NATIONAL TUBERCULOSIS PROGRAMME MANAGERS’ MEETING

Report on the fifth meeting

Wolfheze, Netherlands
7–9 June 2002
ABSTRACT

Tuberculosis (TB) control in some countries of Europe requires urgent attention. Drug-resistant TB is increasing rapidly. In parts of eastern and central Europe economic decline, poverty, prison overcrowding and fractured medical services mean that TB rates are increasing and multidrug-resistant strains are rapidly emerging. There is also a growing epidemic of HIV infection, which is likely to compound TB control problems. Nevertheless, expansion of the DOTS (directly observed treatment, short-course) strategy has shown some improvement in Europe. This fifth meeting of National Tuberculosis Programme Managers facilitated the exchange of information on TB control between the countries of the WHO European Region and international partners. Progress and constraints in DOTS implementation, the influence of health care reform on national TB control programmes, and strategies to respond to multidrug-resistant TB were addressed.

Keywords

TUBERCULOSIS – prevention and control
TUBERCULOSIS, MULTIDRUG-RESISTANT
HEALTH SERVICES – organization and administration
HEALTH POLICY
DRUG THERAPY
PRISONS
NATIONAL HEALTH PROGRAMS
EUROPE
## CONTENTS

<table>
<thead>
<tr>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>List of abbreviations/acronyms</td>
</tr>
<tr>
<td>Introduction and objectives of the meeting</td>
</tr>
<tr>
<td>Summary of the global and European TB situation</td>
</tr>
<tr>
<td>Resources available to improve TB control in the WHO European Region and constraints in the penitentiary system</td>
</tr>
<tr>
<td>Global TB Drug Facility (GDF)</td>
</tr>
<tr>
<td>Green Light Committee (GLC)</td>
</tr>
<tr>
<td>Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM)</td>
</tr>
<tr>
<td>Training and education</td>
</tr>
<tr>
<td>Constraints in TB control in the penitentiary system</td>
</tr>
<tr>
<td>National Programme Managers’ reports on DOTS implementation in Europe</td>
</tr>
<tr>
<td>Russian Federation</td>
</tr>
<tr>
<td>Estonia</td>
</tr>
<tr>
<td>Romania</td>
</tr>
<tr>
<td>Slovakia</td>
</tr>
<tr>
<td>Ukraine</td>
</tr>
<tr>
<td>Georgia</td>
</tr>
<tr>
<td>Italy</td>
</tr>
<tr>
<td>Latvia</td>
</tr>
<tr>
<td>Slovenia</td>
</tr>
<tr>
<td>Moldova</td>
</tr>
<tr>
<td>Presentation and discussion on the DOTS Expansion Plan to Stop TB in the WHO European Region, 2002–2006</td>
</tr>
<tr>
<td>Introduction</td>
</tr>
<tr>
<td>Aims, goals and targets</td>
</tr>
<tr>
<td>Country classification</td>
</tr>
<tr>
<td>Status of DOTS implementation, latest data 2002</td>
</tr>
<tr>
<td>Achievements and constraints in DOTS expansion</td>
</tr>
<tr>
<td>Development process of the DOTS Expansion Plan to Stop TB in the WHO European Region</td>
</tr>
<tr>
<td>Conclusions</td>
</tr>
<tr>
<td>Summary of working group discussions</td>
</tr>
<tr>
<td>Conclusions</td>
</tr>
<tr>
<td>Recommendations</td>
</tr>
<tr>
<td>Annex 1 Participants</td>
</tr>
<tr>
<td>Annex 2 Programme</td>
</tr>
</tbody>
</table>
List of abbreviations/acronyms

AIPO  Italian Association of Hospital Pneumonologists
CCEE  Countries of Central and Eastern Europe
DOTS  WHO recommended strategy for TB control
DOTS Plus  Case management strategy under development to manage MDR-TB using second-line drugs within the DOTS strategy in low and middle-income countries
DRS  Drug resistance surveillance
DST  Drug susceptibility testing
EDEP  DOTS Expansion Plan to Stop TB in the WHO European Region
EURO  WHO Regional Office for Europe
FILHA  Finnish Lung Health Association
GDF  Global Drug Facility
GFATM  Global Fund to Fight AIDS, Tuberculosis and Malaria
GLC  Green Light Committee
IUATLD  International Union Against Tuberculosis and Lung Disease
MDR  Multidrug resistance
MDR-TB  Multidrug-resistant tuberculosis
MoH  Ministry of Health
NGO  Nongovernmental organization
NIS  Newly Independent States
NRL  National reference laboratory
NTP  National tuberculosis programme
PHC  Public health care
SMIRA  Multicentre Italian Study on Tuberculosis Drug Resistance
SRL  Supranational reference laboratory
TB  Tuberculosis
TOM  Treatment outcome monitoring
WHA  World Health Assembly
WHO  World Health Organization
Introduction and objectives of the meeting

In recent years, an alarming increase in the incidence of notified tuberculosis (TB) cases has been observed in the WHO European Region. The majority of people suffering from TB live in the countries of eastern Europe and the former USSR where the most dramatic increases have occurred. Among the factors responsible are economic recession, social upheaval, malnutrition, poor living conditions and overcrowding in prisons. Insufficient health budgets, unpaid or underpaid salaries, poorly maintained health facilities, severe shortages of drugs and laboratory supplies, lack of integration with primary health care of TB control programmes, as well as incorrectly conceptualized control programmes, contribute to inadequate TB control. Strategies not designed according to cost-effectiveness criteria, and based on active case-finding by mass radiography screening of the population and prolonged and often unnecessary hospitalization, have produced suboptimal use of the scarce resources available. Priority has been given to case-finding rather than to achieving high cure rates. Irregular drug supplies, lack of standardized chemotherapy regimens, unsupervised treatment and transmission of infection within congregate settings have resulted in high levels of multidrug-resistant TB (MDR-TB). In addition, whenever savings were possible due to the application of efficient TB control strategies, the rigid structure of the budget did not allow the extra financial resources to be redirected to other TB control activities.

The first meeting of National TB Programme (NTP) Managers was held in June 1994 in Warsaw, Poland. Representatives of 25 countries of central and eastern Europe and the former USSR took part in this meeting at which a five-point policy package for TB control (DOTS) was adopted.

The implementation of the WHO/IUATLD TB control strategy (DOTS) has proven effective in a number of European countries that have fully or partially (in so-called pilot areas) implemented DOTS or have adopted elements of the DOTS strategy in the process of preparing for implementation in the country as a whole. The DOTS strategy includes the following five elements:

- Government commitment to supporting the national TB programme;
- Case detection through bacteriological examination of sputum smear and culture in suspects presenting with symptoms to health services;
- Standardized short-course chemotherapy for at least all smear-positive TB cases under proper case management conditions;
- Regular, uninterrupted supply of all essential anti-TB drugs;
- Monitoring system for programme supervision and evaluation.

At the second meeting held in 1996, also in Poland, a priority plan of action for the enhancement of DOTS implementation was developed. DOTS projects were expanded with attention to advocacy and high-risk groups. The need for further cost-effectiveness analyses was highlighted, as was the need for guidelines regarding prisons and prisoners. An interim third meeting was held in 1998 in Issyk-Kul, Kyrgyzstan, attended by NTP Managers from central Asia, the Caucasus and the Russian Federation. At this meeting the progress in DOTS implementation in the central Asian republics, the Caucasus and the Russian Federation was reviewed.
The fourth meeting of NTP Managers took place from 8 to 10 June 2000 in Helsinki, Finland, and was co-hosted by FILHA and the WHO Regional Office for Europe. During this meeting the progress achieved in DOTS implementation was discussed. Among the 27 countries of central and eastern Europe, only four had not adopted DOTS (by the time of the meeting), while seven countries were fully implementing the WHO-recommended strategy. In 1998, more than 350,000 new cases of TB were reported in the 51 Member States of the WHO European Region compared with 240,000 cases in 1991.

Ten recommendations were agreed in Helsinki. Amongst these was the recognition that national TB programmes needed to be strengthened, there was a need to adopt internationally recognized TB control strategies and accelerate implementation of these strategies, TB services should be integrated into wider (changing) health structures, and drug supplies should be centralized, maintained and quality assured. With regard to MDR-TB, it was agreed that the first priority from a public health perspective was prevention of MDR-TB through an effective and comprehensive TB programme; however, the introduction of an MDR-TB programme should be considered only in areas where there was an NTP with proven effectiveness, according to internationally recommended guidelines. Support from international partnerships and collaboration were recognized as essential components in the improvement of TB programmes in a number of countries of the WHO European Region.

The fifth meeting of NTP Managers was held in Wolfheze, Netherlands, from 7 to 9 June 2002. Dr Richard Zaleskis, on behalf of the Regional Director of the WHO Regional Office for Europe, highlighted the achievements of the previous four meetings and stressed that properly coordinated external assistance for the countries of the Region is necessary to ensure the sustainability of TB control efforts.

The overall objective of the meeting was to follow up on the previous meetings in order to improve TB control in the European Region based on the WHO recommended TB control strategy.

The specific objectives of the meeting were to:

- discuss the extent of the TB problem in the WHO European Region;
- assess the progress made in TB control since the last NTP Managers’ meeting with particular emphasis on DOTS expansion;
- identify the achievements and constraints in the implementation of the DOTS strategy and to formulate priority action in order to achieve the World Health Assembly targets by 2005;
- review the problem of MDR-TB in the WHO European Region, its impact on TB control, and DOTS Plus activities in “hot spot” countries;
- discuss the possible impact of health sector reform on effective TB control, and challenges for integration and decentralization of TB control services;
- discuss TB in prisons as an integral part of national TB control policies and to identify possible ways of establishing strong links between the prison and civilian sectors;
- review and endorse the DOTS Expansion Plan to Stop TB in the WHO European Region, 2002–2006.
Summary of the global and European TB situation

In 1993, WHO declared TB a Global Emergency in response to the dramatic increase in rates of disease in many parts of the world. According to WHO, there were approximately 8.7 million new cases of TB. The geographical distribution of TB notifications is shown in Figure 1 (Page 6).

MDR-TB is defined by WHO as resistance to at least isoniazid and rifampicin, with or without resistance to any other drug. MDR-TB represents one of the greatest challenges to overall TB control. Estimates of the magnitude of the burden of drug resistance have in the past been rendered difficult by the lack of reliable epidemiological data. Recent epidemiological research suggests there is considerable global variation, with several areas representing “hot spots” of high incidence, as shown in Figure 2 (Page 6).

In the WHO European Region there has been an alarming rise in TB rates in recent years. From 1991 to 1996, the number of cases increased by almost 40%. The countries of eastern Europe and the former USSR in particular have witnessed a marked increase, and nearly all of them have rates several times higher than the countries of western Europe, as shown in Figure 3 (Page 7).

In western Europe TB rates declined steadily from the turn of the last century until the mid-1980s when a levelling-off occurred. In some countries small increases in the number of cases have been notified.

In the countries of eastern Europe and the former USSR the decline in TB rates following the Second World War reversed in the 1980s and 1990s. Dramatic socioeconomic and political changes are the underlying factors behind this increase.

In 2000, 369,935 new TB cases were reported in the WHO European Region compared to 231,608 in 1991. Most of these cases occurred in the countries of eastern Europe and the former USSR. Case notification rates have doubled in practically all NIS countries since 1990, and in the Russian Federation the rates have tripled. In 2000, all NIS countries except Armenia and Tajikistan reported more than 50 TB cases per 100,000 population. Kazakhstan, Kyrgyzstan and Romania reported 160, 126 and 122 TB cases per 100,000 population respectively. These figures are to be compared with the TB case notification rates in western and some central European countries (Czech Republic, Slovakia and Slovenia) where most countries report less than or about 20 TB cases per 100,000 population. The global rate of increase of TB is predicted to be 3% per year on average, but is much higher in eastern Europe (8%) and in African countries affected by HIV (10%).

The notification rates per 100,000 population in Europe are summarized in Figure 4 (Page 7).

In Europe the problem of drug resistance parallels the overall TB situation. Multidrug-resistant TB is a man-made problem; poorly functioning TB programmes create MDR-TB. Treatment of MDR-TB costs around 100 times more than treatment of drug susceptible TB, and the treatment success rate does not usually exceed 60%.

In western Europe the median prevalence of newly diagnosed MDR-TB cases is below 1%. In some countries of eastern Europe and the former USSR irregular drug supplies, a lack of standardized treatment regimens, and factors associated with prisons are contributing to an
alarming situation. For example, in the Baltic states drug resistance rates are among the highest in the world, as shown in Table 1.

### Table 1. Prevalence of drug resistance in selected European countries, 1996–1999.


<table>
<thead>
<tr>
<th>Country</th>
<th>Patients tested</th>
<th>Drug resistance in new cases</th>
<th>Patients tested</th>
<th>Drug resistance in previously treated cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>Czech Republic</td>
<td>311</td>
<td>1.6</td>
<td>52</td>
<td>11.5</td>
</tr>
<tr>
<td>Denmark</td>
<td>412</td>
<td>0.5</td>
<td>32</td>
<td>3.1</td>
</tr>
<tr>
<td>England and Wales</td>
<td>3053</td>
<td>0.8</td>
<td>189</td>
<td>13.2</td>
</tr>
<tr>
<td>Estonia</td>
<td>377</td>
<td>14.1</td>
<td>82</td>
<td>37.8</td>
</tr>
<tr>
<td>Finland</td>
<td>410</td>
<td>0.0</td>
<td>2</td>
<td>0.0</td>
</tr>
<tr>
<td>France</td>
<td>787</td>
<td>0.0</td>
<td>65</td>
<td>3.1</td>
</tr>
<tr>
<td>Germany</td>
<td>1455</td>
<td>0.9</td>
<td>256</td>
<td>6.3</td>
</tr>
<tr>
<td>Italy</td>
<td>683</td>
<td>1.2</td>
<td>127</td>
<td>33.9</td>
</tr>
<tr>
<td>Latvia</td>
<td>789</td>
<td>9.0</td>
<td>224</td>
<td>23.7</td>
</tr>
<tr>
<td>Netherlands</td>
<td>1042</td>
<td>0.6</td>
<td>172</td>
<td>0.6</td>
</tr>
<tr>
<td>Norway</td>
<td>138</td>
<td>2.2</td>
<td>6</td>
<td>16.7</td>
</tr>
<tr>
<td>Poland</td>
<td>2976</td>
<td>0.6</td>
<td>994</td>
<td>7.0</td>
</tr>
<tr>
<td>Russian Federation (Tomsk Oblast)</td>
<td>417</td>
<td>6.5</td>
<td>232</td>
<td>26.7</td>
</tr>
<tr>
<td>Russian Federation (Ivanovo Oblast)</td>
<td>222</td>
<td>9.0</td>
<td>54</td>
<td>25.9</td>
</tr>
<tr>
<td>Scotland</td>
<td>299</td>
<td>0.3</td>
<td>8</td>
<td>12.5</td>
</tr>
<tr>
<td>Slovakia</td>
<td>589</td>
<td>0.3</td>
<td>157</td>
<td>8.3</td>
</tr>
<tr>
<td>Slovenia</td>
<td>290</td>
<td>0.7</td>
<td>36</td>
<td>2.8</td>
</tr>
<tr>
<td>Spain (Barcelona)</td>
<td>315</td>
<td>0.3</td>
<td>69</td>
<td>11.6</td>
</tr>
<tr>
<td>Sweden</td>
<td>356</td>
<td>0.6</td>
<td>24</td>
<td>8.3</td>
</tr>
<tr>
<td>Switzerland</td>
<td>322</td>
<td>0.0</td>
<td>40</td>
<td>12.5</td>
</tr>
</tbody>
</table>

The TB notification rates in selected countries of eastern Europe and the former USSR are summarized in Figure 5 (Page 8).

The objectives of WHO’s TB programme, which focuses mainly on eastern European countries, are to reduce mortality, morbidity and disease transmission and to prevent the development of drug resistance.

The DOTS strategy aims to achieve these goals, with the target of detecting at least 70% of existing cases and curing 85% of the infectious cases detected. In 1995, before WHO started to actively promote sound TB control in the Region, only six out of 51 countries were using DOTS compared to 34 countries today. Among the CCEE and NIS countries, only two countries have
not adopted the strategy and 10 countries have implemented it countrywide. However, on average, only 17% of the population in the Region are currently provided with services that use the DOTS strategy.

The advantages of the DOTS strategy are early detection and treatment, as well as strict monitoring of the TB cases detected and treatment outcomes, prevention of drug-resistant TB, and economic benefits. Examples of DOTS successes in the Region are better cure rates, a significant drop in TB mortality in some countries (e.g. Kazakhstan), and a decrease in acquired MDR-TB in Latvia. According to the World Bank, DOTS is among the most cost-effective of all health care interventions available to low and middle-income countries. The strategy has also proven to be cost-effective in the WHO European Region. In 1997, an economic evaluation in the Russian Federation concluded that the cost per cured case of TB using the DOTS strategy was US $1626, while with the former strategy it was US $6293.

The Amsterdam Declaration in 2000 and the Washington Commitment to Stop TB in 2001 endorsed the need for rapid acceleration of DOTS expansion in order to reach the WHA targets by 2005.

The extent to which the DOTS strategy is being implemented in the WHO European Region is shown in Figure 6 (Page 9).

TB in prisons is a particular cause for concern. The number of prisoners in Europe is estimated at between 8 and 10 million. In parts of Europe the number of prisoners is continuing to rise. Many prisoners are socially marginalized, being alcoholics, drug dependent, mentally ill, ethnic minorities, or illegal immigrants. TB rates are increasing among some prison populations, as illustrated in data from Russian prisons (Table 2).

<table>
<thead>
<tr>
<th>TB incidence per 100 000</th>
<th>1995</th>
<th>1996</th>
<th>1997</th>
</tr>
</thead>
<tbody>
<tr>
<td>Detainees in SIZO (Pre-trial detention centre, Russian Federation)</td>
<td>1119.3</td>
<td>1378.7</td>
<td>1592.0</td>
</tr>
<tr>
<td>Rate compared to average in Russian Federation</td>
<td>19.3</td>
<td>20.4</td>
<td>21.5</td>
</tr>
<tr>
<td>Convicted</td>
<td>2481.0</td>
<td>3395.2</td>
<td>4055.9</td>
</tr>
<tr>
<td>Rate compared to average in Russian Federation</td>
<td>42.9</td>
<td>50.3</td>
<td>54.9</td>
</tr>
</tbody>
</table>

The development and spread of MDR-TB within prisons is facilitated by many factors, including lack of funding, delays in diagnosis, delays in referral for treatment and initiation of treatment, inadequate treatment, frequent inmate transfers, overcrowding, and inadequate infection control programmes.

The growth in the incidence of HIV threatens to compound the situation. Although not widespread in much of Europe at present, HIV infection is rapidly increasing in much of the former USSR and threatens TB programmes that are already fragile. The situation in the Russian Federation and Ukraine is summarized in Figure 7 (Page 9).
**Figure 1.** Global TB incidence, 2000

**Figure 2.** Prevalence of MDR-TB among new TB cases in countries and regions surveyed between 1994 and 1999
Figure 3. TB case notification rates per 100 000 population in parts of Europe, 1980–2000

![Graph showing TB case notification rates per 100 000 population in Central & Eastern Europe and Western & Southern Europe from 1980 to 2000.]

Figure 4. TB case notification rates per 100 000 population in Europe, 2000.
The majority of tuberculosis cases occur in the eastern part of the Region

![Map of Europe showing the range of TB case notification rates per 100 000 population in 2000.]

Range of rates (per 100 000)
- < 10
- 10-24
- 25-49
- 50-99
- > 100
Figure 5. TB case notification rates (per 100 000 population) in selected countries of eastern Europe and the former USSR, 1980–2000.
Figure 6. DOTS implementation status in the WHO European Region, 1995–2001

1995

2001

Implementation of WHO TB control strategy
- No acceptance
- DOTS partially implemented
- DOTS fully implemented

Figure 7. Incidence of HIV infection in the Russian Federation and Ukraine, 1993–2000
Resources available to improve TB control in the WHO European Region and constraints in the penitentiary system

**Global TB Drug Facility (GDF)**

Since one of the main principles of the DOTS strategy is to ensure an uninterrupted supply of quality proven drugs, the issue of drug purchase is a priority within NTP activities. The aims and functioning of the Global TB Drug Facility (GDF) were presented. GDF is a mechanism to expand access to, and availability of, high quality TB drugs to facilitate DOTS expansion. It will enable both governmental and nongovernmental organizations to implement effective TB control programmes based on the DOTS strategy.

**Green Light Committee (GLC)**

It is well known how drug resistance, a man-made phenomenon, is produced. After a presentation of the recent epidemiological trends of MDR in the Baltic states and the Russian Federation, the principles of the DOTS Plus strategy were discussed. Through the country example of Peru, a country with an excellent DOTS programme, the possibility of saving more than 90% of the cost of second-line anti-TB drugs was presented and discussed. The mechanism regulating the green light towards the use of second-line drugs through this special channel was summarized, together with the activities performed by the Committee up to now.

**Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM)**

This new public-private partnership was established in 2001 to attract, manage and distribute additional resources to reduce poverty and the burden of the three diseases. Presently, about US $2 billion has been committed and US $1 million is already available to the Fund. Applications to the Fund must be presented to the Secretariat and technically evaluated by a review panel before the Board will approve them. The Fund aims to raise additional resources for the fight against the three diseases. Priority will be given to high-burden countries and growing epidemics. Proposals should contain clear and measurable outcomes. The grants will be mainly channelled through governments, which can use them directly or by involving private institutions and NGOs. Further details of how a grant can be requested were discussed.

**Training and education**

Training and education are essential components of any national TB programme. The issue was discussed in detail with regard to educating the general public and to training health staff involved in the programme.

**Constraints in TB control in the penitentiary system**

The problem of TB control in prisons has been described in several recent reports. In 1993, the incidence of notified cases was 820 per 100 000 population in Siberia. It was 7000 in Tomsk in 1996, 4667 in Azerbaijan in 1994 and 2640 in Moldova in 1996. In the majority of countries the Ministry of Health is in charge of TB control in the civilian sector, while the Ministry of Justice or Internal Affairs is generally responsible for TB control in jails and prisons. As a result of the difficult collaboration between the different ministries, some of the essential components of the
DOTS strategy have not been implemented. Lack of data (case-finding, treatment outcomes) is common, as well as a shortage of drugs and the use of nonstandardized treatment regimens. Staff are often poorly paid and motivated. The risk of transmission of TB and HIV in similar settings is very high, as well as the development of further drug resistance and MDR. The implementation of correctly conceptualized DOTS programmes is a public health priority, particularly in the countries of the former USSR.

The experiences of integration of the prison and civilian TB control programmes in Orel and Tomsk (Russian Federation) were presented and discussed in detail.

National Programme Managers’ reports on DOTS implementation in Europe

Russian Federation

TB incidence rates have more than doubled from 34.2 in 1990 to 88.2 in 2001 per 100 000 population. A major increase in TB mortality rates has also been noted, reaching 19.9 per 100 000 population in 2001. Several DOTS projects have been implemented in the Russian Federation in Tomsk and Ivanovo (1994–1995), Kemerovo prisons (1996), Leningrad Oblast (1997), Murmansk Oblast (1998), Orel Oblast (1999) and Novgorod Oblast (2000). The coverage of DOTS increased from 2% in 1994–1995 to 21% in 2001. The DOTS expansion plan in the Russian Federation was presented for the period 2002–2004. Although treatment results are still low (higher in DOTS than in non-DOTS areas, with treatment success rates of 71.6% and 67.7% respectively) due to the high death, failure and defaulter rates, a significant improvement in government commitment has been achieved at the federal level with the approval of several laws and resolutions. A five-year plan for DOTS expansion is in preparation. The main constraints and opportunities for DOTS expansion in the country were discussed.

Estonia

After a steady decline in the reported notification rate from 417 per 100 000 population in 1953 to 26.1 per 100 000 in 1992, this rate has increased since 1993 to reach 51.9 per 100 000 in 2001. Reported TB mortality has increased from approximately 5 to 7.6 per 100 000 during this period.

Multidrug-resistant *Mycobacterium tuberculosis* is an emerging problem of great importance to public health in Estonia. Estonia participates in the WHO/IUATLD Global Project on Drug Resistance Surveillance. The increase in the proportion of previously untreated pulmonary TB cases caused by MDR strains is alarming. This proportion was estimated at 9% in 1994, 11.6% in 1996, 11.1% in 1997, 15.8% in 1998, 16.2% in 1999, 13.0% in 2000 and 13.9% in 2001. The Government of Estonia is fully committed to dealing with this problem by implementing the DOTS strategy in the country.

In 2001, the GLC approved the DOTS Plus project in Estonia for obtaining consensually priced second-line anti-TB drugs, as it has recently strengthened its TB control strategy to guarantee the proper use of second-line drugs, while preventing the creation of MDR-TB. In the DOTS Plus project there are several problems, such as patient adherence to treatment, alcohol abuse, the recent epidemic of HIV and social problems. These problems should be properly addressed in order to avoid treatment with expensive and toxic second-line drugs. Through the DOTS Plus
project the country should be able to guarantee an uninterrupted supply of second-line anti-TB drugs for patients with MDR-TB and to study how to manage DOTS Plus and cure all patients with TB.

**Romania**

Romania, with an incidence of 134.4 cases per 100 000 population, had one of the highest notification rates in the whole of Europe in 2000. The presentation focused on how the laboratory network is presently operating and on the prevalence of drug resistance. There are 50 Level I, 54 Level II and 75 Level III laboratories. The network performs about 740 000 direct smear examinations (11% positive), 730 000 cultures (13.7% positive) and about 19 000 DST. The prevalence of MDR is 2.8% in cases not treated previously, while it is 21.9% among previously treated cases. Although the survey is presently not carried out strictly according to WHO/IUATLD guidelines, the overall prevalence of drug resistance was consistent over time. The NTP is presently preparing a protocol for proficiency testing and DRS, according to WHO/IUATLD guidelines.

**Slovakia**

Slovakia has a very efficient TB control programme. Since 20 cases and 19 cases per 100 000 population were notified in 1999 and 2000 respectively, the country entered the “below 20” group of low-burden countries. Age and sex distribution has a pattern similar to that of western European countries.

According to the results from 1999, 456 cases performed DST and only three previously untreated cases were found to be MDR (0.7%). The country is classified as a Group A country in which cultures and DST are performed on a routine basis and national data are linked to TB notifications. Treatment success is consistently around 80% (79% in 1999), with 9% deaths (largely due to old age). The organization of TB control, which has led to these excellent results, was discussed in detail.

**Ukraine**

In 2000, the incidence of notified cases was 68.6 and mortality was 22.4 per 100 000 population. Both parameters have been increasing steadily since 1999. According to the results from 2000, the prevalence of MDR in previously untreated patients was 7.3% in the country and 2.9% in Kiev, while in previously treated patients it was 15.4% and 1.8% respectively. The laboratory network is affected by several problems, including the absence of pure substance for DST, the lack of standardization of laboratory methods, the insufficient number of binocular microscopes and the possible selection bias of patients undergoing DST. Furthermore, there are significant biosafety problems. The organization of the DOTS pilot project in Donetsk was discussed. Smear conversion rates for the first quarter at month 2 are around 85% at a preliminary evaluation.

**Georgia**

4397 cases were notified in Georgia in 2000, corresponding to a notification rate of 84 per 100 000 population. Treatment success in new cases was 61% and in retreatment cases it was
43%. The organization of TB control activities in the country was discussed in detail, as well as the ongoing process of health sector reform.

**Italy**

Italy has a notification rate consistently lower than 9 per 100,000 population, with absolute numbers ranging from 4000 to 5000 cases per year. It is considered a DOTS country because the main elements of the strategy have been implemented, according to the recommendations of the New Framework for TB Control in Low-Incidence Countries. However, direct observation of treatment is carried out only during hospital admission. The presentation focused on the approach used to develop a DOTS programme in Italy. In the early 1990s, technical, consensus-based guidelines were developed by scientific societies (AIPO in particular), and a network of TB units, initially based on the AIPO network, started to grow. This network is presently called the SMIRA network and covers about one third of culture-positive cases notified nationwide every year; it was established in 1995 to perform treatment outcome monitoring.

DRS started in 1998. Despite some limitations (it is a convenience sample), results in terms of TOM and prevalence of drug resistance are consistent over time and testify to the good quality of TB control performed in the country so far. Some administrative regions have started to perform DRS and TOM based on the same methodology.

**Latvia**

Latvia has witnessed a dramatic increase in rates of TB and MDR-TB. In 1990, the incidence of TB was 27/100,000 and in 1998, it was 98/100,000, with a decline in 1999 (68.3/100,000), particularly in men of young and middle age. Mortality rates are still high. One third of patients die during their first year of illness and two-thirds of those within a month of diagnosis. Delayed diagnosis leading to severe clinical TB cases is still common.

The DOTS strategy was initiated in Latvia in 1995. In 1997, it was estimated that 91% of hospital patients were covered by the DOTS strategy during the intensive phase of treatment; this fell to 55% of patients for the continuation phase. The DOTS strategy has since been expanded. Treatment interruption and failure rates have decreased from 42% in 1994 to 6.1% in 1998. In 1999, the success rate in new cases was 74%, with 11% deaths, 1% failure, 4% default and 1% transferred out (8% not evaluated).

Other relevant achievements are the implementation of a centralized anti-TB drug supply and distribution, the establishment of the DOTS Plus strategy, and the inclusion of prisons in national programme activities.

The national reference laboratory (NRL) is fully operational and the national TB registry is now consistent with international recommendations.

**Slovenia**

Slovenia, with 368 TB cases notified in 2000, has a notification rate of 19 per 100,000 population. No MDR cases were notified among those not previously treated. Treatment success in new cases is 88%. A register of latent TB infections has recently been established, which aims
to evaluate the results of treatment of latent TB infection. The organization of TB control was discussed in detail.

**Moldova**

From 1995 to 2001, the TB notification rate increased from 58.3 to 89.9 per 100,000 population. During the same period, the prevalence of MDR-TB increased from 0.8% to 5% in new cases, and resistance increased from 14.5% to 29.1%. Considerable efforts were made to implement the DOTS strategy in the country and a central bid for drugs was organized. The implementation of DOTS started in 2001. Moldova was the first country to establish a centralized drug supply through the grant from GDF. The organization of the TB control programme in the country was discussed.

**Presentation and discussion on the DOTS Expansion Plan to Stop TB in the WHO European Region, 2002–2006**

**Introduction**

The background for the development of the DOTS Expansion Plan to Stop TB in the WHO European Region were the following conferences and meetings: Bangkok (November 1998), under the umbrella of the Global Stop TB Partnership, the DOTS expansion working group meetings in Cairo (2000) and Paris (2001), the Global Drug Facility (GDF) meeting in May 2000, the ministerial and Stop TB partners’ conferences in Amsterdam (March 2000, leading to the Amsterdam Declaration to Stop TB), and the Stop TB Partners’ Forum in Washington (October 2001, leading to the Washington Commitment to Stop TB).

In 2000, the WHO/EURO Health Policy Overview clearly identified TB as a top priority in 21 out of the 27 countries surveyed in the Region, and as a first or second priority among 16 countries with increasing TB notification rates.

**Aims, goals and targets**

The aim of the DOTS Expansion Plan is to stimulate social and political commitment in order to achieve the global TB targets as part of the overall health system. The main goal is to define the scope of work needed to reduce TB morbidity and mortality, and to promote accessibility and sustainability of the DOTS strategy as part of health system development.

The objectives and targets of the DOTS Expansion Plan are to: 1) reduce the prevalence of MDR-TB to below 1% in 10 years in previously untreated TB cases; 2) reduce TB prevalence and mortality by 50% in 10 years, i.e. to the same level as in 1990; 3) ensure that DOTS is incorporated into country plans for health system development; 4) achieve 90% DOTS population coverage by the year 2006.

**Country classification**

Countries are classified into three groups according to the following three criteria: 1) features of the TB epidemiological trend since the 1980s; 2) type and quantity of new activities that need to be implemented to expand the DOTS strategy; 3) TB mortality by age, reflecting the TB burden.
in the Region. The highest priority will be given to countries in Group 1 (particularly the five largest ones).

Table 3. Grouping of countries in the WHO European Region

<table>
<thead>
<tr>
<th>Group 1</th>
<th>Group 2</th>
<th>Group 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>High TB burden</td>
<td>Intermediate TB burden</td>
<td>Low TB burden</td>
</tr>
<tr>
<td>Top five priority countries: Russian Federation*, Ukraine, Romania, Uzbekistan, Kazakhstan</td>
<td>Turkey, Poland, Spain, Portugal, Yugoslavia, Hungary, Bulgaria, Bosnia and Herzegovina, Croatia, The former Yugoslav Republic of Macedonia, Albania</td>
<td>Germany, France, United Kingdom, Italy, Greece, Czech Republic, Belgium, Netherlands, Slovakia, Austria, Switzerland, Denmark, Israel, Finland, Ireland, Slovenia, Sweden, Norway, Luxembourg, Malta, Andorra, Iceland, San Marino, Monaco</td>
</tr>
<tr>
<td>Other 11 countries: Tajikistan, Belarus, Kyrgyzstan, Azerbaijan, Republic of Moldova, Lithuania, Turkmenistan, Georgia, Latvia, Armenia, Estonia</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Country belonging to the top 22 countries in the world with the largest TB burden

**Status of DOTS implementation, latest data 2002**

In Group 1 (16 countries), 15 have already implemented DOTS. Among them, five countries have implemented DOTS countrywide and one (Belarus) is in the preparatory phase.

In Group 2 (11 countries), three countries have 100% DOTS coverage, two countries are in the preparatory phase and two have not yet adopted DOTS (Croatia and Spain).

In Group 3 (24 countries), 12 countries have implemented DOTS: 11 have 100% coverage, four countries are in the preparatory phase and eight countries have not yet adopted DOTS.

Overall DOTS coverage of the population in the Region is 17.3%. The estimated DOTS case detection rate is presently 10.1%, which is still far from the 70% target.

**Achievements and constraints in DOTS expansion**

The key achievements and constraints in DOTS expansion in the Region can be summarized as follows:

Group 1: Political commitment, availability of sufficient human and financial resources, high prevalence of MDR-TB and HIV/AIDS.

Group 2: Political commitment, availability of sufficient human and financial resources, political instability.

Group 3: Political commitment, availability of sufficient human resources, need for “ad hoc” plans to control TB in specific risk groups.

The targets and expected results for DOTS expansion are summarized in Table 4.
Table 4. Targets and expected results for DOTS expansion by the year 2006 and milestones for the year 2003

<table>
<thead>
<tr>
<th>Targets</th>
<th>2003</th>
<th>2006</th>
</tr>
</thead>
<tbody>
<tr>
<td>Central TB team established</td>
<td>All countries</td>
<td>All countries</td>
</tr>
<tr>
<td>DOTS coverage achieved (% population)</td>
<td>37%</td>
<td>90%</td>
</tr>
<tr>
<td>Treatment outcomes reported</td>
<td>30 countries</td>
<td>46 countries</td>
</tr>
<tr>
<td>Quality proven purchase of anti-TB drugs</td>
<td>15 countries</td>
<td>All countries in Groups 1 and 2</td>
</tr>
<tr>
<td>TB drug resistance surveillance implemented</td>
<td>30 countries</td>
<td>All countries</td>
</tr>
<tr>
<td>DOTS Plus pilot projects implemented</td>
<td>Three additional countries</td>
<td>Five additional countries</td>
</tr>
<tr>
<td>TB/HIV co-infection surveillance implemented</td>
<td>20 countries</td>
<td>All countries</td>
</tr>
</tbody>
</table>

**Development process of the DOTS Expansion Plan to Stop TB in the WHO European Region**

The draft version of the plan was discussed and approved at the 12th meeting of the Interagency Coordinating Committee (ICC) focusing on tuberculosis in Copenhagen, 22–23 January 2002. The draft plan was then circulated among the NTP Managers of the Member States and their suggestions were included in the document presented at the NTP Managers’ meeting in Wolfheze, June 2002. After inclusion of all recommendations/suggestions proposed by NTP Managers in Wolfheze, the plan will be finalized in summer 2002 and presented for endorsement to the fifty-second WHO EURO Regional Committee in September 2002.

**Conclusions**

1. DOTS (five core elements) is a basic strategy for the DOTS Expansion Plan to Stop TB in the WHO European Region (EDEP);
2. The goal of the EDEP for 2002–2006 is to define the scope of work needed to reduce TB morbidity and mortality, and to promote accessibility and sustainability of DOTS as part of health system development;
3. A coordinated approach (emphasizing country needs and collaboration with governments, national and international agencies, and NGOs) will reinforce political commitment, mobilize national and external resources and increase efficiency.

**Summary of working group discussions**

*TB control and health sector reform*

The experience of different countries was discussed. There was agreement on the necessity to maintain a central office and coordinating unit in countries where TB services are fully integrated within PHC.
Intervention strategies to achieve the WHA targets for TB control
The discussion started by evaluating how measurable can be considered the 70% detection WHO target in Europe. Indirect methods of estimating TB case detection rates were discussed. Furthermore, it was noted that 85% success is hard to reach in the majority of western European countries. In fact western Europe is facing high (age-related) mortality. The main obstacles to reaching these targets were identified and discussed, focusing on those that can and those that cannot be changed in the short term.

Organization, management and budgeting of the national TB programme
The discussion started with management activities at central, regional and district level (assessment, planning, implementation and monitoring). Case management issues were also discussed, focusing on the necessity to further integrate TB services within primary health care. The different budgetary sources were identified and discussed (health insurance, national governmental budget, international funding), and the need for the development of proper costing was stressed.

Monitoring system and TB surveillance
Constraints and opportunities for improving the existing monitoring and surveillance systems in different countries were discussed in detail.

Drug resistance surveillance
The experience of different countries was discussed, focusing on methodological problems, such as representativeness, the opportunity to perform periodic surveys versus ongoing surveillance, taking into account the different priority given to TB control in different countries, funding problems, and the issue of quality control of both surveillance and laboratory data.

Sound TB control to prevent MDR-TB
The discussion started with the need to prevent the emergence of MDR strains and then examined the features needed by specialized centres in order to manage MDR cases.

Laboratory quality control and drug resistance
The models adopted in different countries were discussed in detail. While the vast majority of countries perform strain exchange with one SRL within the WHO/IUATLD project, the system for performing the proficiency testing exercise from NRL to regional laboratories shows relevant country differences.

Infection control and drug resistance
The discussion focused on the targets for prevention and treatment. The main issues examined were the identification of risk groups, the identification of a proper strategy of intervention, the importance of developing new diagnostic tools for diagnosis of infection, and the use of biosafety measures.

Conclusions
1. TB is a serious public health problem in the WHO European Region, particularly in some countries of eastern Europe and the former USSR. A common effort by governments and nongovernmental and international organizations within the Region is needed to fight the disease effectively.
2. An alarming increase in TB notifications, the high rates of MDR-TB in some NIS countries, the rapid spread of HIV infection, and the dramatic situation of TB in prisons pose additional threats to TB control in the Region.

3. As a response, significant efforts have been initiated in some countries in order to identify priorities, funding gaps and opportunities for improving TB control.

4. DOTS has been implemented in 34 of the 51 countries in the Region. However, only 17% of the population live in areas where all elements of the DOTS strategy have been implemented.

5. New opportunities for controlling TB have recently become available, including the Global Drug Facility, the Green Light Committee for MDR-TB, and the Global Fund to Fight AIDS, Tuberculosis and Malaria.

6. Political commitment at the government level is essential for successful implementation of TB control at the country level.

7. TB monitoring and surveillance, including drug resistance surveillance, are powerful tools for the evaluation and improvement of TB control performance.

8. Human resource development and public education are essential prerequisites for effective TB control.

9. A well functioning and quality controlled laboratory network is essential for applying appropriate measures to control TB and MDR-TB.

**Recommendations**

1. The ongoing process of health sector reform should reorient TB control programmes. Planning, budgeting and supervisory activities should remain a priority at the national level, and the delivery of services should be gradually decentralized and integrated within the primary health system, taking into account country-specific needs.

2. TB control in prisons should be integrated within the national TB programme and should apply the policies and strategies recommended in the country.

3. Cost-effectiveness and cost-benefit analyses should be used to identify possible savings and to guide the rational reallocation of scarce resources within TB control.

4. In order to prevent the further emergence of drug resistance, DOTS Plus should only be implemented in areas where DOTS is fully in place.

5. Since HIV is a growing problem in some countries of the WHO European Region, strong links between TB and HIV programmes should be established in order to address the dual epidemic.

6. The expansion of DOTS should be accelerated in order to reach the global TB control targets by the year 2005 (cure of 85% of infectious cases and detection of at least 70% of such cases).

7. The DOTS Expansion Plan to Stop TB in the WHO European Region, highlighting the priority actions that need to be undertaken, should be adopted by all WHO EURO Member States.
Annex 1

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Annex 2

PROGRAMME

7 June 2002

Chairperson D. Kozma

13:00-14:00  Registration

14:00-14:15  Opening and objectives
             R. Zaleskis, J. Veen

14:15-14:45  Global TB Drug Facility
             R. Matiru

14:45-15:15  Green Light Committee
             K. Lambregts

15:15-15:30  Global Fund to Fight AIDS, Tuberculosis and Malaria
             F. Luelmo

15:30-16:00  Tea/coffee break

16:00-16:15  TB control in Europe: successes and challenges for DOTS expansion
             R. Zaleskis

16:15-17:30  Working group discussions
             Group 1:  TB control and health sector reform
             Group 2:  Intervention strategies to achieve the World Health Assembly targets for TB control
             Group 3:  Organization, management and budgeting of the national TB control programme
             Group 4:  Monitoring system and TB surveillance

17:30-18:30  Plenary reports from the working groups

8 June 2002

Chairperson G. Rakishev

09:00-09:20  Training and education in TB control
             K. Bergström

09:20-09:40  Public health education in TB control
             A.M. Brassé
09:40-10:30  TB in prisons: links with civilian sector  
*Country presentations: Orel and Tomsk experience  
(Russian Federation)*

10:30-11:00  Tea/coffee break

11:00-11:30  Discussions on TB in prisons

11:30-12:30  MDR-TB as a constraint to the sustainability of DOTS  
*Country presentations: Estonia, Romania, Slovakia, Ukraine*

12:30-14:00  Lunch

**Chairperson H. Hafizi**

14:00-15:30  Working group discussions  
*Group 1: Drug resistance surveillance  
Group 2: Sound TB control to prevent MDR-TB  
Group 3: Laboratory quality control and drug resistance  
Group 4: Infection control and drug resistance*

15:30-16:00  Tea/coffee break

16:00-17:00  Plenary reports from the working groups

17:00  Draft recommendations of the meeting  
*G.B. Migliori*

**9 June 2002**

**Chairperson E. Heldal**

09:00-09:15  Overview of global TB control and DOTS expansion  
*M. Grzemska*

09:15-09:30  Overview of European TB control and DOTS expansion  
*R. Zaleskis*

09:30-10:30  Challenges for DOTS expansion in Europe  
*Country presentations: Georgia, Italy, Latvia, Slovenia*

10:30-11:00  Tea/coffee break

11:00-11:30  Challenges for DOTS expansion in Europe  
*Country presentation: Russian Federation*

11:30-11:45  DOTS Expansion Plan to Stop TB in the WHO European Region, 2002-2006  
*R. Zaleskis*
11:45-12:30 Discussions on DOTS Expansion Plan to Stop TB in the WHO European Region, 2002-2006

12:30 Conclusions and recommendations

G.B. Migliori