</td>
<td>1.9%</td>
<td>2.9%</td>
<td>1.2%</td>
</tr>
<tr>
<td>Treatment success</td>
<td>33.4%</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

ANALYSIS

The DOTS strategy was adopted in Peru in 1990 with the designation of a programme manager (Director of Communicable Diseases) and the authorization of national funds. Technical guidelines were developed with advice from the Pan American Health Organization (PAHO) and the strategy was implemented with national coverage from 1991 onward.

The rapid expansion was possible because the country had already in place for decades a TB programme and trained general staff, to which political commitment, sufficient resources for drugs and a dynamic leadership were added.

Today programme activities are integrated in general health services. Multi-purpose managerial and supervisory staff dedicate specific time to the TB programme at district, provincial, regional and national levels. Persons attending public health facilities pay for consultations and diagnostic procedures, but TB diagnosis and treatment are fully exempted from payment. Drugs, equipment and main supplies are purchased centrally and provided by the national level. Food packages are provided to patients as an incentive to comply with treatment, and the programme has promoted and financed the Organization of patient and family groups for self-support.

Status Report on the Elements of DOTS

Political commitment is evidenced by the stability of the TB management team and an annual budget of over US $5 million, now fully provided by the Ministry of Health. The Presidency of the Republic has given the programme personal attention, and has maintained continuous public reporting on progress achieved as well as information on the TB problem and recommended actions.

Case detection is through sputum microscopy in persons with respiratory symptoms attending health facilities at all levels and for any cause. Annual targets for case detection are by region. Over 83 percent of pulmonary TB cases are confirmed by smear microscopy. A well functioning laboratory network with 987 microscopy units includes quality control of smears, and culture facilities are available at regional level (57 laboratories, 1996).

Treatment is with WHO-recommended regimens including rifampicin throughout (six months for new cases), with daily administration in the initial phase and twice weekly in the continuation phase. All doses are directly observed.
Drug supply is regular and sufficient for all cases, through central consolidated purchase by the Division of Communicable Diseases.

Recording and reporting is according to WHO recommendations, with data analysis at district level, monitoring and supervision from regional level, twice a year programme evaluation meetings consisting of about 250 staff (medical, nursing and laboratory) from all regions and organizations treating TB, and an annual comprehensive national report.

Research and Other Issues

Operational research is conducted by programme staff at district and regional levels and reported during the evaluation meetings. Research projects at the national level include studies of drug resistance prevalence (1995-1996) with support from the WHO Global TB Programme (GTB), prevalence of tuberculosis infection in school children (1997-1998), drug toxicity (annual, continuous), TB meningitis in children under five (continuous), and causes of TB deaths. Studies on the results of treatment of drug-resistant cases by the national programme and by a group with Harvard University support are in progress.

Other institutions, such as the Institute of Social Security, armed forces, police, and prisons, carry out the TB programme in co-ordination with the Ministry of Health. The private sector has a relatively minor role, and refers most diagnosed cases to the public sector for treatment. The lower levels of the health structure and the community are actively involved, particularly in patient support for treatment completion and in maintaining programme visibility.

Occasional financial support from external sources (Japanese government, World Bank development loan) and WHO/PAHO technical cooperation have contributed to the success of the programme, which is used as a model for training of managerial staff from other Latin American countries and of WHO consultants.

Risks and Constraints

To date health sector reform has not damaged the TB programme because central support and drug procurement, and free diagnosis/treatment services have been protected.

The development and maintenance at all levels of a cadre of trained personnel, many of whom migrate to other positions, ensures the capacity of the system to maintain the programme. The main concern is that to achieve substantial epidemiological impact, the programme should continue with its present form and resources for several decades, and it is not easy to maintain political commitment and staff interest for such a long period.

Activities to Address Constraints

The Government monitors programme development and results; supports less successful regions and areas to improve the achievement of targets; promotes operational and epidemiological research, and will hold annual courses to train staff from other countries in the Region. PAHO/WHO provides regular technical advice and supports local activities, research projects and regional training courses.
TB in PHILIPPINES

TB cases, 1996

<table>
<thead>
<tr>
<th>Estimated # of TB cases</th>
<th>Officially reported # of TB cases</th>
<th>Estimated # SS+</th>
<th>Officially reported # SS+</th>
<th>% of SS+ cases detected by DOTS**</th>
<th>% of SS+ cases detected by Non-DOTS</th>
<th>% of SS+ cases detected</th>
</tr>
</thead>
<tbody>
<tr>
<td>194000</td>
<td>276295</td>
<td>87000</td>
<td>86595</td>
<td>0.5</td>
<td>98.8</td>
<td>99.3</td>
</tr>
</tbody>
</table>

* SS+ = Sputum smear positive  ** DOTS detection rate

Treatment outcomes, 1995

<table>
<thead>
<tr>
<th>Registered cases (new SS+)</th>
<th>Cured</th>
<th>Complete treatment</th>
<th>Defaulted</th>
<th>Failed</th>
<th>Died</th>
<th>Transferred out</th>
<th>% not evaluated</th>
</tr>
</thead>
<tbody>
<tr>
<td>DOTS</td>
<td>-</td>
<td>-%</td>
<td>-%</td>
<td>-%</td>
<td>-%</td>
<td>-%</td>
<td>-%</td>
</tr>
<tr>
<td>Non-DOTS</td>
<td>90297</td>
<td>54.1%</td>
<td>5.9%</td>
<td>4.7%</td>
<td>0.7%</td>
<td>1.0%</td>
<td>1.9%</td>
</tr>
</tbody>
</table>

Treatment success: -%

Note: In non-DOTS areas, the reported treatment outcomes are not based on a WHO standard cohort analysis.

ANALYSIS

The national tuberculosis programme (NTP) was implemented nationwide in 1978. Short-course chemotherapy (SBC) was provided beginning in 1987. However, the tuberculosis situation has not improved in the last two decades because of inadequate management skills; poor quality of diagnosis and emphasis on active case-finding; weak case-holding; shortage of anti-TB drugs due to poor management of drug supply and over-diagnosis; and lack of collaboration between the NTP and private sector. The DOTS strategy was adopted in the Philippines in March 1996. The government and WHO agreed to collaborate in the revision and restructuring of NTP using the DOTS strategy, with the aim of covering 80 percent of the total population by the end of year 2000. Following the development of new guidelines and training documents, a DOTS pilot demonstration and training area started in October 1996 covering a population of 1.5 million (2 percent of the total) in two provinces and one city. In the areas where the DOTS strategy is being implemented, excellent treatment results have been achieved with success rates of between 80 and 86 percent. Eight percent of the total population has some access to the DOTS strategy.

Status Report on the Elements of DOTS

Political commitment is documented by the availability of funds for the NTP from the Department of Health (approximately US $ 5 million annually) and the number of staff at the central level. However, the Government needs to take a crucial decision to allocate additional funds for anti-TB drugs as case-detection in pilot areas has shown improvement. Over-diagnosis and poor radiological reading are a national-wide problem. Standardized quality control of sputum smear examination is being established in DOTS areas. Treatment is according to the WHO-recommended regimens (six months for new smear-positive cases) with daily supervision for the initial two months, followed by weekly supervision in the continuation phase. Drugs are used in blister packs. In most of the cases, it is the Barangay volunteer health workers who directly observe the medication. A preliminary result in pilot areas has shown around 80 percent treatment success rate. Drug supply in pilot provinces is conducted regularly from central to provincial level. The Government has an allocation of approximately US$ 4 million for anti-TB drugs every year, which is sufficient for all smear-positive cases and for about 60 percent of the smear
negative cases. However, complicated procedures for drug procurement and poor management skills cause delay in the supply of drugs. TB drugs are available over-the-counter without prescription. The recording and reporting system has improved in pilot areas through training and close supervision. All DOTS recording and reporting forms are prepared according to WHO recommendations. For non-DOTS areas, the quality of recording and reporting is still very poor. The managerial skills of the central TB Control Service have improved and the central team is now well motivated.

Research and Other Issues

Research activities at universities and non-governmental organizations (NGOs) include drug resistance (in planning stage), comparison of treatment results with different regimens, impact of devolved health system to NTP, and private or community-based DOTS. A study on cost-effectiveness of the DOTS strategy is under way with the Research Institute of Tropical Medicine and support from INCLEN (International Clinical Epidemiological Network). The private sector plays an important role in diagnosis of TB and approximately half of patients appear to be diagnosed by private practitioners using x-ray examination. However, the quality of radiology in most places in the country is poor and many false diagnoses are made by radiology examination. It is common for patients to start treatment with private practitioners, and interrupt it due to financial constraints. Although the Philippine Coalition of Anti-Tuberculosis (PHILCAT) has a good potential to support NTP, its participation is limited at the moment. Among international agencies, the Japan International Cooperation Agency (JICA) has supported the Government to develop a demonstration area in Region 7 since 1992, but data has not been systematically included in country reports to GTB up to 1996. The Department of Health-JICA TB programme now covers around 3 million population, and the project achieved 80 percent cure rate and established a well-qualified Regional laboratory. Directly observed treatment was applied in DOH-JICA areas in Region 7 from mid-1997. The TB component of Urban Health Nutrition Project (UHNIP) supported by the World Bank has not been active so far. However, UHNIP has planned to expand DOTS strategy in urban poor populations near Metro Manila recently. The Canadian International Development Agency (CIDA) recently supported the NTP through World Vision International.

Risks and Constraints

Over-diagnosis of smear negative cases is leading to drug shortages. Insufficient fund allocation by the Government for all TB cases and absence of buffer stocks worsens the situation. Long, complicated procurement procedures and a poor distribution system have caused problems. Thus the cure of properly diagnosed TB patients may be compromised. Laboratory microscopic service and radiological examination still need to be improved. Collaboration between private and public sector, and a control mechanism in over-the-counter purchase of TB drugs without prescription (causing drug resistance) is also necessary.

Activities to Address Constraints

In collaboration with PHILCAT, the Government has strengthened its advocacy activities to secure more funds for NTP. The Government has procured anti-TB drugs for use in 1998 through the WHO system to shorten the procurement procedure. TBCS has enhanced its technical support to regions and provinces to develop a Regional Demonstration Area in each region by early next year.

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LGU plans to create a diagnostic committee composed of a qualified chest physician, radiologist, and a programme manager to ensure high quality diagnosis. Private DOTS is being piloted in one university hospital. In early 1996, the WHO Regional Office for the Western Pacific provided US $1 million for training and supervision in DOTS areas as well as provision of microscopes. The second phase of DOH-JICA project (1997-2002) aims to establish a National Reference Laboratory and expand DOTS programme to new regions in collaboration with WHO.
TB in RUSSIA

TB cases, 1996

<table>
<thead>
<tr>
<th>Estimated # of TB cases</th>
<th>Officially reported # of TB cases</th>
<th>Estimated SS+</th>
<th>Officially reported # SS+</th>
<th>% of SS+ cases detected by DOTS**</th>
<th>% of SS+ cases detected by Non-DOTS</th>
<th>% of SS+ cases detected</th>
</tr>
</thead>
<tbody>
<tr>
<td>147000</td>
<td>111075</td>
<td>66000</td>
<td>42634</td>
<td>0.4</td>
<td>64.1</td>
<td>64.5</td>
</tr>
</tbody>
</table>

* SS+ = Sputum smear positive

Treatment outcomes, 1995

<table>
<thead>
<tr>
<th>Registered cases (new SS+)</th>
<th>Cured</th>
<th>Completed treatment</th>
<th>Defaulted</th>
<th>Failed</th>
<th>Died</th>
<th>Transferred out</th>
<th>% not evaluated</th>
</tr>
</thead>
<tbody>
<tr>
<td>DOTS</td>
<td>54</td>
<td>53.7%</td>
<td>11.1%</td>
<td>11.1%</td>
<td>5.6%</td>
<td>14.8%</td>
<td>3.7%</td>
</tr>
<tr>
<td>Treatment success:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>64.8%</td>
</tr>
<tr>
<td>Non-DOTS</td>
<td>0</td>
<td>-%</td>
<td>-%</td>
<td>-%</td>
<td>-%</td>
<td>-%</td>
<td>-%</td>
</tr>
</tbody>
</table>

Note: In non-DOTS areas there was no reporting on treatment outcomes.

ANALYSIS

Russia has a long history in tuberculosis control. Many high-level experts in the country are not convinced that DOTS is an appropriate and cost-effective strategy. The old Soviet TB control system was based on active case finding within large population groups, multiple BCG revaccination of children and adolescents, prolonged hospitalization (sometimes up to two years in TB sanatoria), and individualized chemotherapy regimens often combined with thoracic surgery. That system can no longer cope with the increasing caseload and an increase of multi-drug resistant TB cases produced as a result of inadequate treatment.

The TB situation is very serious due to shrinking health budgets, unpaid salaries, poorly maintained health facilities, shortages of drugs, confusion among staff resulting from unclear guidelines and lack of support from health authorities.

In 1995 a pilot project was implemented in the Ivanovo oblast. Although well organised, initial treatment results were unsatisfactory with death rates as high as 15 percent. These initial results have been attributed to late referral of severe cases, high drug resistance—particularly within the large proportion (25%) of ex-prisoners—and social problems leading to treatment interruption and failure. In late 1997 smear conversion rates started to increase in Ivanovo, possibly due to the fact that previously treated cases accumulated by the previous inefficient system are diminishing. This positive trend should be confirmed by 1998 results of smear conversion in new cases and by the study on drug resistance in preparation. The local government is convinced that DOTS is the only possible and cost-effective solution to increase cure rates, decrease transmission and gradually reduce the number of drug-resistant cases in the community.

Two other regions have implemented WHO-recommended treatment protocols with assistance from international non-governmental organizations (NGOs) and a third region has requested that WHO assist in DOTS implementation. With current under-funding of the health system and with no political decision to reform TB control, Russia is not able to expand DOTS without the external support of the donors.
Status Report on the Elements of DOTS

Political commitment is still insufficient. The Ministry of Health supports DOTS but no additional funding is available and there is still strong opposition against DOTS from some Russian TB experts who claim that donor policies would destroy the Russian TB Programme.

Treatment is standardized and directly observed only in DOTS areas.

Case detection and diagnosis in DOTS project areas is based on smear microscopy and active case detection has been abandoned.

A sustainable supply of anti-TB drugs for the country is lacking. Access to specialized TB dispensaries is becoming more and more difficult, resulting in increased default from treatment. Even where drugs are available there is no possibility of providing treatment on an ambulatory basis, as primary health staff are not trained in TB management and the legal system does not permit it.

The WHO recording and reporting system is in place in DOTS areas, but elsewhere there is no standardized system and treatment follow-up is also based on chest x-rays. Many patients, who according to WHO standards should have been discharged from treatment, are followed up over long periods and not allowed to return to work. Other patients are discouraged from seeking treatment, resulting in late diagnosis and high death rates.

Research and Other Issues

Research includes clinical, laboratory and epidemiological studies carried out by the TB Research Institute in Moscow; operational research in the Ivanovo project supported by the Central TB Institute; and DOTS cost-analysis in the Ivanovo oblast. Major efforts are under way to implement drug resistance surveillance, and WHO has supported a drug resistance study in the Ivanovo oblast.

Risk and Constraints

Up to now the main constraints have been lack of government commitment to introduce DOTS; lack of clearly defined national leadership in TB control to conduct changes; absence of a structured national tuberculosis programme; shortages in drugs and laboratory supplies; anti-TB drug resistance; and lack of trained staff in primary health care.

Particularly in the regions there is misunderstanding and confusion: there are no resources available to continue old practices and no other cost-effective solution proposed by health officials.

The Central TB Research Institute has been instrumental in implementing DOTS pilot projects and has recently been nominated as a WHO Collaborating Centre in tuberculosis. The Russian Research Institute of Physiology and Pulmonology (RRIPP) has been so far against changing Russian TB policies and the adoption of DOTS.

Increases in homelessness, growing drug resistance in the detention system, and other social and economic problems increase the risk of TB infection and breakdown to disease.

Activities to Address Constraints

Many donors are ready to assist Russia in controlling TB (e.g., SOROS Foundation, World Bank, NGOs). All of them have insisted that the Russian government should accept and implement DOTS rather than continue old expensive practices. A project for the SOROS Foundation to support TB control in Russia, including sufficient supply of TB drugs, is at present in advanced preparation.
TB in SOUTH AFRICA

TB cases, 1996

<table>
<thead>
<tr>
<th>Estimated # of TB cases</th>
<th>Officially reported # of TB cases</th>
<th>Estimated # SS+</th>
<th>Officially reported # SS+</th>
<th>% of SS+ cases detected by DOTS</th>
<th>% of SS+ cases detected by Non-DOTS</th>
<th>% of SS+ cases detected</th>
</tr>
</thead>
<tbody>
<tr>
<td>106000</td>
<td>91578</td>
<td>48000</td>
<td>37178</td>
<td>0.0</td>
<td>78.0</td>
<td>78.0</td>
</tr>
</tbody>
</table>

* SS+ = Sputum smear positive

* *DOTS detection rate

Treatment outcomes, 1995

<table>
<thead>
<tr>
<th>Registered cases (new SS+)</th>
<th>Cured</th>
<th>Completed treatment</th>
<th>Defaulted</th>
<th>Failed</th>
<th>Died</th>
<th>Transferred out</th>
<th>% not evaluated</th>
</tr>
</thead>
<tbody>
<tr>
<td>DOTS</td>
<td></td>
<td>-%</td>
<td>%</td>
<td>-%</td>
<td>-%</td>
<td>-%</td>
<td>-%</td>
</tr>
</tbody>
</table>

Treatment success: -%

| Non-DOTS | 28209 | 40.4% | 17.5% | 14.5% | 4.1% | 4.1% | 19.3% | 0.0% |

Note: In non-DOTS areas, the reported treatment outcomes are not based on a WHO standard cohort analysis. Data from DOTS areas was not included in the reports to WHO.

ANALYSIS

DOTS was implemented in the Mpumalanga province of South Africa (population 3 million) in 1994 with the technical assistance of WHO. Based on observed cure/completion rates of 80 percent in that area, a revised National Tuberculosis Control Programme was introduced in 1995. Guidelines and standardized treatment policies were developed. Prior to 1995, there was no standardized policy in the country and fragmented TB services were provided based on high-cost diagnostic tools, hospitalization and self-administered short-course chemotherapy.

A joint review of the TB programme, conducted by WHO and the government in June 1996, noted that South Africa had one of the highest rates of TB in the world. In cooperation with the Director General of Health Services, a five-year strategic plan was developed to implement DOTS in phases.

During 1997, TB was declared a "provincial emergency" in Western Cape province and a national priority in the country. However, with the exception of Mpumalanga, very limited progress has been made in implementing DOTS in demonstration areas, and there are no changes in TB services in the rest of the country.

Status Report on the Elements of DOTS

Despite the political commitment demonstrated by the national and some provincial governments, district and provincial co-ordinators have not yet been nominated in all provinces of the country. Consequently, the TB services are neither well coordinated nor evaluated for outcome. Sufficient financial resources are available in the country for TB control. The Government spends Rands 500 million (US $125 million) on tuberculosis each year. However, funds are misdirected by giving priority to interventions such as cultures on all patients, hospitalization of patients for prolonged periods in detriment of the organization of case detection and effective treatment of smear positive patients to prevent transmission of TB in the community, and focused on the treatment of MDR-TB cases.

The policy for case detection is through sputum-smear microscopy but the laboratory network to implement this policy in the 300 districts is yet to be implemented. X-rays and sputum cultures are still used for diagnosis of new patients, thus consuming a large amount of resources.
Treatment regimens are standardized in accordance with WHO guidelines. However, not all peripheral health facilities provide directly observed treatment during the intensive phase. Follow-up procedures are not strictly adhered to, resulting in many defaulters and emergence of multidrug resistance.

There are no problems with drug supply, which is reliable and in sufficient quantities. The distribution system varies between the provinces, but generally functions well. Procurement is from locally registered firms through national tender.

Although manuals and standardized recording/reporting forms, registers and stationery have been provided to all facilities in the country, the recording and reporting system is poorly implemented. TB registers are placed at health centers where data reporting starts, rather than at district level. As a result, data from DOTS demonstration projects are not easily aggregated into cohort reports on case finding and treatment outcome.

Research and Other Issues

The South African Research Council supports a programme of research on laboratories, clinical studies and new drugs. Recently, the Council received a mandate to address health services and patient needs. WHO supports two projects on provision of TB care through community-based organizations and appropriate supervision strategies.

Risks and Constraints

Government commitment has not translated into action. Career opportunities are not available in TB control, and the programme is unable to attract high-level personnel with experience and knowledge. TB co-ordinators have been designated in only half of the provinces and districts. DOTS has been introduced without adequate training of personnel and with limited supervision from central level.

Resources are consumed by unnecessary hospitalization, retrieval of defaulters and treatment of MDR-TB cases. Already 1-2 percent of the patients in the country is multidrug-resistant. Treatment of these patients costs between a quarter to a third of the annual expenditure on TB.

Activities to Address Constraints

There is no indication that the National TB programme will be elevated to a divisional level within the Department of Health. In the provinces, there is a concerted effort to designate/recruit TB co-ordinators and some commitment to do the same at least in the districts where DOTS demonstration projects are being implemented. Following two technical support missions from WHO during 1997 and strong recommendations to introduce cohort reporting at district level, the central unit is in the process of implementing changes to the present recording system.

Support and supervision of DOTS demonstration projects will be enhanced from the central unit (training, monitoring and analysis of reports) in order to replicate the Mpumulanga success and develop provincial model centers for training. A national policy for hospitalization of TB patients, treatment of multidrug-resistant cases and protection of health care workers is in development.
TB in SUDAN

TB cases, 1996

<table>
<thead>
<tr>
<th>Estimated # of TB cases</th>
<th>Officially reported # of TB cases</th>
<th>Estimated # SS+</th>
<th>Officially reported # SS+</th>
<th>% of SS+ cases detected by DOTS*</th>
<th>% of SS+ cases detected by Non-DOTS</th>
<th>% of SS+ cases detected</th>
</tr>
</thead>
<tbody>
<tr>
<td>57000</td>
<td>29200</td>
<td>26000</td>
<td>8978</td>
<td>2.0</td>
<td>32.6</td>
<td>34.6</td>
</tr>
</tbody>
</table>

* SS+ = Sputum smear positive  
* DOTS detection rate

Treatment outcomes, 1995

<table>
<thead>
<tr>
<th>Registered cases (new SS+)</th>
<th>Cured</th>
<th>Completed treatment</th>
<th>Defaulted</th>
<th>Failed</th>
<th>Died</th>
<th>Transferred out</th>
<th>% not evaluated</th>
</tr>
</thead>
<tbody>
<tr>
<td>DOTS</td>
<td></td>
<td>%</td>
<td>%</td>
<td>-%</td>
<td>-%</td>
<td>-%</td>
<td>-%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Treatment success</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>%</td>
</tr>
</tbody>
</table>

Non-DOTS

<table>
<thead>
<tr>
<th>%</th>
<th>%</th>
<th>%</th>
<th>%</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>8326</td>
<td>44.0%</td>
<td>34.6%</td>
<td>10.7%</td>
<td>7.1%</td>
</tr>
</tbody>
</table>

Note: In non-DOTS areas, the reported treatment outcomes are not based on a WHO standard cohort analysis.

ANALYSIS

Sudan adopted the DOTS strategy in 1995 and started the rehabilitation of the national tuberculosis programme (NTP) with support from the Norwegian Lung and Heart Association (LHL), the International Union Against Tuberculosis and Lung Disease (IUATLD), and WHO/EMRO. Prior to 1995, the Sudan NTP had few TB activities except for the publication of the NTP guidelines in 1993 (with WHO and IUATLD support). The rehabilitation of the NTP was planned in two phases: expand the programme with passive case-finding by sputum smear microscopy, a standardized 12-month treatment regimen, and a WHO recording and reporting system; and implement the full DOTS strategy in areas where programme performance is better.

Close to 50 percent of the total population is covered by the programme. However, the DOTS projects have shown limited expansion and only cover 5 percent of the total population. Moreover, the anti-TB drugs donated by the LHL are used in non-DOTS areas, and primarily without direct observation.

Overall responsibility for TB control rests with the NTP central unit in the Federal Ministry of Health (MOH). State TB coordinators in the State Ministries of Health (SMOH) have responsibility at that level. Provincial TB coordinators have responsibility for TB control in the field. With health sector reform, the SMOH have autonomous authority, including the recruitment of staff and procurement of anti-TB drugs.

Status Report on the Elements of DOTS

Political commitment is evidenced by the allocation of additional staff and funds to control TB during the past few years. The Federal MOH designated more than five health personnel including two medical officers to the NTP central unit.

Case detection has shown improvement in the programme. However, the national reference laboratory unit for TB control is technically weak and has not conducted effective quality control of sputum smear microscopy.
The treatment regimen policy for new cases is 12-month standardized chemotherapy while the WHO-recommended eight-month regimen is to be used only in DOTS project sites. One non-governmental organization (NGO) in Khartoum working with displaced populations has implemented DOTS and achieved 82 percent treatment success rate. However, drugs for the eight-month regimen are often used outside of the DOTS projects, and without direct observation.

The drug supply is fairly regular and sufficient for the areas covered by the programme. Drugs for the 12-month regimen are provided by most SMOH and drugs for short-course chemotherapy and laboratory supplies are provided by the LHL. However, in the rest of the country, the drug supply is usually insufficient. A problem is that anti-TB drugs are available at private pharmacies.

The WHO-recommended recording and reporting system has been introduced in the programme and is functioning and gradually improving. Case notifications and treatment outcomes are regularly reported from the state TB coordinators who compile the information from provinces in their states. Supervision from the central level to states and provinces is not regular or sufficient enough to provide necessary advice and correct mistakes in the field.

Research and Other Issues

The private sector has a considerable role in TB diagnosis and treatment in Sudan. However, coordination between the programme and the private sector is weak and the private sector does not follow the NTP strategy.

Many national and international NGOs dealing with health services for refugees and displaced populations in Sudan are involved in TB control, and the NTP coordination with these NGOs is good. One NGO (Sudan Council for Churches), which is dealing with displaced populations in Khartoum, has implemented the DOTS strategy since 1996.

Risks and Constraints

Concerns include the slow expansion of the DOTS projects, the use of anti-TB drugs for short-course chemotherapy in non-DOTS areas, and the lack of competent TB coordinators who have the knowledge and skills necessary to implement DOTS.

The economic difficulties in the government and the implications of health sector reform may impact the ability of the state Ministries of Health to procure 12-month supplies of anti-TB drugs. Also, the NTP has limited access to the southern region of Sudan, which is experiencing on-going social upheaval.

Activities to Address Constraints

The Ministry of Health, in close collaboration with WHO/EMRO, LHL and IUATLD, is planning to conduct an in-depth NTP review in mid-1998. The review is to evaluate NTP policies and procedures, particularly the activities of the on-going DOTS projects, and prepare an explicit plan of action to move toward meeting global targets.

LHL has committed resources to support the rehabilitation of the NTP. LHL support includes provision of anti-TB drugs for short-course chemotherapy and laboratory supplies and recruitment of TB consultants from IUATLD.
TB in TANZANIA

TB cases, 1996

<table>
<thead>
<tr>
<th>Estimated # of TB cases</th>
<th>Officially reported # of TB cases</th>
<th>Estimated # SS+</th>
<th>Officially reported # SS+</th>
<th>% of SS+ cases detected by DOTS</th>
<th>% of SS+ cases detected by Non-DOTS</th>
<th>% of SS+ cases detected</th>
</tr>
</thead>
<tbody>
<tr>
<td>58000</td>
<td>44416</td>
<td>26000</td>
<td>21472</td>
<td>82.8</td>
<td>0.0</td>
<td>82.8</td>
</tr>
</tbody>
</table>

* SS+ = Sputum smear positive

**DOTS detection rate

Treatment outcomes, 1995

<table>
<thead>
<tr>
<th>Registered cases (new SS+)</th>
<th>Cured</th>
<th>Completed treatment</th>
<th>Defaulted</th>
<th>Failed</th>
<th>Died</th>
<th>Transferred out</th>
<th>% not evaluated</th>
</tr>
</thead>
<tbody>
<tr>
<td>DOTS</td>
<td>19955</td>
<td>68.7%</td>
<td>4.8%</td>
<td>5.7%</td>
<td>0.6%</td>
<td>8.8%</td>
<td>3.9%</td>
</tr>
<tr>
<td>Treatment success</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>73.5%</td>
</tr>
</tbody>
</table>

ANALYSIS

The National Tuberculosis and Leprosy Programme (NTLP) was established in Tanzania in 1977. Short-course chemotherapy (SCC) for smear-positive patients followed in 1982, first in one region of the country, and then extended to 20 regions covering the entire country in the following two years. The diagnostic procedures, treatment services, supplies and recording and reporting of the NTLP were by then well established.

Programme activities are now integrated into the general health services. There are specialized co-ordination, supervisory and managerial tuberculosis/leprosy staff at national, regional and district levels. Persons attending public health facilities pay for consultation and diagnostic services. After they are diagnosed, TB patients are exempted from payment for treatment and microscopy services. The national TB/Leprosy Unit provides drugs, laboratory and other supplies.

However, in recent years the increasing case load due to HIV, and administrative and managerial problems have weakened programme delivery and the quality of information.

Status Report on the Elements of DOTS

Political commitment in the last two decades has been insufficient. The programme has been sustained by external co-operation on drugs, monitoring and technical support. A new government plan of action has recently been developed.

Case detection is through sputum-smear microscopy for patients with respiratory symptoms who attend health facilities. Smear microscopy is done in hospitals and a small number of health centers. Culture facilities are available in three reference laboratories. At the central reference laboratory, susceptibility testing is done on samples of smear-positive patients.

All patients receive short-course chemotherapy, according to the DOTS strategy: eight months of treatment, the first two supervised. In rural areas, patients are admitted to the hospital for the first two months to ensure observation of therapy. In Dar es Salaam, most patients receive ambulatory treatment throughout. Due to the increasing caseload there, modified intermittent regimens for new smear-positive, smear-negative and extra-pulmonary patients were introduced in 1991.

Regular supplies of good quality drugs have been guaranteed up to now. Until 1996, six-month supplies of the drugs were ordered through the International Union Against TB and Lung Disease (IUATLD). Since 1993, with additional funding from the Directorate-General of
International Co-operation of the Dutch Government, one year's reserve stock of drugs has been established.

The reporting and recording system was the model for the WHO-recommended system. From observations during field visits, analysis of the reports and comparison of case-notification and treatment outcome reports, it appears that quality of reporting has deteriorated in past years in some regions.

Research and Other Issues

Operational research and development of the modern TB control strategy; studies on risk of infection supported by IUATLD and the Royal Netherlands Tuberculosis Association (KNCV); surveillance of HIV prevalence among TB patients (supported by IUATLD and WHO); studies on cost of treatment for patients and their families and on the effectiveness of new regimens for HIV infected patients (supported by WHO). No data on MDR-TB is available to WHO's Global Tuberculosis Programme under the Global Project initiative. IUATLD has data on MDR-TB not yet validated by a supranational reference laboratory.

Although there has been a vast increase in private practitioners, they play a minor role in TB control.

Health sector reform is piloted in two regions but it is too early to draw any conclusions about its effects on the quality of TB control services.

Risks and Constraints

Preparation for managerial and administrative changes has drawn attention away from the quality of the control services, including supervision and monitoring, for over one year. Administrative and procedural problems led to lack of information on drug stocks at regional and district levels, drug shortages in some areas and large buffer stocks in others.

The increase in caseload due to HIV, particularly in urban areas, puts additional burdens on the capacity of health facilities to provide ambulatory supervised treatment with high cure rates.

Uncertainties about the possible consequences of health sector reform have affected the performance of regional and district co-ordinators. Annual operation plans contain too many activities that are not primarily related to improving/maintaining the quality of the DOTS strategy.

Activities to Address Constraints

In July 1997, the NTLP entered a new phase of implementation after a detailed Development Plan was written for the period July 1997-2000. The hope is for increased ownership and responsibility by the Tanzanian authorities, which will perform functions that were previously carried out by international and local non-governmental organizations (NGOs) as executing agencies.

This phase includes an NTLP management committee of donors and the Ministry of Health to oversee NTLP operations; joint funding between government and external donors managed by the Tanzanian Ministry of Health through a single account; procurement and distribution of supplies by the Medical Stores Department; contracting external consultants for programme monitoring, resource utilization, and drug procurement; and contracting local consultants for auditing and financial capacity building, for procurement and management of transport and for supervision.
TB in THAILAND

TB cases, 1996

<table>
<thead>
<tr>
<th>Estimated # of TB cases</th>
<th>Officially reported # of TB cases</th>
<th>Estimated # SS+</th>
<th>Officially reported # SS+</th>
<th>% of SS+ cases detected by DOTS**</th>
<th>% of SS+ cases detected by Non-DOTS</th>
<th>% of SS+ cases detected</th>
</tr>
</thead>
<tbody>
<tr>
<td>101000</td>
<td>39871</td>
<td>46000</td>
<td>16997</td>
<td>0.3</td>
<td>36.9</td>
<td>37.2</td>
</tr>
</tbody>
</table>

* SS+ = Sputum smear positive  
* DOTS detection rate

Treatment outcomes, 1995

<table>
<thead>
<tr>
<th>Registered cases (new SS+)</th>
<th>Cured</th>
<th>Completed treatment</th>
<th>Defaulted</th>
<th>Failed</th>
<th>Died</th>
<th>Transferred out</th>
<th>% not evaluated</th>
</tr>
</thead>
<tbody>
<tr>
<td>DOTS</td>
<td>-</td>
<td>%</td>
<td>-%</td>
<td>-%</td>
<td>-%</td>
<td>-%</td>
<td>-%</td>
</tr>
<tr>
<td>Treatment success:</td>
<td></td>
<td>%</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non-DOTS</td>
<td>20273</td>
<td>35.6%</td>
<td>28.0%</td>
<td>9.4%</td>
<td>0.3%</td>
<td>2.4%</td>
<td>17.1%</td>
</tr>
</tbody>
</table>

Note: In non-DOTS areas, the reported treatment outcomes are not based on a WHO standard cohort analysis.

ANALYSIS

A National Tuberculosis Control Programme (NTP) was founded in Thailand in 1967. The BCG vaccination campaigns were highly successful in reaching infants but little progress was made toward the integration of TB control services for the treatment of youth and adults into the primary health care system.

The Tuberculosis Division at the Ministry of Public Health, in collaboration with WHO, conducted a review of TB control activities in June 1995. A reorganization of tuberculosis control services, based on the DOTS strategy, was recommended. DOTS implementation started in 1996 with the establishment of eight demonstration districts. In 1997, a five-year development plan was adopted.

DOTS has expanded to all 12 regions of the country, with additional demonstration sites in the Bangkok Metropolitan Administration and a prison in Bangkok. A new national tuberculosis manual was prepared in 1996. However, this document has not yet been translated into Thai. A summary version of the new policy guidelines has been produced, approved by the Permanent Secretary, and is currently distributed to all levels of health care services.

Far-reaching organizational changes have been implemented within the Department of Communicable Disease Control since the WHO review. Zonal TB centers have been virtually dismantled countrywide, except for core clinical activities. Responsibility for training and supervision activities now lies with the Regional Offices of Communicable Disease Control.

Status Report on the Elements of DOTS

Political commitment is evidenced by tuberculosis control becoming one of the priority programmes within the Ministry. The five-year expansion plan for the NTP was endorsed by the Permanent Secretary of the Ministry of Public Health in 1997, who stated his commitment to ensuring the funding of the plan including an additional 182 Million Baht over a period of five years. However, the economic crisis during 1997 has instead led to severe budget cuts.

Case detection and diagnosis are still performed at the district hospitals, but all patients are now referred to their local health centers for follow-up and treatment. Laboratory services
remain a weak link in the DOTS strategy. There is an urgent need to improve the quality of training for laboratory technicians, and to establish a mechanism for quality control of smear microscopy.

Standardized treatment regimens recommended by WHO are now used for all patient categories. Health center staff are responsible for direct patient supervision or the monitoring of alternative supervisors such as village health volunteers and family members.

All supervisors receive "DOTS cards" on which daily drug intake is recorded. There are now uniform requirements for sputum control at two and five months, as well as at the end of treatment. However, reporting is irregular and incomplete.

Research and Other Issues

Thailand participated in the global drug resistance surveillance project initiated by WHO. Other research includes community and family participation in patient observation, the feasibility and cost-effectiveness of preventive therapy for HIV-positive patients, the economic aspects of TB control in Thailand, and the general socio-economic background of patients.

Private clinics and hospitals are supposed to play an insignificant role in TB control in Thailand. However, no empirical data is currently available to substantiate this assumption. The NTP has recently mailed a questionnaire to a representative sample of private providers to gain information on their case loads and treatment practices. Results are expected during 1998.

Risks and Constraints

The economic crisis affecting South-East Asia is having a significant impact on Thailand, resulting in cuts in public spending, including health services. Failure to protect the drug budget may lead to shortages, which will promote the development of drug resistance as patients receive inadequate treatment.

The frequency of supervision and the attention given to monitoring TB control activities are inadequate even during the early stages of DOTS implementation. The high level of demand for DOTS in Thailand has led to rapid and unplanned expansion. Many districts have implemented DOTS without adequate preparation. A lack of understanding of what DOTS involves has led to inappropriate selection of districts. Although districts state that DOTS has been implemented, many do not submit regular reports on case finding and treatment outcomes.

Activities to Address Constraints

The NTP is currently exploring the possibility of adopting intermittent drug regimens that would reduce drug costs dramatically without impeding the efficacy of drug therapy. The resulting savings could be used to continue training and supervision activities.

Meanwhile, additional funding for training and supervision is being sought from WHO. In a series of DOTS meetings for regional and provincial staff, the NTP is instructing peripheral personnel to strictly adhere to the NTP expansion plan, which stipulates the establishment of only one or two demonstration districts per province during 1998. This will be further supported by the new policy guidelines issued by the Permanent Secretary.

With WHO assistance, comprehensive guidelines for laboratory training, supervision and quality control were developed this year. These will be translated into Thai and the system will be introduced in demonstration areas this year.
TB in UGANDA

TB cases, 1996  Infectious cases (SS+)*, 1996

<table>
<thead>
<tr>
<th>Estimated # of TB cases</th>
<th>Officially reported # of TB cases</th>
<th>Estimated # of SS+</th>
<th>Officially reported # SS+</th>
<th>% of SS+ cases detected by DOTS**</th>
<th>% of SS+ cases detected by Non-DOTS</th>
<th>% of SS+ cases detected</th>
</tr>
</thead>
<tbody>
<tr>
<td>61000</td>
<td>27336</td>
<td>27000</td>
<td>15175</td>
<td>0.0</td>
<td>55.5</td>
<td>55.5</td>
</tr>
</tbody>
</table>

* SS+ = Sputum smear positive  
* *DOTS detection rate

Treatment outcomes, 1995

<table>
<thead>
<tr>
<th>Registered cases (new SS+)</th>
<th>Cured</th>
<th>Completed treatment</th>
<th>Defaulted</th>
<th>Failed</th>
<th>Died</th>
<th>Transferred out</th>
<th>% not evaluated</th>
</tr>
</thead>
<tbody>
<tr>
<td>DOTS</td>
<td>-</td>
<td>-%</td>
<td>-%</td>
<td>-%</td>
<td>-%</td>
<td>-%</td>
<td>-%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Treatment success</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non-DOTS</td>
<td>15301</td>
<td>25.6%</td>
<td>18.1%</td>
<td>13.2%</td>
<td>0.5%</td>
<td>6.8%</td>
<td>4.3%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>31.4%</td>
</tr>
</tbody>
</table>

Note: In non-DOTS areas, the reported treatment outcomes are not based on a WHO standard cohort analysis.

ANALYSIS

The Uganda Ministry of Health and the National Tuberculosis and Leprosy Programme (NTLP) officially adopted the principles of the DOTS strategy in late 1995. The Work Plan 1996-2000 was designed to create a framework for TB control activities using DOTS, phasing its implementation in the country over four years.

The NTLP strategy became fully operational at the end of 1995 with trained supervisors appointed by the Ministry of Health for all 39 districts of Uganda and an established standardized system for data recording and reporting and drug supply. At the same time, an intensive training programme for laboratory microscopists was designed to increase the number of diagnostic health units in all districts. All activities are fully integrated in the general district health services.

Poor results in case-finding and case management showed that some structural problems - poor access to most rural health units and low population density - were likely to make the NTLP strategy ineffective. After preparing a protocol for a WHO pilot study, the NTLP elaborated a proposal for community-based DOTS, to achieve an effective integration between the existing health system and the primary health care infrastructure.

DOTS implementation is now in its initial phase. It is anticipated that seven districts will have started DOTS implementation by the end of 1998.

Status Report on the Elements of DOTS

The Ministry of Health has recently reiterated its political commitment to support TB control activities as a matter of priority, and to appoint the staff required to make the NTLP fully functional.

The NTLP has a laboratory component that consists of a Central Reference Laboratory and a network of microscopy units situated in the health units. Most rural health units are now relying on microscopy services for case detection.

Treatment with short-course chemotherapy is available free throughout the country. In DOTS districts, the treatment lasts eight months with daily observation of drug intake five days a week for both initial and continuation phase. A 15-day drug supply is pre-packed by the National
TB and Leprosy Programme and made available, through district health staff, to community volunteers observing treatment.

There is regular supply of quality drugs. The current stock is sufficient for the whole country for the next two years, with priority and separate stock for pilot areas adopting DOTS.

The reporting and recording system has been standardized in all 39 districts during the past five years, following WHO guidelines. Medical and public health staff in DOTS districts undergo re-training on the NTLP information and monitoring system.

Research and Other Issues

Research includes a WHO study of community-based TB care in Kiboga District (rural area) and Kawempe Division, Kampala City (urban setting). Several studies are supported by Case Western Reserve University including TB transmission in households, preventive treatment of TB in HIV-infected adults, the role of ethambutol in the consolidation phase of TB treatment regimens, and laboratory diagnosis of microscopy negative pulmonary TB. Drug resistance surveillance also takes place.

The private sector is particularly important to the diagnosis of new cases in the capital city Kampala where patients are often discouraged from seeking attention in overcrowded public facilities. There is no notification of cases by the private sector to the NTLP. Anti-TB drugs are not generally available in private pharmacies in rural areas far from the capital city.

Non-governmental organizations (NGOs) and missionary hospitals are generally complying with the NTLP guidelines for treatment regimens and reporting system.

All districts in Uganda are involved in a Community Capacity Building Programme that aims to give greater responsibility to the community in health and development.

Under the decentralization policy implemented by the Government of Uganda, districts receive a block grant to manage health services, including TB control.

Risks and Constraints

Constraints of the NTLP districts include poor access to TB management services and overcrowding in the hospitals and diagnostic and treatment units.

Lack of staff at intermediate and central level affects managerial efficiency and may easily leave some districts without the required level of support and supervision during the expansion phase. The National Referral Laboratory is equally understaffed and unable to provide the necessary support to improve the quality of peripheral labs.

Although Ministry of Health officials have expressed their commitment to resolving these problems, necessary action may take some time and the NTLP is at serious risk of losing momentum.

Activities to Address Constraints

The National TB and Leprosy Programme is planning to use data gathered in districts implementing DOTS for advocacy purposes. The NTLP is establishing good working relationships with most NGOs, missions and private not-for-profit organizations in order to standardize TB control measures in the entire health sector. Most NGOs working in the health sector at district level receive technical advice from NTLP district supervisors.
TB in VIETNAM

TB cases, 1996

<table>
<thead>
<tr>
<th>Estimated # of TB cases</th>
<th>Officially reported # of TB cases</th>
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<th>% of SS+ cases detected</th>
</tr>
</thead>
<tbody>
<tr>
<td>125000</td>
<td>74711</td>
<td>56000</td>
<td>48911</td>
<td>67.1</td>
<td>20.0</td>
<td>87.1</td>
</tr>
</tbody>
</table>

* SS+ = Sputum smear positive
* *DOTS detection rate

Treatment outcomes, 1995

<table>
<thead>
<tr>
<th>Registered cases (new SS+)</th>
<th>Cured</th>
<th>Completed treatment</th>
<th>Defaulted</th>
<th>Failed</th>
<th>Died</th>
<th>Transferred out</th>
<th>% not evaluated</th>
</tr>
</thead>
<tbody>
<tr>
<td>DOTS</td>
<td>21954</td>
<td>89.1%</td>
<td>2.1%</td>
<td>2.2%</td>
<td>1.4%</td>
<td>2.7%</td>
<td>2.4%</td>
</tr>
<tr>
<td>Treatment success</td>
<td>91.3%</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

| Non-DOTS                  | 16235 | 76.4%               | 8.8%      | 6.3%   | 3.0% | 3.3%           | 2.3%            | 0.0%            |

Note: In non-DOTS areas from Viet Nam, the reported treatment outcomes are based on a WHO standard cohort analysis. Patients are classified as non-DOTS because the treatment used is not short course chemotherapy.

ANALYSIS

The Ministry of Health launched a national TB programme (NTP) in Vietnam in December 1985 and has implemented it gradually since then. From the onset of the programme, the Medical Committee Netherlands Vietnam (MCNV), a Dutch non-governmental organization (NGO), has supplied material and financial support. The Royal Netherlands Tuberculosis Association (KNCV) provides technical assistance. The Government of The Netherlands has donated approximately US $3 million to the government of Vietnam for implementation of a national TB plan.

Following a World Bank study in 1995, the National Health Support Project (NHSP) was formulated. The project is financed jointly by the Governments of Vietnam, Sweden and The Netherlands. This project includes US $23.4 million to the NTP for the period 1996-2002.

During the initial ten-year period, the NTP was developed gradually with modest external financing. Short-course chemotherapy (SCC) with a closely supervised intensive phase of treatment was introduced in 1988. By the end of 1997, 90 percent of the districts were covered by SCC, and full national coverage will be reached in 1998.

Status Report on the Elements of DOTS

The government’s political commitment is strong. With the launch of the NHSP in 1995, tuberculosis control was declared a national priority. Political leaders and health authorities at all levels emphasize the need for proper tuberculosis control services. Organizations such as the farmers’, women’s and youth leagues are promoting tuberculosis control at community level.

Case detection is based on direct microscopy of three sputum samples in self-reporting suspects. Microscopy is provided by 572 laboratories at the district level. A quality control system routinely monitors the performance of the laboratories.

Treatment is provided at district and commune levels. During the intensive phase all patients take drugs supervised by health staff. Treatment is monitored by a smear examination
after two, five and eight months. Strict adherence to supervised intake of rifampicin is a key component of the programme.

The government has purchased drugs with a World Bank loan since 1997 and follows international competitive bidding (ICB) procedures. Only rifampicin with proven bio-availability is purchased. Drugs are stored at national, provincial and district levels. There have been no drug shortages since the formation of the NTP.

The recording and reporting system follows WHO-recommended guidelines. Case-finding data and treatment results of smear-positive patients are reported quarterly by all districts. Complete data sets of all cohorts of all districts are available from 1986 onward.

Research and Other Issues

The NTP is involved in a number of research projects in collaboration with KNCV, the Centers for Disease Control and Prevention (CDC) and the Karolinska Institute from Sweden. Studies have focused on tuberculin surveys in children, relapse rates, drug resistance, HIV prevalence, private sector TB services, and how gender affects access to care, among others.

The private sector in Vietnam started to develop only recently and is restricted mainly to large cities.

NGOs started to operate in Vietnam relatively recently as well. Therefore, tuberculosis services are provided for the most part through the national health system of Vietnam.

Risks and Constraints

The NTP will have to address future challenges such as urban populations (homeless, less privileged, unregistered inhabitants), increased private sector collaboration, legislation to control the quality and provision of anti-TB drugs by private pharmacies, the threat of HIV/TB co-infection, and providing TB care in remote mountain regions.

Activities to Address Constraints

By declaring tuberculosis a priority, the government has taken a major step in re-enforcing the NTP. Strong government commitment and the guaranteed financing through 2002 have created a stable environment in which to address the challenges presented above. In technical matters, the NTP will continue to collaborate closely with KNCV.

The NTP plans to further develop management skills of staff at national, provincial and district levels, with support from the Government of The Netherlands. Technical inputs for the training programme are provided by the International Union Against Tuberculosis and Lung Disease (IUATLD), WHO and KNCV. The World Bank-supported development plan has a component for operational research, which offers the NTP opportunities to target its research efforts on critical areas described in the research section.
GLOBAL CONSTRAINTS TO TB CONTROL
GLOBAL CONSTRAINTS TO TB CONTROL

Over the last two years GTB has made several attempts to analyze the reasons for slow progress in implementing DOTS. GTB has yet to formulate a consistent framework for discussion of the constraints to expansion and sustaining of DOTS. Yet a framework which is rigorous, not overlapping, and clear to most audiences is certainly needed. So many of the constraints are interlinked that their systematic presentation has thus far eluded staff, and this remains true for presentation at this meeting. GTB expects that Committee discussions will lead toward greater clarity and consistency in discussing constraints.

The material which follows is intended to help focus discussion by committee members but should not be seen as rigid or exclusive. It is intended to facilitate analysis and discussion in order to lead to focused, specific recommendations. It is a generality, but not therefore less true or powerful, that the main constraint impeding progress on the TB epidemic is lack of political will. For this reason, as recommended by GTB governing bodies (CARG and TRAC) over the last several years, effective public education and advocacy must remain a core function of WHO's TB efforts. We also believe capacity in implementing this mandate must be decentralized to Regions and to the countries themselves over time. Significant events such as release of new reports and meetings such as this one in London remain and should be used as opportunities to both heighten and accelerate progress on the public education and advocacy agenda. But, while we expect progress on this front as an immediate result of the Committee's work, this function does not provide sufficient basis for recommendations which address other key constraints to TB control aside from political will. For this purpose, as a suggestion for the Committee's work, we have grouped major constraints to sharply improved Global TB control into four broad topic areas.

1. CONSTRAINTS RELATED TO FINANCING:

a) Financing to expand the DOTS strategy within the general health services (countries especially affected include half of China, Nigeria, Pakistan, Congo, Russia, Myanmar, Afghanistan).

b) Financing to sustain the DOTS strategy within general health services for the future. Some countries have obtained external financing to establish and expand their DOTS programs. This includes TB control programs in half of China, and Bangladesh, and parts of India, all funded by the World Bank. Ethiopia, Tanzania, Sudan, and parts of India are funded by bilateral aid sources. The commitment of the respective governments to gradually take financial responsibility to sustain high performing programs for several decades remains unclear.

c) Misallocation or inefficient use of existing financial resources. Where DOTS programs are not in place financial resources available for TB control are often spent on ineffective interventions such as hospitalization, repeated BCG vaccination and over reliance on X-rays for diagnosis and follow-up (for example in South Africa, half of China, Russia, Thailand, the Philippines and most of India). In some places, financial resources are used for proper tools or interventions, but these are implemented inappropriately due to failure to spend on other needed inputs, especially human resources, leading to very low quality TB services (e.g., Indonesia).

d) Financial barriers or disincentives inhibit effective response by patients and by health service providers. In some countries where financial scarcity characterizes tuberculosis activities, health services try to mobilize additional funding by charging patients for services or for the
drugs. With rare exceptions, these arrangements are counter productive as they result in infectious cases not entering treatment or prematurely stopping treatment when costs cannot be paid. In other places excessively low health worker salaries and/or incentives for service delivery and performance are such that staff are unwilling or cannot effectively implement the DOTS approach.

These constraints require either sustaining the funding, reallocation of funding or increases in funding. While it is obvious that this requires national government commitment of a high political level, such commitments can change, as do governments themselves, very frequently in some parts of the world. Possible solutions include earmarked/dedicated sources of funding (a hypothecated tax); or an acknowledgement by the global community that under certain conditions, the global community itself will sustain the funding of these disease control activities (as has been the case for some costs related to vaccines for children or for UN Peacekeeping activities) in order to avoid the negative consequences which will accrue to the world if the tuberculosis epidemic continues or if MDR TB is allowed to become more prevalent.

Overall, it is often observed that TB control receives an insufficient proportion of already under-funded health budgets. This neglect of TB is despite its recognition in numerous studies as an extremely cost-effective way to use public funds. The absolute low cost of tuberculosis control is also not yet widely recognized in most developing countries settings. Yet the fact is that effective TB control conducted through primary health services usually costs between U.S. 5 and 25 cents per capita. This amount represents about 1 to 4 percent of health spending in even the poorest countries, perhaps not excessive for a disease that accounts for 3% of the global disease burden. Accordingly, DOTS programs simply cannot be viewed as a serious financial challenge to any of the large or middle income countries and yet this is often the excuse used when questions of sustaining or replicating effective programs is raised. The Committee’s serious and sustained engagement to find solutions to the financial constraint is needed.

2. CONSTRAINTS RELATED TO HUMAN RESOURCES:

Human resource constraints, in various disguises, are a serious problem in most TB endemic countries and relate to lack of staff, poor conditions of service, the absence of appropriate training and support, and ineffective management.

As TB has remained neglected for so long, many TB programs lack dynamic leaders with good managerial skills, capable of undertaking the advocacy, leadership, technical guidance and bureaucratic/financial administration required. As a result competent advocates and administrators to deal with the tuberculosis epidemic are rare, from the most peripheral level of health service delivery to the national and international levels. Tuberculosis remains neglected in national health services, and stigmatized as an uninteresting feature of public health, unattractive and unappealing to bright, capable young staff as a career path. In many countries poor salaries in government health services further compound these elements.

At all levels, in TB endemic countries staff morale and motivation can be undermined by a lack of training, support to their activities, and wise technical supervision to coach and enhance their skills for good performance. When compounded by lack of TB drugs and scarcity of financial resources for simple activities, this is a cocktail for inaction by the front line workers.

Lack of simple TB training and supportive supervision for field staff in general health facilities and frequent changes of supervisory personnel at local level add to serious training and managerial impediments to DOTS. “Training of trainers” schemes in these circumstances have a high rate of inefficiency and demand refresher training for all levels.
The overall environment for staff working against TB, their recognition and motivation, the global and national institutions needed to support this and to provide opportunities for both training and research, and thus career advancement, provide the variables which can yield some improvement against this constraint. Solutions like prizes, non-monetary incentives, fellowships for higher studies, and prestigious career streams will have to be tailored to each country, and will be easily subverted without sustained global attention to this constraint. Global institutions to provide recognition and high level training could help to both focus and sustain continued improved performance at the national level and below. As an example, the developed nations of the world have long ago recognized by the importance of these considerations when it comes to international security and national defence. This is evidenced by the cross national training, recognition and interchange provided for national military training academies and defence schools. Lessons may emerge from this example for the war which mankind must wage with the tubercle bacillus.

It is obvious that the training, prestige and motivational aspects of the human resource constraint are related to the financing constraints. However, provision of financing by itself will not be an adequate remedy to the human resource constraint, which requires its own carefully prioritised and structured solution.

The Committee’s creativeness is needed.

3. ANTI-TB DRUGS:

Effective policies, sufficient financing and well-trained and motivated human resources are all useless without a dependable supply of high quality anti-tuberculosis drugs. There is, of course, a connection between the amount of financing available and the ability of the country to have a sustained supply of quality drugs.

Availability of financing is not, by itself, the solution. Even where money for drugs is available, administrative weaknesses arising from the human resource constraint mean that timely, effective purchase and distribution of drugs often does not occur. Corruption in various forms is a related factor, as are highly bureaucratic systems not accountable for good performance.

The absolute importance of the availability of high quality drugs (to avoid the emergence of drug resistance) and the form of presentation of the drugs cannot be overstated. For some years the WHO and the IUATLD have been recommending that fixed dose combination drug (FDC1) products of proven quality be used whenever possible. Thus far most TB endemic countries have felt that they could not afford to purchase these products. On the other hand, if FDC products would be used in most poor countries this could substantially ease risks and costs associated with the direct observation component of the DOTS strategy, at least allowing less well trained care givers to observe and record the intake of medicines. This is so for the simple reason that patients could not selectively reduce their intake of one or another of the drugs. A patient who was not compliant in regularly taking medicines might fail to be cured but the TB bacilli in that patient’s body would remain sensitive to the antibiotics originally given, thus allowing still effective, repeat treatment without the risk of drug resistance in the patient or in those he might infect.

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1 An FDC product is one where the appropriate amounts of the various medicines are combined into a single pill or capsule so that the patient, or the prescriber, cannot make mistakes or selectively take only one or two of the needed medicines. For reasons which are not well understood, when the anti-TB drugs are compounded into a single pill the effectiveness of the most important of the drugs is easily compromised with the consequence that drug resistance can be created by using a mediocre quality product.
Experience thus far in the TB endemic countries has shown that the process of securely funding, properly ordering, obtaining reasonable prices for, and ensuring the timely distribution and safe storage of the individual product forms of the anti-TB medicines is highly problematic in almost all of the worst affected countries. Where the epidemic is the worst, the problems in procurement of good quality pharmaceuticals also tend to be the worst.

Given the public health implications of the emergence of multi-drug resistant TB, there may be a strong case to be made, as there was in providing (from global supply sources and with global financing) vaccines for childhood immunization, for the international community to finance and provide the quality drugs which the developing countries need to receive in a dependable way, at least for a decade or two.

This kind of external supply of a pharmaceutical product could be criticized as creating dependency and undermining the importance of political will to be achieved in a country. However it could also be a provocative catalyst by which the main excuse for not taking effective action against TB is removed from the political and social dialogue be faced in the endemic countries. From the viewpoint of wise use of public funds on a global scale, there are few alternatives in the health sector, which would be such a good buy as a “Global Facility” to supply anti-TB drugs to all countries that wished them.

Committee discussion of the many complex issues involved with drug supply is invited.

4. CONFUSION IN HEALTH INFORMATION SYSTEMS ABOUT TB

Confusion about both targets to aim at and measures to judge progress abounds. The simplification of health information systems is an appropriate and needed objective for most countries. However, it is essential for tuberculosis that the minimum required information must exist for the purpose of ensuring good performance in TB control.

The world is accustomed to using benchmarks such as infant mortality rate, survival rate to age 65, maternal mortality rate, and life expectancy to judge whether health systems are making progress or not. To ensure sustained, appropriately focused action against the tuberculosis epidemic requires no less than equally simple, clear and understandable health outcome measures. The intellectual and administrative resources to formulate and disseminate, as internationally accepted, the key measures in the DOTS system must be accomplished. Within the next two or three years global acceptance of the idea of cure rate, with proof thereof, should become the “gold standard” the community concerned with TB control. Countries can then be motivated to report all cases and to be judged by the results which they achieve. Donors, and development institutions, can thereby also focus on the impact of their resources. The erosion of political will which is caused by the confusion arising from specialized interests debating the measure and the approach could be moderated and the debate could be channelled to move productive avenues. Lastly, but most importantly, standard acceptance of the measures inherent in the DOTS system will substantially strengthen the capacity of even poor health systems to: a) know what they are achieving; b) focus supervision where it is needed to correct sub-optimal performance; and c) plan and direct the inputs needed to sustain good performance.

The experience of the Committee, applied to this constraint, can surely yield important recommendations.
WHAT COULD BE DONE?

Suggestions from the Secretariat to address some of the above constraints are presented below. These are intended to stimulate, not confine, Committee work and are points of departure for debate, not recommendations.

1. Financing:
   
   (a) Governments should analyse their priorities for the health sector (based on burden of disease, DALYS and availability of cost-effective interventions) at present and in the next 20-25 years. National budgets for health services in general and TB control in particular should be increased appropriately in order to address the above priorities and sustain effective control interventions.
   
   (b) Bilateral and multilateral donor support to TB control in developing countries should be increased (especially for the least developed countries) and sustained for 1-2 decades at least.
   
   (c) Governments should make a cost analysis of current expenditure on TB control interventions (both effective and less effective). Strong commitment should be employed to reallocate spending on less effective interventions to the more effective interventions such as the DOTS strategy.

2. Human resources
   
   (a) Governments should increase the profile of tuberculosis in their organisation structure to attract high calibre public health professionals, select dynamic leaders for the TB programme and ensure that well trained staff are in place to support, monitor and supervise programme activities in the general health system.
   
   (b) National governments should (be assisted) in strengthening managerial capacity and leadership skills, and in recognising effective leadership and staff achievements.
   
   (c) The international community should invest resources in developing a core group of national and international technical experts on TB control.

3. Anti-TB drugs
   
   (a) Governments must ensure efficient and stable procedures for procurement of good quality TB drugs at internationally competitive costs for treatment of all patients, as well as sufficient buffer stocks. To ensure quality, lower cost and uniformity, drug procurement should be done at national or international level.
   
   (b) Fixed drug combinations of known quality should be used for TB control programmes.
   
   (c) The procurement and provision of drugs at global level and with global funding should be considered.

4. Information system
   
   (a) Governments should adopt and implement the WHO/IUATLD TB information system, and ensure that data from all sectors involved in TB services is reported to the national TB programme. Appropriate legislation should be introduced where necessary and feasible.
   
   (b) WHO should continue to collect data from countries and report on global TB surveillance annually; and should provide support to national governments to modify national methods of monitoring surveillance as necessary.

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<th>Country</th>
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