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**7–12 February 2005**



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# CONTENTS

	<i>Page</i>
Abbreviations .....	1
Executive summary and main recommendations .....	2
Background .....	2
Main findings .....	2
Main recommendations .....	4
1. Introduction.....	6
2. Epidemiology of tuberculosis and HIV/AIDS .....	7
Epidemiology of tuberculosis .....	7
Epidemiology of HIV/AIDS .....	8
3. The National TB Programme .....	8
3.1 Goal, objectives and strategy .....	8
3.2 DOTS achievements .....	10
3.3 Management and organization.....	11
3.4 Financial resources .....	12
3.5 Cooperation with partners .....	15
3.6 Diagnostic services.....	17
3.7 Treatment services.....	21
3.8 Drug supply and management .....	22
3.9 Monitoring and evaluation .....	24
3.10 Training.....	26
3.11 Information, education, communication .....	27
3.12 Research .....	28
3.13 National drug resistance surveillance .....	28
3.14 DOTS-Plus .....	29
3.15 Tuberculosis in prisons.....	31
3.16 HIV-related tuberculosis .....	33
Annex 1. Map of the Republic of Armenia.....	35
Annex 2. Agenda of the mission.....	36
Annex 3. Persons met during the mission.....	37
Annex 4. Background documents .....	39
Annex 5. Organizational chart of the Armenian National TB Control Programme.....	41
Annex 6. Selected data on TB case-finding and treatment outcomes in Armenia.....	42



## Abbreviations

AIDS	Acquired Immunodeficiency Syndrome
ARCS	Armenian Red Cross Society
ART	Antiretroviral treatment
BTEP	Biological Technology Engagement Programme
CCM	Country Coordination Mechanism
CDC	Centers for Disease Control and Prevention (United States)
CT	Counselling and testing for HIV
DOT	Directly Observed Treatment
DOTS	WHO-recommended strategy for tuberculosis control
DOTS-Plus	WHO-recommended strategy for drug-resistant tuberculosis control
DRS	Drug Resistance Surveillance
DST	Drug Susceptibility Testing
EURO	WHO Regional Office for Europe
FAP	Feldsher Accoucheur Post
FDC	Fixed Dose Combination
GDF	Global TB Drug Facility
GDP	Gross Domestic Product
GFATM	Global Fund to Fight AIDS, Tuberculosis and Malaria
GLC	Green Light Committee of the Working Group on DOTS-Plus for MDR-TB
GTZ	Deutsche Gesellschaft für Technische Zusammenarbeit
HIV	Human Immunodeficiency Virus
KfW	Kreditanstalt für Wiederaufbau
KNCV	KNCV Tuberculosis Foundation
ICRC	International Committee of the Red Cross
IDU	Injecting drug user
IEC	Information, Education, Communication
IPT	Isoniazid preventive treatment
MDR	Multidrug-resistant
MMR	Mass Miniature Radiography
MOH	Ministry of Health
MOJ	Ministry of Justice
MSF	Médecins Sans Frontières
MSH	Management Sciences for Health
NAP	National HIV/AIDS Programme
NGO	Nongovernmental organization
NIH	National Institute of Health
NRL	National TB Reference Laboratory
NTP	National Tuberculosis Programme
PHC	Primary Health Care
PLWH	People living with HIV
RTBD	Republican TB Dispensary
SAI	Sanitary and Anti-epidemic Inspection
SRL	Supranational TB Reference Laboratory
TB	Tuberculosis
TB/HIV	HIV-related tuberculosis
UNAIDS	Joint United Nations Programme on HIV/AIDS
WHO	World Health Organization

## **Executive summary and main recommendations**

### **Background**

Tuberculosis is an important public health problem in the Republic of Armenia. DOTS, which started its pilot phase in 1995, is presently implemented in the whole country, including the penitentiary system. However, not all tuberculosis patients are properly registered and DOTS is achieving low case detection and treatment success rates. However, important progress was observed in recent months following the establishment of the National Tuberculosis Programme Central Office and the considerable support from external partners.

In June 2004, the Ministry of Health requested the assistance of the World Health Organization, Regional Office for Europe, in approaching the Green Light Committee of the Working Group on DOTS-Plus for multidrug-resistant tuberculosis. In October 2004, the Ministry of Health requested further assistance to develop a project proposal for tuberculosis control, to be submitted to the Global Fund to Fight AIDS, Tuberculosis and Malaria. International partners agreed to organize a joint mission to assess DOTS implementation in the country, including the drug supply component, so as to identify specific needs for implementing interventions addressing the problem of multidrug-resistant tuberculosis and to advise on the proposal to the Global Fund to Fight AIDS, Tuberculosis and Malaria. The tuberculosis assessment mission took place from 7 to 12 February 2005.

### **Main findings**

In Armenia, tuberculosis incidence is estimated at a total of 77 new TB cases and 35 pulmonary smear-positive new TB cases per 100 000 population (2002). The National Tuberculosis Programme reports the highest number of patients in the age group 15–24 and a very low female/male ratio of 0.2/1. Incomplete data from the National TB Reference Laboratory (national drug resistance surveillance has not been established yet) indicate a prevalence of multidrug-resistant tuberculosis of 12% and 57% respectively in new and previously treated patients. HIV is still at the level of a concentrated epidemic, however, with increasing numbers of newly registered cases each year. The latest estimates by the Joint United Nations Programme on HIV/AIDS (UNAIDS) are of 2800–3000 people living with HIV in Armenia. Fifty percent of the HIV infections are registered in Yerevan and fifteen percent among injecting drug users.

DOTS has covered all the country since 2002. However, the National Tuberculosis Programme has placed under DOTS management only 58% of the new cases detected and achieved a detection rate of only 35% with wide variations among the regions (marz). The latest treatment success achieved is 77% and 49% respectively among new and relapsed TB cases.

For years, the National Tuberculosis Programme was just a “DOTS project” with limited resources and organization. Since February 2004, however, the programme has closer links with the Ministry of Health and the Central Office with overall responsibilities. One person from each Governor’s Office has been appointed for coordination of tuberculosis control

activities in each marz since September 2003. Coordination at marz level still needs some improvement.

Funding of the health sector is foreseen to increase and consequently the budget for tuberculosis control. Nevertheless, a proper long-term implementation plan needs to be developed. External partners have provided considerable support for the National Tuberculosis Programme in various areas, including DOTS implementation, training, supervision, research and DOTS-Plus. Support from the Global Fund to Fight AIDS, Tuberculosis and Malaria could also be instrumental in adequately financing priority areas of intervention during the next five years.

Most tuberculosis patients from all over the country are diagnosed in Yerevan. Tuberculosis cases are notified and sanitary disinfection of residences is practised. Radiography is preferred to sputum microscopy. Tuberculosis screening is practised in broad groups of population. Sputum microscopy is poorly accessible in marz because of the lack of involvement of family medicine doctors and primary health care nurses. Low laboratory performance will be addressed in 2005 by the distribution of new binocular microscopes, centralized procurement and preparation of laboratory reagents, retraining, quality assurance and supervision. A well organized National Tuberculosis Reference Laboratory (NRL) has been established in Abovyan and is working with the Supranational Laboratory in Borstel (Germany). NRL has a key role to play in the current and future activities for tuberculosis control in Armenia and urgently needs to increase its staff and obtain official status from the Ministry of Health.

International standard treatment regimens are applied to DOTS patients. However, many are placed under other, less effective forms of treatment, including “chronic” patients following the old classification in use during Soviet Union times. Seasonal preventive treatment and treatment with second-line anti-tuberculosis drugs are practised. All patients are admitted during intensive treatment, mainly in Abovyan. The environmental measures for limiting nosocomial transmission are insufficient. During the maintenance phase of treatment, the patients collect drugs every 2–4 weeks from a tuberculosis facility, while family doctors and the primary health care network are not utilized.

Anti-tuberculosis drugs are purchased by KfW from the Global Tuberculosis Drug Facility. A new stock will be available in Yerevan by September 2005. The National Tuberculosis Programme distributes the drugs to the tuberculosis facilities in the country. Stock-outs have not been registered, despite some problems with distribution. Significant improvements in drug management have been observed in recent months after training of staff and introduction of a new drug management information system.

Recording and reporting is regularly maintained on paper and through an electronic database. Supervision in marz has been ensured in recent months and will benefit from new vehicles procured by KfW.

The majority of the medical and laboratory personnel working in tuberculosis control were trained recently. Family doctors are only marginally involved in tuberculosis services and consequently have very limited training. Primary health care providers are not involved in DOTS and the present guidelines do not address them.

Information, education and communication have been traditionally limited to the celebration of World TB Day. There is general consensus to increase activities significantly and to oppose social stigma and poor information on free-of-charge tuberculosis services.

Operational research for tuberculosis control is supported by external partners. There is a plan to undertake a national tuberculosis prevalence survey.

Country representative anti-tuberculosis drug resistance surveillance is planned to start in 2005. A similar survey will start in the penitentiary system. The National Reference Laboratory and the Supranational Laboratory in Borstel will be intensively involved.

Data on tuberculosis drug resistance are presently incomplete, although indicative of the need to establish DOTS-Plus interventions in Armenia. Nevertheless, and despite the recent progress achieved by the National Tuberculosis Programme, a specific pilot project cannot start until some important programmatic conditions have been put in place. These programmatic conditions are addressed by the recommendations of the mission. Meanwhile, the DOTS-Plus pilot project to be implemented by Médecins Sans Frontières (France) in two districts of Yerevan municipality will require closer collaboration with the National Tuberculosis Programme and the Green Light Committee of the Working Group on DOTS-Plus for multidrug-resistant tuberculosis.

Quality DOTS is implemented in the penitentiary system with the support of the International Committee of the Red Cross (ICRC). It is accessible to 85% of detainees, avails of regular tuberculosis screening of the prison population, has links with the civilian system for the follow-up of released detainees still under treatment, and will receive drugs from the National Tuberculosis Programme. Treatment success is only 63%, mainly due to high anti-TB drug resistance, which motivates the Ministry of Justice to apply to the Green Light Committee jointly with the Ministry of Health.

The National AIDS Programme benefits from a US\$ 7.25 million grant from the Global Fund to Fight AIDS, Tuberculosis and Malaria. Only counselling and testing of tuberculosis patients for HIV and isoniazid preventive therapy are included among internationally-recommended TB/HIV interventions. Both activities are difficult to implement.

## **Main recommendations**

### ***To the Government of Armenia:***

1. The Government of Armenia should progressively increase its financial support to TB control, raise staff salaries and introduce incentives linked to performance and professional hazard.

### ***To the Ministry of Health:***

2. to start developing a TB project proposal which considers the funding gaps identified in TB control in the next 5 years for submission to GFATM by the deadline of Round 5. Only one CCM should be established, with balanced representation for HIV/AIDS, tuberculosis and malaria, and with a manageable number of participants.

3. to establish a working group to develop the TB proposal, which includes the following areas for GFATM support: implementation of DOTS through PHC, social support to TB patients and mechanisms of incentives/enablers, drug supply and management, TB/HIV collaborative interventions, drug resistance surveillance, DOTS-Plus, nosocomial infection control and IEC;
4. to apply to GLC at a later stage when all required programmatic conditions are in place;
5. to decentralize TB case detection and case management by involving the PHC level. To ensure early TB diagnosis, directly observed treatment, tracing of defaulters, and health education through family doctors and nurses whose job descriptions and training should be revised accordingly;
6. to recognize officially the TB laboratory at the Republican TB Dispensary in Abovyan as the National TB Reference Laboratory and ensure a distinct budget line and additional staff; and
7. to ensure the leading role of the National TB Programme through improved staffing and organization of the Central Office, and increased communication and coordination with all partners. To ensure that national TB counterparts of WHO Regional Office for Europe are also part of the National TB Programme.

***To the National Tuberculosis Programme:***

8. to urgently revise the current guidelines for DOTS at PHC level and strengthen TB case detection and case management through family doctors and nurses;
9. to develop comprehensive national guidelines and document them in the form of a manual to be widely distributed;
10. to treat all TB patients through DOTS-based national guidelines and ensure their registration and reporting;
11. to revise the current national plan and include a clear goal and purpose, input, activities, output and indicators, according to a logical framework. To start developing a medium-term national plan beyond 2006;
12. to meet all necessary conditions and start anti-TB drug resistance surveillance as soon as possible; and
13. to ensure collaboration and coordination with all current and potential partners through the TB Interagency Steering Committee.

***To the partners of the National Tuberculosis Programme***

14. All partners: to continue supporting the National Tuberculosis Programme, preserving national ownership and ensuring delegation of responsibilities and capacity-building.
15. MOJ should strength coordination and collaboration with NTP in drug supply, information systems, supervision, DRS and TB/HIV management, and follow-up of ex-prisoners. A plan for taking over ICRC-supported activities should be prepared.
16. MSF (France): apply to GLC before starting treatment of MDR-TB patients under its DOTS-Plus pilot project jointly with the Ministry of Health.
17. National HIV/AIDS Programme and National TB Programme: plan and implement jointly TB/HIV collaborative interventions.

## 1. Introduction

The Republic of Armenia is a country in transition, which gained independence in 1992 following the break-up of the Soviet Union. It is a mountainous, landlocked country in the South Caucasus with a population of 3.21 million, 64% living in urban areas and 30% in the capital city of Yerevan. Armenia has a Gross National Income per capita of US\$ 910, and 43% of the population live below the poverty line. A substantial negative migration pattern has contributed to a nearly 0.5 million decrease in the population size during the past decade. There are 11 administrative units: 10 regions (marz) and Yerevan municipality (see Annex 1).

Like the other Newly Independent States, during the last decade Armenia experienced the re-emergence of infectious diseases, such as tuberculosis (TB), which is an important public health problem in the country. Implementation of the DOTS strategy in the country started in 1995 with support from the World Health Organization (WHO). At present, DOTS is considered to cover the whole country and population, including the penitentiary system.

Faced with the growing challenge of anti-TB drug resistance, in June 2004 the Ministry of Health (MOH) requested the WHO Regional Office for Europe to provide technical assistance and facilitate cooperation with the Green Light Committee of the Working Group on DOTS-Plus for MDR-TB (GLC). In October 2004, another request was made to the Regional Office to assist with the preparation of a TB grant proposal for Round 5 of the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM). Consequently, it was agreed that a TB assessment mission to Armenia would be jointly undertaken by GLC, the WHO Regional Office for Europe, the KNCV Tuberculosis Foundation (KNCV), the Deutsche Gesellschaft für Technische Zusammenarbeit (GTZ), the International Committee of the Red Cross (ICRC) and the Global TB Drug Facility (GDF) during the period 7 to 12 February 2005. The mission had the following objectives:

- to assess the current status of DOTS implementation in the country, which is essential for implementing the WHO-recommended strategy for drug-resistant TB control (DOTS-Plus), including the drug supply component, via GDF;
- to assist the National TB Programme (NTP) in evaluating the current burden of multidrug-resistant TB (MDR-TB) in the country;
- to identify specific needs for implementing a DOTS-Plus pilot project and offer technical assistance in achieving the necessary programmatic conditions for a successful DOTS-Plus programme;
- to assist MOH and NTP in preparing the MDR-TB component in the application to GFATM.

The TB assessment mission to Armenia was conducted with close collaboration between national and international partners. The team was composed of Kai Vink (mission team leader, on behalf of Deutsche Gesellschaft für Technische Zusammenarbeit, KNCV Tuberculosis Foundation, The Hague, Netherlands), Pierpaolo de Colombani (WHO Regional Office for Europe, Copenhagen, Denmark), Andrei Mosneaga (WHO Country Office, Tbilisi, Georgia), Massoud Dara (KNCV Tuberculosis Foundation, The Hague, Netherlands), Claudine Dauby (International Committee of the Red Cross, Tbilisi, Georgia), Cornelia Hennig (Deutsche Gesellschaft für Technische Zusammenarbeit, Baku, Azerbaijan), Jim Bates (Deutsche Gesellschaft für Technische Zusammenarbeit, Yerevan, Armenia), and

Susanna Khachatryan (Management Sciences for Health, Arlington, United States). The mission was organized with the support of the WHO Country Office in Armenia and the offices of other partners, to whom the mission is very grateful: Elizabeth Danielyan and Stepan Astvatsaturyan (WHO Regional Office for Europe), Anna Boshyan (Gesellschaft für Technische Zusammenarbeit), and Gegham Petrosyan (International Committee for the Red Cross).

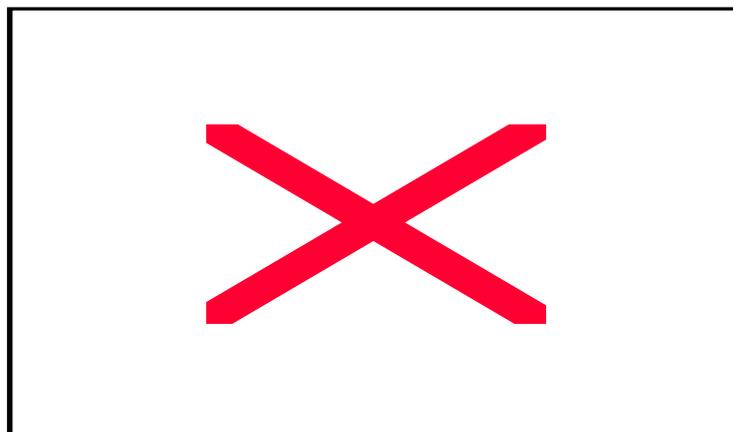
The mission visited TB and other health facilities and met people in six marz and at central level (see the agenda of the mission in Annex 2 and the persons met in Annex 3). The mission reviewed existing documents (see Annex 4), forms and records, and distributed the responsibilities of writing the final report among its members. The mission discussed its main recommendations with the 1st Deputy Minister of Health and the Deputy Minister of Health (International Relations) on 12 February 2005, the last day of the mission

## 2. Epidemiology of tuberculosis and HIV/AIDS

### Epidemiology of tuberculosis

In Armenia, WHO estimates an incidence of 77 total new TB cases and 35 pulmonary smear-positive new TB cases per 100 000 population (2002). From these estimates, it can be calculated that around 2400 new TB cases occur in Armenia each year. Armenia has the 13<sup>th</sup> highest TB incidence rate among the 52 countries of the WHO European Region.

In 2002, the NTP reported 295 new pulmonary TB smear-positive patients by age and gender with a female/male ratio of 0.2/1. The highest number of both male and female patients was reported in the age group 15–24 years (see figure). The peak of new smear-positive patients



in the age group 15–24 years indicates the prevalence of TB exogenous re-infection and ongoing TB transmission in the community. The very low female/male ratio of the new TB cases reported by NTP is striking.

There is no national anti-TB drug resistance surveillance (DRS) in Armenia. The TB laboratory at the Republican TB Dispensary in Abovyan performs systematic

sputum culture and drug susceptibility testing (DST) for its patients. These results are not representative of the whole country, although they may provide some understanding of the levels of resistance to first-line anti-TB drugs. In 2003, among 426 patients never previously treated for TB and with a DST result, 51 (12%) were found with MDR-TB. Among the 137 previously treated TB patients tested, 78 (57%) had MDR-TB. There are no DST data available on second-line anti-TB drugs.

## **Epidemiology of HIV/AIDS**

Human Immunodeficiency Virus (HIV) infection in Armenia is still at the level of a concentrated epidemic. However, an increasing number of HIV persons are registered each year. In 2002, HIV infection was found in 15% of injecting drug users (IDU) and 3% of female sex workers (SW). The prevalence of HIV among TB patients is not known. The first HIV infected person was officially registered in 1998. By January 2005, the National HIV/AIDS Programme (NAP) had registered 305 HIV infections, of which 4 (1.3%) were children. Seventy-seven Acquired Immunodeficiency Syndrome (AIDS) patients were also reported, fifty-seven of whom had died. HIV infection prevails among males (78%) and in the age group 20–39 years (77%). Most of the HIV infections are reported from Yerevan (50%) and Lorri marz (8%). HIV transmission through injecting drug usage is predominant (53%) and increasing; it is mainly observed in men. The second means of HIV transmission is heterosexual intercourse (38%), which is mainly observed in women. A number of HIV infections have been found in Armenian immigrants to high prevalence HIV areas, such as in the Russian Federation (e.g. Moscow, St. Petersburg, Irkutsk, Rostov and Surgut) and Ukraine (e.g. Odessa, Kiev and Mariupol). The latest estimates by the Joint United Nations Programme on HIV/AIDS (UNAIDS) are of 2800–3000 people living with HIV (PLWH) in Armenia.

A survey was performed by ICRC in the penitentiary system in 2004. Out of 542 inmates tested (i.e. 20% of the total population), 7 (1.3%) were found to be positive for HIV, 14 (2.6%) for hepatitis B, and 123 (22.7%) for hepatitis C. Out of 42 TB patients tested, 19 (45%) were positive for hepatitis C, 3 (7%) for HIV, and 2 (5%) for hepatitis B.

## **3. The National TB Programme**

### **3.1 Goal, objectives and strategy**

The Poverty Reduction Strategy Paper (PRSP) was adopted by the Government of Armenia in November 2003. Regarding TB, the document mentions that “poverty is closely related to such contagious diseases as tuberculosis, sexually transmitted diseases and AIDS. Given the drastic increase of these diseases in the recent decade (twice for tuberculosis, triple for syphilis, etc.), it is necessary to strengthen preventive measures, carry out early diagnosis and identification, and carry out thorough treatment programmes. Redistribution of budget resources, in particular, will contribute to the implementation of the above measures”. Although PRSP does not include quantitative indicators/targets related to TB (as well as to HIV/AIDS), it states that “the sharp increase in the financing of health care projected within the PRSP will provide for more effective countermeasures against socially dangerous diseases, particularly HIV/AIDS, malaria, and tuberculosis” and will aim to “sharply reduce tuberculosis mortality, and thus achieve Millennium Development Goal n° 6”.

#### **Goal and objectives**

The NTP was adopted by government decree n° 1680 of 4 December 2003. Covering the period until the end of 2006, NTP aims to “protect the population of Armenia from all forms of TB, to ensure permanent and coordinated implementation of prevention, case-finding and treatment activities, to provide anti-TB drugs free of charge, and to reduce morbidity, mortality and disability caused by TB in the society”. The targets, to be reached by 2006, are

70% detection rate, 85% sputum conversion rate and 80% cure rate among new pulmonary TB smear-positive cases.

NTP has 10 objectives: a) to develop and implement the national TB control policy; b) to implement TB prevention in all population groups; c) to detect TB patients; d) to promote the role of the national TB reference laboratory; e) to ensure treatment of TB patients, including those with drug-resistant TB; f) to cooperate closely with the National HIV/AIDS Programme; g) to ensure continuous care of the TB patients in the penitentiary system, as well as after their release; h) to ensure continuous care of the TB patients doing military service, as well as after their demobilization; i) to increase attention and respect for all TB patients and staff employed in TB services; j) to ensure the monitoring of NTP performance.

### **Strategy**

An NTP manual with operational guidelines has not been issued yet, although a draft has been available since February 2004. At present, the only official reference document is the Prime Minister's decree n° 1680, which provides the strategy and activities for implementing NTP during the years 2003–2006. It is a key document for TB control in Armenia, although it is too general and sometimes inconsistent with the DOTS strategy.

The Prime Minister's decree calls for increased funding for TB control, strengthened laboratory diagnosis, standardized treatment regimens, and monitoring and evaluation of the programme. It emphasizes the need for more effective intersectoral cooperation, involvement of primary health care (PHC) providers in TB detection, follow-up of released prisoners under anti-TB treatment, and DRS and MDR-TB management. However, it also includes interventions that are not recommended internationally, such as Bacillus Calmette-Guérin revaccination (activity 1.2.b), mass miniature radiography (MMR) of broad population groups (1.2.c), seasonal prophylactic treatment of chronic patients (1.4.c), and emphasis on TB control in animals (1.2.f).

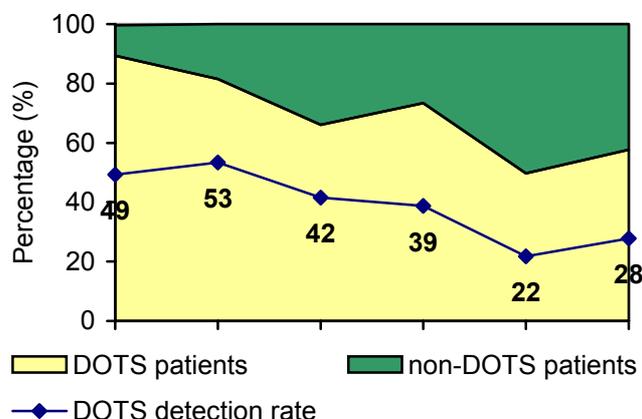
The decree lacks a detailed timetable and appropriate indicators for implementing and monitoring the activities. Furthermore, it does not have a budget and therefore cannot be used as a medium-term plan for TB control in Armenia or as a guide in identifying funding gaps for potential support by external partners.

### **Recommendations:**

- NTP should develop national guidelines and document them comprehensively in the form of an NTP manual to be widely distributed. All those interventions with a known low cost-effective balance and not recommended under the DOTS strategy should be abandoned.
- NTP should revise its implementation plan for the next two years and start developing a medium-term NTP plan beyond 2006. A clear goal, purpose, input, activities, output and indicators should be stated, according to a logical framework.

### 3.2 DOTS achievements

DOTS implementation in Armenia started in 5 pilot areas in 1995 and covered all TB facilities in Armenia by 2002. However, only part of the TB patients were registered under DOTS in this period. According to the official data reported to WHO, the new smear-positive cases registered under DOTS were 89.8% in 1997, 81.5% in 1998, 66.1% in 1999, 73.4% in 2000, 49.7% in 2001, 57.7% in 2002, and 74.3% in 2003 (see figure and also tables in Annex 6). This can explain the low case detection rate of



NTP. In 2003, the overall case detection rate was 35.5%, ranging from 47.2% in Yerevan to 5.7% in Gegharkunik marz. Out of the total new TB cases registered under DOTS in 2003, only 35.2% were pulmonary smear-positive, 43.2% were smear-negative and 21.6% extrapulmonary. The lowest rate of smear-positive cases was detected in Gegharkunik marz (21.7%) and the highest in Yerevan (46.9%), where the largest proportion of newly registered TB cases is smear-positive and where there is better access to microscopy services.

In the 2002 cohort of new smear-positive patients, NTP achieved an overall treatment success rate of 77.1%. The patients not evaluated were 9.3%, with the highest rate in Ararat (11 out of 21 patients or 52.4%). It should be considered that selecting patients for DOTS or non-DOTS management can be a practice that excludes the most “difficult” patients (severe clinical condition, high risk of defaulting, etc.) and favours higher treatment success rates.

In the 2002 cohort of relapsed smear-positive patients, overall treatment success was only 49.3%. The patients not evaluated were 22.4%, with the highest rate in Ararat (8 out of 8 patients or 100%). The high proportion of relapsed patients not evaluated can indicate poor treatment follow-up and the presence of MDR-TB.

#### **Recommendations:**

- NTP should treat all TB patients through DOTS-based national guidelines and ensure their registration and reporting.
- NTP should give the highest priority to improving access to laboratory diagnosis outside Yerevan and to identification of sputum smear-positive patients, thus aiming to improve the NTP detection rate significantly and achieve the global target of 70%.
- NTP should significantly decrease the proportion of patients not evaluated.
- NTP should analyse the case detection and treatment success rates in each marz and undertake specific actions locally to improve performance.

### 3.3 Management and organization

#### **Management**

Since the start of DOTS implementation in Armenia, NTP has been a “DOTS project” run by a group of specialists from RTBD and implemented through the available TB facilities network. The Prime Minister created the “National Intersectoral Board of Health Programmes” in December 2003 (decree n° 1680). The Board is composed of representatives from MOH, 9 other ministries and 6 state departments; its role is to steer NTP implementation and ensure interagency collaboration and coordination for TB control. MOH, through NTP, is directly responsible for implementation. NTP is organized as shown in Annex 5.

An important achievement for strengthening NTP has been the establishment of the NTP Central Office as a distinct entity accountable to MOH (February 2004, order n° 90/A). The NTP Central Office is responsible for overall management and coordination of TB control activities, including training of staff, management of drugs and laboratory supplies, data collection and maintenance of the national database, supervision, and organization of information, education and communication (IEC). It is staffed by 11 persons and has access to a separate line of the MOH budget covering salaries and office operational expenses. The NTP Central Office is located in the Republican Centre of Mother and Child Care in Yerevan. The premises are presently being renovated with KfW support. This renovation will be completed by September 2005 and will provide the NTP Central Office with proper space for administrative work, training and storage of drugs.

Eleven regional NTP coordinators were appointed by MOH in September 2003 (order n° 913) for the 10 *marz* and Yerevan city. These coordinators are heads or deputy heads of the Health and Social Protection Department in the Governor’s Office of the *marz*. They are accountable for NTP implementation in their respective territories and are supported by TB specialists for training coordination, distribution of anti-TB drugs, monitoring and supervision, and reporting.

The establishment of the NTP management structure described above is seen as a very important development, which creates the necessary conditions to address the complex challenges faced by the country, e.g. with regard to coordination across sectors, and expanding the framework to include other aspects of TB control, such as TB/HIV and management of drug-resistant tuberculosis.

The NTP Central Office has made considerable progress since its establishment. However, some operational constraints are still present: most of the staff work part-time, the position of epidemiologist is not filled, and training responsibilities are not clearly distributed. The NTP Central Office has not yet established effective working relationships with the Ministry of Justice, National AIDS Centre, State Hygienic and Anti-epidemic Inspection, National Centre for Disease Control (NCDC), NGOs and external partner agencies, although this is outlined in its terms of reference. The official TB counterpart for the WHO country office in Armenia is not part of the NTP Central Office, a situation that has created misunderstandings in the past and slows down the implementation of the Biennial Collaborative Agreement between MOH and WHO. As suggested in a recent report on organizational development (consultancy supported by GTZ), there is a need for improvement in office administration, information management and communication between team members.

The new NTP coordinators have a key role to play in the process of decentralization of management, coordination with the general health care services, and increased accountability to MOH. Moreover, they could be essential for ensuring local coordination with other programmes (e.g. HIV/AIDS and PHC) and other ministries (e.g. education, justice, etc.). However, their specific functions have never been communicated clearly, and nor has their relationship with the TB reference professional in the *marz*.

### **Organization**

TB services in Armenia are provided by 43 facilities: the Republican TB Dispensary (RTBD), 7 other TB dispensaries, 2 inpatient units in general hospitals, and 35 TB cabinets located in polyclinics. The TB services provided under other systems (penitentiary, military, private) are not included here.

TB Dispensary	Beds
RTBD	330
Gumri	50
Yerevan City	40
Aparan	30
Artashat	30
Sevan	30
Kapan	30
Goris	30
Vanadzor	15
Oktemberyan	10
Total	595

The RTBD, the main TB institution in the country, is located in Abovyan, 20 kms from Yerevan. The RTBD has 330 beds, of which 40 are for patients under investigation, 140 for adult patients under medical treatment, 30 for paediatrics, 30 for psychiatry, 35 for orthopaedics, 30 for urology and 25 for thorax surgery. Inpatient care is also provided in 9 additional sites (see table).

In total, there are 595 hospital TB beds in Armenia, not including about 25 beds in the Dilijan sanatorium. The penitentiary, military and private sectors are not included here. The staff that provide TB services consist of 78 TB specialists, 31 microbiologists, 102 nurses and 51 laboratory technicians.

### **Recommendations:**

- MOH should ensure that NTP plays a leading role in all aspects of DOTS implementation, and that communication, coordination and efficiency are reinforced within the NTP Central Office and with all partners involved.
- MOH should ensure that TB counterparts for the WHO Regional Office for Europe are also part of NTP.
- MOH should define and communicate the terms of reference of regional (*marz*) coordinators and clarify their functions and responsibilities vis-à-vis the NTP Central Office and TB specialists.
- NTP should fill the position of epidemiologist. All staff in the NTP Central Office should have clear, full-time responsibilities, without any overlapping.

### **3.4 Financial resources**

The overall fiscal situation has been very difficult during most of the transition period in Armenia and has led to precariously low public sector funding for health care. As a result of the sharp decline in the Gross Domestic Product (GDP) (in 2000 it was only two thirds of the 1990 level) and the associated fiscal retrenchment, health sector spending in Armenia

dropped by about 40% during the first half of the 1990s. The effects of the 1998 crisis in the Russian Federation and a high debt service burden called for further fiscal adjustments during 1999–2001, and the government largely failed to protect social sector spending during this time. As a result, health sector spending dropped to under 1% of GDP by 2000, while actual sector financing amounted to less than half the approved budget during that year. Efforts were made to increase budgetary allocations and actual budget execution to the health sector as of 2002. However, overall spending on health care in Armenia remains among the lowest in the former Soviet Union countries: public sector expenditure on health amounted to only 1.2% of GDP or 6.3% of total public sector spending in 2003 (compared to the EU average of 6–8% of GDP and 13% of total public sector spending).

	1998	1999	2000	2001	2002	2003
GDP growth (%)	7.2	3.3	6.0	9.6	12.9	13.9
Budgetary expenditure/GDP (%)	21.4	24.5	21.6	20.8	19.4	19.3
Health sector spending (AMD billion)	13.7	13.6	9.8	15.7	16.0	18.5
Health sector spending (US\$ per capita)	8.9	8.4	6.1	9.4	9.3	10.8
Health sector spending/GDP (%)	1.1	1.1	0.7	1.3	1.2	1.2
Health sector spending/total state budget (%)	5.4	4.6	3.1	6.4	6.0	6.3
Health sector financing/approved state budget (%)	84	78	47	88	98	93

During the last 6 years, Armenia has taken decisive steps towards reforming the health financing system. With the support of the World Bank-funded Health Financing and Primary Health Care Development Project (1998–2003), the central State Health Agency (SHA) was created, purchasing and provider functions were separated, the Ministry has withdrawn from direct provision care, and providers are financially autonomous, receiving public funds through contracts with SHA. Public funding for health care has been streamlined into a Basic Benefit Package (BBP) financed by SHA. However, the continuing low overall level of health spending results in underfunding of BBP and low reimbursement rates, thus leading to rationing and informal payments, which negatively affects the access of lower income groups to care.

The state budget is the main source of funding for TB control activities in Armenia. Tax revenues are collected at central level; the health sector budget is agreed between the Ministry of Finance and MOH and then administered by SHA by contracting health care institutions. It is difficult to distinguish exact spending on TB care within overall health care spending, as the latter consists of 5 categories, the major two being hospital care and primary/ambulatory care. However, MOH and NTP estimated that expenditure for TB control (both inpatient and outpatient care) was around AMD 1550 million (about US\$ 3.0 million) in 2004.

Adopted by governmental decree n° 1030-N, the Medium-Term Expenditure Framework (MTEF) 2004–2006 intends to increase the share of the social sector in public funding, including health care. In the table below, forecasts for overall health sector expenditure and spending on TB control through 2007 are presented.

Among international organizations assisting Armenia in the area of TB control, the most important support has come from the German Government (GTZ and KfW) since 2002. The GTZ technical assistance programme is worth about EUR 0.5 million (2002–2005). KfW support began at the beginning of 2004; its commitment of EUR 2.25 million extends until the end of 2008. The International Committee of the Red Cross (ICRC) has been assisting

with DOTS implementation in the penitentiary system since 2000, and the current agreement with the government is until the end of 2008; financial commitments are reviewed on a yearly basis. Médecins Sans Frontières (MSF) France obligated US\$ 3.8 million for a pilot DOTS-Plus project in 2005–2008.

	2004 budget	2005 planned	2006 forecast	2007 forecast
Health sector spending (AMD billion)	25.0	31.7	36.8	50.1
- including hospital care spending (AMD billion)	12.9	13.5	14.3	18.3
- including primary/ambulatory care spending (AMD billion)	8.7	12.5	15.4	21.2
- including spending on TB control	1.5	1.7	2.0	2.4
Health sector spending/GDP (%)	1.4	1.6	1.7	2.1
Health sector spending/total state budget (%)	7.4	8.7	9.2	11.3

Regarding provider payment mechanisms, SHA allocates funds to outpatient TB dispensaries and cabinets using a combination of capitation and fee-for-service principles. For inpatient care, 60 days of stay (55 in 2004) are now covered with a daily rate of AMD 6800 (about US\$ 14.5 at the current exchange rate), i.e. a total of AMD 408,000 (about US\$ 870) per inpatient. Although it looks like a per-case payment, the linkage to the number of days (i.e. the hospital does not receive money if the patient is discharged before 60 days of stay) actually transforms this scheme into payment according to bed-days. This creates an incentive for hospital managers to keep patients in bed for exactly 60 days to receive optimal payment from SHA (during site visits, it was observed by mission members that the average length of stay of inpatient units in 2004 was very close to 55 days, i.e. the number of days paid by SHA in that year). At the same time such a scheme creates problems, if a patient needs to stay longer, and may lead to distortions in reporting.

Although health care institutions received greater autonomy, also with regard to payment of staff, TB service providers still receive very low salaries; no performance-based or hazard-based motivation payments are made. This deters graduates and young professionals from joining the service and makes the existing staff seek jobs in other specialties or outside the profession.

MOH is willing to develop a TB project proposal for GFATM Round 5 (deadline for submission is 10 June 2005); technical assistance in proposal development will be provided by KNCV and the WHO Regional Office for Europe. For this purpose, a funding gap analysis should be undertaken.

**Recommendations:**

- The Government of Armenia should progressively increase its financial support to TB control, raise staff salaries, and introduce incentives linked to performance and professional hazard.
- MOH should identify the financial resources required for TB control in a medium-term perspective and identify the funding gaps.
- MOH should revise its methods for calculating funds allocation to TB inpatient care, which should not penalize TB outpatient care.
- MOH should start developing a TB project proposal, which considers the funding gaps identified in TB control during the next 5 years, for submission to GFATM by the deadline of Round 5.
- MOH should especially consider the following areas for GFATM support: implementation of DOTS through PHC, social support to TB patients and mechanisms of incentives/enablers, drug supply and management, TB/HIV collaborative interventions, drug resistance surveillance, DOTS-Plus, nosocomial infection control and IEC.
- MOH should start planning for long-term sustainability of NTP and for ensuring funding of activities after the current external support has stopped.

**3.5 Cooperation with partners**

A number of international partners are supporting TB control activities in Armenia (see table).

Area of support	CDC	GDF	GTZ	KfW	ICRC	MSF	ARCS	WB	WHO
Policy			T						T
Training			T		T	T		T	T
Laboratory			T	F	F/T	F/T			T
Drug supply		T	T	F		F			
Surveillance	T		T	F					T
Supervision			T						
Research	F/T								
IEC			T				F/T		
DOTS-Plus						F/T			T
TB in prison					F/T				
TB/HIV			T		T		F/T		

Note: F = financial support; T = technical support

The most significant support comes from the German Government, i.e. the Kreditanstalt für Wiederaufbau (KfW) and GTZ. KfW (2002–2005) covers the procurement of first-line drugs (directly purchased from GDF), laboratory equipment and supplies, and vehicles for supervision. KfW also supports national DRS and the renovation of the NTP Central Office. GTZ (2002–2005) provides local policy advice and technical assistance, and supports training, supervision and IEC. It is anticipated that GTZ and KfW interventions will merge their projects in the middle of 2005 under the responsibility of KfW.

ICRC (2000–2008) supports DOTS in the penitentiary system through technical assistance, infrastructure, equipment, drugs and other supplies, training and IEC.

The Centers for Disease Control and Prevention (CDC, Atlanta, United States) is assisting a three-year project (2005–2007) funded by the United States' government under the Biological Technology Engagement Programme (BTEP). This project is implemented together with the State Sanitary and Anti-epidemic Inspection (SAI), the National Institutes of Health (NIH), the Armenian branch of CDC and RTBD. It focuses on selected issues of TB surveillance and research, including the evaluation of the TB surveillance system, estimation of TB prevalence, and strengthening data management systems at different levels.

Médecins Sans Frontières (MSF) – France (2005–2008) supports a DOTS-Plus pilot project in Yerevan city, which includes the upgrading of laboratory and inpatient care infrastructure and the treatment of approximately 30 new MDR-TB patients per year.

The World Bank supports NTP indirectly through the retraining of PHC providers under the Family Medicine Development component of the Health Care Modernization Project.

The Armenian Red Cross Society (ARCS) has recently been involved in a number of small-scale projects focusing on social support to TB patients and IEC.

WHO (2004–2005) provides support for international training, NTP monitoring and technical assistance through its TB Office for South Caucasus, based in Tbilisi (Georgia), and its other offices at country, Regional and headquarters level.

A TB Interagency Steering Committee was established in 2003 to improve the coordination of all NTP partners, with GTZ as secretariat. Later the NTP Central Office took over this responsibility. For some reason, no further meetings have been organized since then, the last Steering Committee meeting having been held in March 2004. Moreover, effective collaboration is still missing between NTP and key partners such as the Ministry of Justice (MOJ), National AIDS Centre, SES, CDC, nongovernmental organizations (NGO), and other potential partners.

The existing Country Coordination Mechanism (CCM) applied successfully to GFATM (Round 2) for HIV/AIDS under the name of “Country Coordination Mechanism on HIV/AIDS Prevention in the Republic of Armenia”. It is specifically tailored to the HIV/AIDS area and is composed of 28 members. MOH plans to establish separate CCMs for submitting separate TB and malaria proposals, which is not an accepted procedure by GFATM.

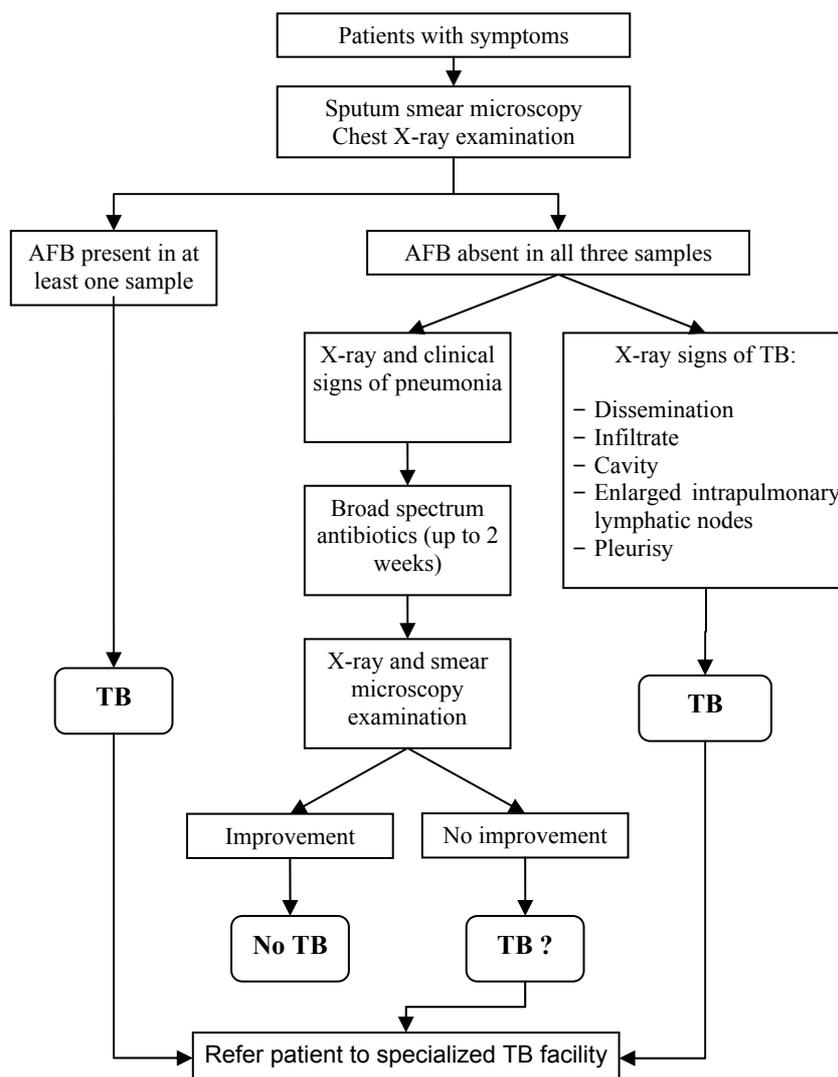
**Recommendations:**

- NTP should take the lead in coordination with partners and re-instate regular meetings of the TB Interagency Steering Committee.
- NTP should expand its collaboration and coordination with additional partners, such as the Ministry of Justice, the National AIDS Centre, the State Sanitary and Anti-epidemic Inspection, NGOs, and other relevant and potential partners.
- NTP partners should continue their support in the areas of expertise that ensure NTP ownership and delegation of responsibilities to national partners in the process of capacity-building.
- MOH should establish only one CCM to apply to GFATM, with balanced representation for HIV/AIDS, tuberculosis and malaria, and with a manageable number of participants.
- MOH should establish a working group to develop the TB proposal for submission to GFATM.

### **3.6 Diagnostic services**

NTP case-finding is mainly dependent on the self-reporting of patients to TB facilities. NTP also practises active TB case-finding in specific groups of population.

Respiratory patients approach the doctor, who should follow a specific algorithm recommended by NTP for the diagnosis of pulmonary TB in adults (see figure). Extra-pulmonary TB and TB in children are investigated by specialists. Since they do not have an NTP manual, this algorithm is unknown to a large number of health providers. Sputum samples are collected at the TB laboratory and never at PHC level.



Although direct sputum smear microscopy is recommended, most TB patients (according to many people interviewed by the mission) are diagnosed by miniature or standard radiography. Sputum microscopy and bacteriological culture are mainly used to determine the infectiousness of the patient.

In practice, TB is diagnosed mainly by specialists in TB facilities, while other health providers working in hospitals, polyclinics and feldsher accoucheur posts (FAP) are not involved. This may contribute significantly to the low NTP case-finding and late TB diagnosis resulting in the frequent observation of complicated forms of disease. Under the World Bank-supported project, an increasing number of doctors are trained in family medicine where the curriculum includes the identification of TB suspects for referral to specialists.

TB active case-finding is performed in accordance with current MOH orders. MMR is requested every 6–12 months for broad groups of population. However, it is not always performed due to lack of functional equipment and supplies and difficulty in reaching some populations. The targets for TB screening are:

- people with social problems, such as refugees, the homeless, detainees, former prisoners, orphans and people in hospices, and people in narcology and psychiatry institutions;
- people with medical problems, such as those with occupational pulmonary disease, diabetes mellitus, gastric and duodenal ulcer (including those who undergo surgery), treatment with corticosteroids, cytostatic drugs, radiotherapy, and with HIV and post-TB radiological anomalies;
- persons having contact with TB-infected people or animals; and
- employees of schools, municipal services, public transport, catering and grocery stores.

Once a sputum smear-positive TB case is identified, it is notified to SES. An SES team is expected to visit the residence of each TB patient for contact tracing, health education, vaccination, preventive treatment and environmental disinfection. TB environmental disinfection is currently considered an obsolete practice with a very low cost-effectiveness balance.

Sputum microscopy is performed in 15 laboratories variously located in the country. Most of them have an old monocular microscope. Laboratory consumables are purchased locally. NTP has produced national guidelines for TB sputum smear microscopy.

Respiratory patients, besides paying for transport to reach the laboratory, have to pay for microscopy, which is reimbursed only after diagnosis of TB has been confirmed. This charge discourages many people from seeking care promptly. In January 2005, MOH introduced free-of-charge sputum microscopy through an order that needs to be reinforced by close monitoring.

In 2003, most peripheral laboratories visited by the mission had a workload of only 5–10 slides per quarter, with very often less than three sputum smears examined per TB suspect patient. The positivity rate of sputum microscopy ranged from 8% to 75%. Such a wide range can be explained by a varying working performance and the selection of patients sent for investigation.

With KfW and GTZ support and the greater involvement of the National TB Reference Laboratory (NRL) in Abovyan, laboratory capacity under NTP will increase in the coming months. More TB laboratories will be established, although the number is still to be decided, as well as their location inside and outside polyclinics. New binocular microscopes will be supplied shortly. Laboratory consumables will be procured centrally and laboratory reagents will be prepared by NRL for quarterly distribution. Sixty-five percent of staff have already been trained or retrained during 2004 by NRL. Twelve laboratories have been visited twice by NRL; some discrepancies were detected during cross-checking of slides and were corrected by written feedback and a second supervisory visit.

ICRC funded the construction and equipping of a new TB laboratory on the premises of the RTBD in 2001 to serve both the penitentiary and civilian systems. This well equipped and organized laboratory with trained staff became de facto the NRL in Armenia; however, it was never officially appointed by MOH. RTBD covers the running costs, including staff salaries and consumables.

The staff working at NRL are composed of three doctors, seven laboratory technicians and two sanitarians. TB patients from the whole country are sent to RTBD and investigated by NRL. During the first 9 months of 2004, NRL performed 7000 smears, 2880 cultures and 513 DST. The TB Dispensary in Yerevan city also performs TB bacteriological cultures, although of unconfirmed quality. NRL is linked to the Supranational TB Reference Laboratory (SRL) in Borstel (Germany) and has already passed two proficiency tests for external quality control. Internal quality control is routinely performed. Maintenance of laboratory equipment is routinely provided with ICRC support. A recording system is in place, supported by an excellent individual database developed with ICRC.

NRL, besides its services for TB control in prisons, has a key role to play in the current and future activities of NTP. It is in charge of the national programme of laboratory training. It has started to provide supervisory visits to the peripheral laboratories and cross-checking of sputum slides. It will soon start national DRS and support to the DOTS-Plus pilot project implemented by MSF. The workload of NRL is planned to increase significantly in the coming months and will require a proportionate increase in staff. To streamline its administrative management and to allow for future increases in its budget and staffing, NRL needs to receive official status from MOH.

**Recommendations:**

- NTP should expand its strategy for case detection and include family medicine providers and the primary health care level.
- NTP should increase access to sputum direct microscopy by collecting sputum samples or smearing slides at peripheral level and sending them to the TB laboratory.
- NTP should revise the present TB laboratory network and optimize it, ensuring a balance between accessibility, workload, staffing and infrastructure.
- MOH should ensure that diagnosis of TB is provided free of charge and without any advance payment.
- NTP should ensure the most appropriate allocation of the new laboratory equipment and the uninterrupted supply of laboratory consumables.
- MOH should officially designate the TB laboratory in the Republican TB Dispensary in Abovyan as National TB Reference Laboratory (NRL).
- MOH should provide NRL with a distinct line in the annual budget of the ministry and increase the number of staff proportionate to the increasing functions and workload.
- SES should abandon environmental disinfection of TB patients' residences and redirect resources to more cost-effective interventions (e.g. health education, tracing of defaulters, etc.).

### 3.7 Treatment services

NTP categorizes TB patients into four categories for treatment and accordingly recommends treatment regimens of international standard (see table). Fixed dose combination (FDC) drugs are supplied by KfW/GDF. In prisons, all TB patients are placed in three categories, daily treatment is maintained during the maintenance phase, and the formulation of drugs is different because they were not procured through GDF until recently. From 2005, all drugs will be provided to prisons by NTP.

Category of patients	Intensive phase	Maintenance phase
I and III	2HRZE	4H <sub>3</sub> R <sub>3</sub>
II	2(HRZE)S/1(HRZE)	5H <sub>3</sub> R <sub>3</sub> E <sub>3</sub>
IV	Individualized	

Armenia, as in other former Soviet Union countries, has a backlog of registered “chronic” TB cases, which do not correspond to the WHO definition of Category IV patients. These people receive seasonal preventive

treatment (isoniazid or isoniazid and rifampicin) or treatment with second-line anti-TB drugs when symptomatic.

Many TB patients are placed by NTP under “non-DOTS” treatment in various circumstances, such as the presence of concomitant diseases, the past defaulting of treatment, the occurrence of adverse reactions to drugs, etc. Both the absence of written NTP guidelines and “non-DOTS” practice very often lead to poor quality, individualized treatment regimens, which are at high risk of developing drug resistance. Treatment with only two susceptible anti-TB drugs was observed by the mission in one site.

All TB patients, including those who are sputum smear-negative, are admitted to the TB dispensary during their intensive phase treatment. The main institution for inpatient care is the RTBD. Patients are referred here from all over the country, while the TB dispensaries at *marz* level have a rather low bed occupancy rate. The environmental measures for controlling TB nosocomial infection are usually poorly applied, and patients are often distributed in the wards with little regard for their infectiousness.

The maintenance phase of TB treatment is mostly outpatient care, however without directly observed treatment (DOT). Patients collect anti-TB drugs every 2 to 4 weeks from the TB dispensaries and TB cabinets in polyclinics, depending on the distance from the patient’s residence. Non-DOT practice is especially alarming in certain groups of patients. The long distance to cover for TB treatment seems to be the major factor for treatment defaulting. Stigma and low education in TB and health issues are contributing factors. A limited incentive scheme has been introduced in Vanadzor and Stepanavan by the Armenian Red Cross and the Nordic Red Cross, consisting of US\$ 5 reimbursement to nurses visiting TB patients and ensuring DOT. Each *marz* has a number of family doctors and registered nurses working in FAP and providing basic health care services. They seem the most appropriate health care level where anti-TB drugs can be provided under DOT.

There is a need to revise the pool of “chronic” cases in order to clarify their total number, the number of sputum-positive patients and the most common anti-TB drug resistance pattern.

This will allow for proper planning of DOTS-Plus interventions. Drug susceptible sputum-positive “chronic” cases should be treated with the standard Category II treatment regimen.

**Recommendations:**

- NTP should limit the hospitalization of sputum smear-negative patients without serious medical or socioeconomic conditions requiring inpatient care.
- NTP should prevent TB over-infection in hospitals by separating the different categories of patients (smear-positive and smear-negative, new and retreatment/chronic cases).
- NTP should involve family doctors and the primary health care network to ensure directly observed treatment during the maintenance phase and tracing of defaulters.
- NTP should strengthen directly observed treatment during the maintenance phase by introducing, after piloting in limited areas, a system of incentives and enablers for patients and providers.
- NTP should revise the pool of chronic smear-positive patients and consider their treatment with the Category II regimen in cases where the drug susceptibility pattern is not known and a full course of this regimen was never provided.
- NTP should abandon the “seasonal” preventive treatment of “chronic” TB patients.

### **3.8 Drug supply and management**

There are several sources of TB drugs in the country, including agencies providing humanitarian assistance (HAA), other international organizations, and centralized state procurement. Currently, TB drugs are provided by KfW through the GDF Direct Procurement mechanism. In addition, many programme sites still use TB drugs donated by HAA for treatment of “non-DOTS” or “chronic” patients. In the penitentiary system, TB drugs were supplied by ICRC; a further supply has been and will be provided through NTP.

Another source of TB drugs is the retail sector; TB drugs are sold freely in local pharmacies. The drug policy in the country prohibits the sale of TB drugs without prescription; however, there is a need for enforcement of this policy. The pharmaceutical department of MOH is responsible for monitoring sales in pharmacies. Further investigation is needed to identify and address the underlying factors.

There are no local manufacturers of TB drugs in the country and all TB drugs are imported. TB drugs supplied by GDF are not registered; MOH issues a one-time permit for each shipment from GDF. Registration of other TB drugs provided through HA channels expires in 2007. Furthermore, the Essential Drug List (EDL) and national formulary do not reflect most TB drugs/strengths recommended by NTP. The national formulary and EDL need updating, based on finalized national guidelines (to be completed by NTP) in the light of future procurement efforts to secure TB drug supplies upon completion of the KfW grant in 2008.

Streamlining TB drug management practices has been an important step for the TB programme. The establishment of the NTP Central Office has allowed for improvement in

programme capacity at national and marz levels and addressing the drug management aspects of the programme. Major issues experienced by NTP in drug management pertain to the availability of TB drugs. According to the baseline study carried out by GTZ and NTP in June 2004, TB drugs of the strengths recommended by WHO and NTP were not always available in the programme sites. In the meantime, the strengths of some TB drugs made available through HAA differed from those recommended for standardized regimens by NTP. Based on the findings, a number of interventions were implemented, including the development of the drug management information system (DMIS) and training. With technical assistance from GTZ, NTP developed a manual for drug distribution that incorporates standardized forms for drug distribution and dispensing. The study carried out in January 2005 documented the considerable progress made in ensuring the availability of all NTP-recommended TB drugs/strengths, proper reporting and recording, regular distribution (and redistribution, as needed) of TB drugs among the sites, and increase in knowledge of the staff.

Since June 2004, there have also been improvements in drug storage conditions at the NTP Centre and programme sites. Thanks to the efforts of GTZ and NTP, storage has been centralized at the NTP facility, where TB medicines are delivered upon clearance by the customs (the process can take up to 14 days). Currently, TB drugs are stored under satisfactory conditions in a temporary storage room at the NTP Centre. The NTP pharmacist, who was trained by GTZ, has been able to properly organize the storage room and maintain an accurate record-keeping system. Renovation of the central storage facility, including two storage rooms equipped with means for temperature and humidity control, is expected to be completed in 2005.

TB drugs are distributed semi-annually from the NTP Centre to each TB facility, based on pipeline data and estimates of need. Fourteen out of the thirty-four sites have already been trained in record-keeping and quantification of drug needs. Drastic improvements have been observed in the trained sites visited by the team. Nevertheless, even in the trained sites, there is a need for further improvements, e.g. monitoring rotation of stock, redistributing TB medicines etc. The training is ongoing, and DMIS is expected to be introduced in an additional 20 sites by the end of March 2005.

While progress in the above-mentioned areas has been reported, there are also areas where improvement is needed, including DOT in the continuation phase (see *Treatment services*). The accessibility of TB drugs could be improved by decentralizing drug dispensing to the closest primary care provider level. Currently, the TB programme is not integrated into primary care. However, the first steps have been taken towards this, such as translation of the WHO TB manual for primary health care providers. Further steps entail identifying the level of personnel to be involved, developing a regulatory basis, and training providers. NTP needs to have at least one full-time pharmacist and develop a structure, approach and plan to address drug management at marz and rajon levels.

Drug prescribing in general complies with WHO guidelines, as the DOTS strategy is accepted nationwide. However, providers refer to the WHO-recommended guidelines, which are not currently supported by a regulatory framework. Lack of national TB guidelines officially approved by MOH contributes to shortcomings in the programme and can serve as grounds for error and irrational prescribing. For instance, some patients are differentiated into a “non-DOTS” (see *Treatment services*) group without proper justification of such a

differentiation or clear guidelines for managing these patients. In some cases, errors in prescribing may occur due to differences in the strengths recommended by WHO and those supplied in the sites. Currently, a new stock record-keeping system enables supervisors to track prescription patterns.

TB drug quality assurance is another area that needs improvement. The SCDMTE responsible for drug control has developed forms for reporting adverse reactions. However, NTP staff and clinical sites are not aware of the existence of these forms with the result that this mechanism has not been used for TB. The forms developed by the Centre can be adapted to the needs of NTP.

**Recommendations:**

- MOH should restrict procurement and use of TB drugs circulating in the MOH system to those provided by NTP.
- MOH should support NTP in its efforts to decentralize dispensing of TB drugs, so that TB patients are able to access TB drugs at the closest primary care provider level.
- NTP should finalize the national guidelines and add an explicit drug management component that includes guidance on ordering, receiving, storing, reporting and dispensing of drugs at all levels.
- MOH should update the EDL and national drug formulary to ensure consistency with the finalized version of the national guidelines.
- NTP should develop a structure, approach and plan to address drug management issues at marz and rajon levels in the light of the upcoming decentralization of drug dispensing.
- NTP needs to have at least one full-time pharmacist on the staff at central level and designate a person responsible for drug management at the level of each marz.
- NTP should guarantee long-term sustainability for the security of TB drugs through:
  - a) continuing the implementation of the new drug management information system, so that all 34 sites are covered as soon as possible;
  - b) ensuring that future supervisory visits cover the functioning of the drug management information system and include monitoring of drug use;
  - c) developing a financial plan for long-term sustainability of the TB drug supply; and
  - d) including a drug management component in the application to GFATM.
- The Scientific Centre of Drug and Medical Technology Expertise, in conjunction with NTP, should develop a system to report adverse reactions caused by TB medicines.
- NTP should evaluate the feasibility of introducing patient kits for future procurement from GDF.

### **3.9 Monitoring and evaluation**

#### ***Recording and reporting***

Registers, forms and cards for TB recording and reporting have been introduced by NTP, according to international standards, since the piloting of DOTS in the country. However, these records have not been printed regularly and TB facilities have had to use photocopies

for years. Through GTZ support, TB records are currently in printed form and widely available. TB patients are entered in the TB treatment register of the TB facility where the maintenance phase of treatment will be completed. The TB dispensaries have their own inpatient records. Non-DOTS patients are recorded in separate records.

Data from the TB treatment register at facility level are consolidated into quarterly reports for case-finding, sputum conversion and treatment results, which are submitted to the NTP Central Office where the TB quarterly reports are consolidated further on paper. GTZ introduced an individual TB database in 2003, which does include the DOTS patients reported in the civilian system. In addition to DOTS reporting, all facilities should notify new TB cases to SES and report monthly to MOH.

The mission team reviewed the TB records in the facilities visited. They were generally found satisfactory. Some discrepancies were found when compared with the entries at the NTP Central Office. The NTP Central Office needs a full time epidemiologist and staff training in computer entry. There is no collaboration between NTP and SAI.

### **Supervision**

NTP policy is to supervise all facilities every quarter. A supervision checklist was developed for this purpose and a team of supervisors from the NTP Central Office was established in 2004. This team is composed of one responsible person each in the areas of drug management, laboratory, statistics and clinical management. With GTZ support, all TB facilities have been supervised during the last 10 months. Twelve new vehicles were imported by KfW in December 2004. After customs clearance, which is expected very soon, 2 vehicles will be used for supervision and coordination by the NTP Central Office and 10 vehicles will be stationed at the Governor's Office of the *marz* and used for collection of drugs and laboratory items from Yerevan, supervision of facilities, collection of laboratory specimens and laboratory quality control, and transport of staff for training. The costs of fuel and maintenance will be borne by the Governor's Office.

Monitoring and supervision of NTP performance is of paramount importance for quality implementation of DOTS and should be ensured quarterly by NTP. The roles of the NTP coordinators and the TB professional in *marz* are not sufficiently clear and written job descriptions should be drawn up.

**Recommendations:**

- NTP should maintain only one recording and reporting system, which includes DOTS and non-DOTS patients and civilian and penitentiary systems. Close cooperation and coordination with SAI is recommended.
- NTP should further strengthen the complete and timely reporting of case-finding, sputum conversion and treatment outcome. Formal and on-the-job training should be provided on DOTS recording and reporting for the staff assigned at marz level.
- NTP should consider employing one full-time epidemiologist in its Central Office and organizing training in computer entry.
- MOH should ensure clear collaboration and coordination among the NTP coordinators and TB professionals at marz level for quality monitoring and supervision of NTP activities.

### **3.10 Training**

NTP has developed two training courses, one for TB managers and the other for laboratory technicians. The first course lasts 5 days and is adapted from the WHO training modules on “Managing TB at district level”. The second course, which lasts 10 days, takes place at NRL and is based on various materials produced internationally. In 2004, two persons from the NTP Central Office were appointed as trainers. During 2003–2004, 47 out of 78 TB doctors and 21 laboratory staff (11 doctors and 10 technicians) were trained through GTZ support.

Through the support of external partners, two persons from NTP are sent each year to the WHO TB Collaborating Centre in Warsaw (Poland) for training on TB management and laboratory training. Selected NTP staff are sponsored to attend at least one of the international TB conferences organized in the region each year, such as the Wolfheze workshops and the IUATLD conferences.

Under the “Health Care Modernization Project” financed by the World Bank, general practitioners are retrained in family medicine. This includes a 5-day course on TB diagnosis and treatment, which is provided by the Medical University and National Institute of Health Care. However, the job description of the future family doctor includes only clinical screening for early referral to a TB specialist. Unlike other conditions, such as hypertension or diabetes, the family doctor is not requested to monitor TB treatment, which is a lost opportunity to scale up DOT practice.

NTP has developed “Clinical guidelines on TB prevention and detection by the specialists of the somatic departments of Republic of Armenia general hospital facilities and PHC for TB detection”. These guidelines were endorsed by MOH in May 2004. The mission strongly recommends reviewing these guidelines to ensure that they comply with international recommendations on delivering DOTS at PHC level. WHO and the New Jersey Medical School National Tuberculosis Center have produced the “Brief Guide on Tuberculosis Control for Primary Health Care Providers”. This guide was recently translated into Armenian and can be used as the main reference for reviewing the NTP guidelines.

**Recommendations:**

- MOH should utilize the PHC level to decentralize TB case detection and management, and consequently to revise job descriptions and develop task-oriented training for doctors and nurses.
- MOH should ensure that directly observed TB treatment, together with early referral for TB diagnosis, is included among the tasks given to family doctors. Their training should be revised accordingly.
- NTP should urgently revise its guidelines for DOTS at PHC level. Available publications, including the “Brief Guide on Tuberculosis Control for Primary Health Care Providers” by WHO and the New Jersey Medical School, should be used as a reference.
- NTP should further develop the training skills of its staff and adopt the most appropriate adult learning methods.
- The Medical University and National Institute of Health Care should include DOTS in the curriculum of nursing and medical schools.

### **3.11 Information, education, communication**

There has been a lack of information, education and communication (IEC) provided by NTP in recent years, mainly due to financial constraints. Activities have been limited to the celebration of World TB Day (24 March) through press conferences, interviews on TV, and radio and newspaper articles. External partners have mainly funded these activities. Communication has never addressed potential gender differences in self-reporting of patients.

The GTZ project includes an IEC component, which focuses on the production of visual aids informing TB patients that treatment is free of charge. There is a plan to expand IEC to the general population. ICRC has been implementing IEC in prisons since 2002, targeting both TB patients and all inmates.

All the people met by the mission, including MOH and NTP managers and field providers, acknowledged the great need to expand IEC. The knowledge of the general population as to whether TB is a curable disease is poor, and the widespread perception is that only marginalized individuals, such as the unemployed and/or those with specific risk behaviour, can contract TB. TB is strongly linked to social stigma.

**Recommendations:**

- NTP should develop an IEC strategy which targets the general population and vulnerable groups. Gender differences in NTP case detection should also be considered. A knowledge-attitude-practice survey should be undertaken to provide the necessary information.
- NTP should plan and implement IEC campaigns aimed at decreasing social stigma and informing that TB is curable and treatment is free of charge.
- NTP should include a person responsible for IEC in its Central Office.

### 3.12 Research

The NTP needs for operational research are importantly addressed by BTEP, the 3-year project (2005–2007) jointly implemented by SES, NIH, CDC (Armenia) and RTBD, and assisted by CDC (USA). BTEP started in November 2004 and has 4 research-related tasks:

- to clarify uncertainty regarding TB incidence. It is planned to undertake a population TB prevalence survey in 3 areas (Yerevan, Shirak, Lori) or among TB high-risk groups;
- to improve understanding of undetected TB cases. It is planned to undertake focus group and exit interviews of patients referred by TB cabinets and polyclinics for sputum smear examination;
- to determine private sector use of TB medications. It is planned to undertake a retrospective survey regarding type and quantity of anti-TB drugs imported and registered in Armenia and their distribution to major wholesale sites; and
- to evaluate the population of so-called chronic TB patients. It is planned to undertake a review of hospital records and reclassify previously diagnosed chronic TB patients.

The TB prevalence survey would provide the possibility of revising the present WHO estimates for Armenia (and possibly for all South Caucasus), and calculating the actual TB case detection rate achieved by NTP. This survey will be implemented by NIH and will therefore not divert NTP resources from DOTS implementation. No surveys of this kind have been performed in Europe for many years. All other operational research under BTEP is directed towards documenting the efficacy and effectiveness of DOTS compared with other strategies to control TB.

Considering the relevance of the BTEP tasks to NTP and improving the quality of DOTS implementation, closer links need to be established between the institutions concerned. Moreover, the ultimate responsibility for TB laboratory investigation and TB recording and reporting should be clarified.

#### **Recommendations:**

- BTEP partners should ensure regular communication and collaboration with NTP, under the common goal of achieving TB control in Armenia.
- MOH should ensure quality monitoring of NTP performance, of international comparison, and clarify ultimate responsibilities and linkages between NTP and BTEP partners.
- BTEP partners should undertake a TB prevalence survey involving NTP, but avoiding diversion of important resources from DOTS implementation.

### 3.13 National drug resistance surveillance

Country representative DRS is planned to start in 2005 with the assistance of KfW and WHO. The draft survey protocol considers including all sputum smear-positive cases (new and previously treated) registered in all TB facilities in both civilian and penitentiary systems. Consecutive sampling will be adopted to investigate a minimum of 450 patients within a period of 12 months. Culture, identification and DST of first-line anti-TB drugs will be

performed at NRL. External quality control and DRS for second-line drugs will be performed by the SRL in Borstel (Germany). The current legislation prohibits the shipment of biological isolates outside the country and needs to be revised urgently.

While DRS can start in prisons shortly, several conditions must be met before starting DRS in the civilian system:

- all TB laboratories have a working new binocular microscope
- all laboratory staff are trained
- laboratory quality control is checked in all peripheral laboratories
- referral and classification systems are checked
- additional staff, as required, are posted at NRL
- safe transport of sputum specimens to NRL is ensured
- present limitations for shipping samples outside the country are overcome.

**Recommendations:**

- MOH should revise the current regulations and allow the shipment of TB strains between NRL and SNL for implementing DRS and external quality control.
- ICRC should support the start of DRS in the penitentiary system as soon as possible.
- NTP must meet the following conditions and start DRS in the civilian system as soon as possible:
  - all TB laboratories have a working new binocular microscope
  - all laboratory staff are trained
  - laboratory quality control is checked in all peripheral laboratories
  - referral and classification systems are checked
  - additional staff, as required, are posted at NRL
  - safe transport of sputum specimens is ensured to NRL
  - present limitations for shipping samples outside the country are overcome.

### **3.14 DOTS-Plus**

MOH requested technical assistance from GLC in addressing the problem of MDR-TB in the country, including the identification of specific requirements for implementing a DOTS-Plus pilot project and preparing the MDR-TB component for the application to GFATM (Round 5).

There has been considerable progress in DOTS implementation during the last year and a half. NTP is committed to implementing the DOTS-Plus strategy and willing to develop a short and long-term plan to manage MDR-TB in the country, including an application to GLC. The mission acknowledges the need for DOTS-Plus interventions in Armenia.<sup>1</sup>

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<sup>1</sup> It is estimated that about 110–120 new MDR-TB cases occur each year, of which 40 from new and 70 from previously treated sputum smear-positive cases. In addition, about 250 MDR-TB cases can be expected from the pool of estimated 500 “chronic cases” registered with NTP.

Nevertheless, the mission considers that NTP is not yet ready to implement a DOTS-Plus pilot project until the following programmatic conditions required by GLC are in place:

- Anti-TB drug intake is directly observed throughout the whole treatment course (Rifampicin is used in Armenia during both the intensive and the maintenance phases).
- NTP has full control over the distribution of all anti-TB drugs.
- All patients diagnosed with TB are registered and receive the same standard of care. Treatment outcomes should be available for all cases; there should not be any “non-DOTS” cases (see Chapter 3.2 of this report), which are likely to receive suboptimal treatment regimens and be difficult to manage clinically.
- Well-functioning quality assured laboratory network. Specifically, the peripheral laboratory network should be strengthened and routine quality assurance of DST should be in place.
- Data are available from a representative survey/surveillance of resistance to first- and second-line anti-TB drugs.
- Appropriate training on management of MDR-TB is provided to staff (e.g. at the WHO Collaborating Centre in Riga, Latvia).

MOH, the Mayor of Yerevan city and MSF-France are finalizing the procedures for collaboration under a Memorandum of Understanding signed in October 2004 for implementing a DOTS-Plus pilot project in two districts of Yerevan municipality, i.e. Shengavit district and Malatia-Sebasia district. Under this project, MDR-TB patients will be detected and treated at local PHC centres, respectively n° 18 and n° 19, with back-up from the Yerevan City TB Dispensary and the RTBD. The MSF/MOH project represents a golden opportunity to pilot DOTS-Plus interventions. However, it is at risk of creating duplication of existing NTP services, such as laboratory supply, procurement of first-line anti-TB drugs, and recording and reporting. The NTP should be fully involved in this project to ensure national ownership, capacity-building and the future sustainability of the interventions. MSF/MOH should apply to GLC before starting the treatment of anti-TB drug-resistant patients in order to ensure that the most up-to-date, evidence-based, standards of care are considered.

Starting a DOTS-Plus project in the penitentiary system seems less challenging. DOTS has been successfully implemented in prisons by the Ministry of Justice (MOJ) and ICRC, and TB patients are followed up after their release from prison.

**Recommendations:**

- NTP should apply to GLC at a later stage and after the following programmatic conditions are in place:
  - DOTS implementation is strengthened; DRS of first-line anti-TB drugs is carried out;
  - DRS of second-line anti-TB drugs is carried out;
  - A short and long-term strategy for MDR-TB management is prepared; and
  - Staff are trained in all aspects of MDR-TB management (e.g. at the WHO Collaborating Centre in Riga, Latvia).
- NTP should consider the following components in preparing the application to GLC:
  - inclusion and exclusion criteria for enrolling patients;
  - treatment regimens for MDR-TB patients which take into account the prevailing drug resistance pattern, history of previous drug intake and availability of second-line anti-TB drugs in the open market;
  - procedures for managing side-effects of second-line drugs;
  - database for MDR-TB as integral part of NTP recording and reporting;
  - strategies for regular monitoring, supervision and evaluation of the project;
  - strategy to ensure DOT, including incentives and enablers; and
  - infection control measures in inpatient facilities.
- MSF/MOH should apply to GLC before starting the treatment of MDR-TB patients.

**3.15 Tuberculosis in prisons**

In 2004, 391.3 new sputum smear-positive TB cases and 1673.9 total new TB cases per 100 000 were notified (the annual turnover of the prison population is used as a denominator). Available data, even if not fully representative, document that 11% of new and 46% of previously treated smear-positive cases have MDR-TB.

The penitentiary system in Armenia is under the authority of the Ministry of Justice and consists of twelve Criminal Executive Institutions: seven for pre-trial detainees, four for sentenced detainees and one hospital facility (mainly for sentenced detainees). The annual turnover of detainees was about 7500 until August 2003, when the Penal Law changed and

Year	Detained population (annual turnover)	Number of notified TB cases, all forms	Number of notified new smear- pos. cases
1999	7 900	236	42
2000	7 700	203	35
2001	7 800	229	21
2002	7 500	180	26
2003	6 500	180	31
2004	4 600	77	18

new forms of implementing sentences were introduced. In the following year, the annual turnover of detainees drastically decreased to 4600.

In August 2000, ICRC signed a cooperation agreement with MOH, MOJ and the Ministry of Internal Affairs. This agreement includes the improvement of infrastructure, training of medical staff working in prisons, supply of laboratory equipment and consumables, first-line anti-TB drugs and drugs for management of adverse reactions, health education, and treatment follow-up after the release from prison of TB patients.

Through the support of ICRC, a new TB department in the Hospital for Detainees was constructed and DOTS treatment started in November 2002. This date should be considered the start of DOTS in the penitentiary system in Armenia. In October 2003, DOTS was expanded to the largest pre-trial TB colony of Novbarashen. Another pre-trial TB colony for women and minors in Abovyan was included in the programme in October 2003. At present, DOTS is estimated to cover 3900 detainees (85%).

Active case-finding methods are used. Since 2004, the TB screening of all detainees has been implemented through MMR (ideally every 6 months), and active case-finding questionnaires applied to a list of pre-selected "TB suspects". First, a health education session is conducted in the prison. MMR of all inmates follows after one week. Then all the following cases are interviewed by means of a questionnaire:

- TB suspects during regular check-ups
- symptomatic inmates with complaints consistent with TB
- all TB suspects from MMR
- all inmates being followed up after successful treatment.

All those suspected of TB after the interview have their sputum investigated and those found sputum smear-negative are sent for additional assessment to the TB department. The direct microscopy of sputum is carried out by the Hospital for Detainees, while culture and DST is carried out by NRL.

TB treatment takes place in the TB department of the Hospital for Detainees and in the Novbarashen pre-trial institution. The TB department has 220 beds, most of which are not utilized. There are 5 doctors, 3 nurses, 2 feldshers and 2 laboratory technicians. All three treatment categories are used, according to NTP definitions.

From November 2002 to February 2005, the TB patients under the DOTS programme in the penitentiary system were: 49 (19%) new sputum smear-positive, 56 (22%) new sputum smear-negative, 4 (2%) relapses, 11 (4%) after failure, 4 (2%) after interruption, and 128 (50%) others. In the patients evaluated, the treatment success rate was 62.8% in new smear-positive cases and 54.1% in retreatment cases. Failure and defaulting rates were high in both groups (see table).

Treatment outcome	New SS+ cases (43 patients evaluated)	Retreatment cases (133 patients evaluated)
Cured	62.8%	34.6%
Tr. completed	0.0%	19.5%
Death	0.0%	3.8%
Failure	20.9%	22.6%
Default	16.3%	11.3%
Transfer out	0.0%	8.3%

All MDR-TB patients (confirmed by DRS) are concentrated in the MDR-TB unit of the TB hospital during the whole sentence period, and receive only symptomatic treatment and vitamins. After being released, these patients are followed up at home.

Immediately after the release of a TB patient under treatment, the prison staff hand over personally all clinical documentation to the TB facility of referral. Despite this strict arrangement, 30 (23%) patients defaulted out of the 92 released during August 2003–December 2004.

Since July 2004, the case-finding and treatment outcome quarterly reports have been sent to NTP. However, the data from prisons are not consolidated with those from the civilian system. MOJ, ICRC and NTP have agreed to share a unified patient database shortly.

DRS will start in the penitentiary system this year, covering all newly detected TB cases during a period of 12 months. MOJ and MOH are planning to apply jointly to GLC in future.

***Recommendations:***

- MOJ should start planning how to take over all ICRC-supported activities after 2008.
- MOJ should improve its collaboration with NTP in drug supply, information systems, supervision, DRS and TB/HIV management. Special efforts must also be applied to ensure effective follow-up of ex-prisoners who need to complete DOTS treatment in the civilian sector.
- MOJ and MOH should define a joint strategy to tackle the problem of MDR-TB in prisons.

### **3.16 HIV-related tuberculosis**

The Regional Office includes Armenia among those countries with a high priority for interventions to control TB and intermediate priority for interventions to prevent and control HIV/AIDS. This is explained by the high TB burden and growing burden of HIV/AIDS in all South Caucasus, following the collapse of the Soviet Union.

NAP in Armenia benefits from a 5-year GFATM grant of US\$ 7.3 million, which was signed in October 2003 with World Vision International (Armenian branch) as principal recipient. The Regional Office will assign a “3 by 5” Programme Officer to Armenia in April 2005. The main interventions supported by GFATM are: IEC, counselling and testing for HIV (CT) among risk groups (youth, IDU, SW, men who have sex with men, prisoners, migrants and refugees), construction of a new HIV national reference laboratory, antiretroviral treatment (ART) for 40 patients for two years, isoniazid preventive therapy (IPT), TB screening (by referring suspects to TB facilities), and blood screening. A new building will accommodate the National Centre for AIDS in summer 2005.

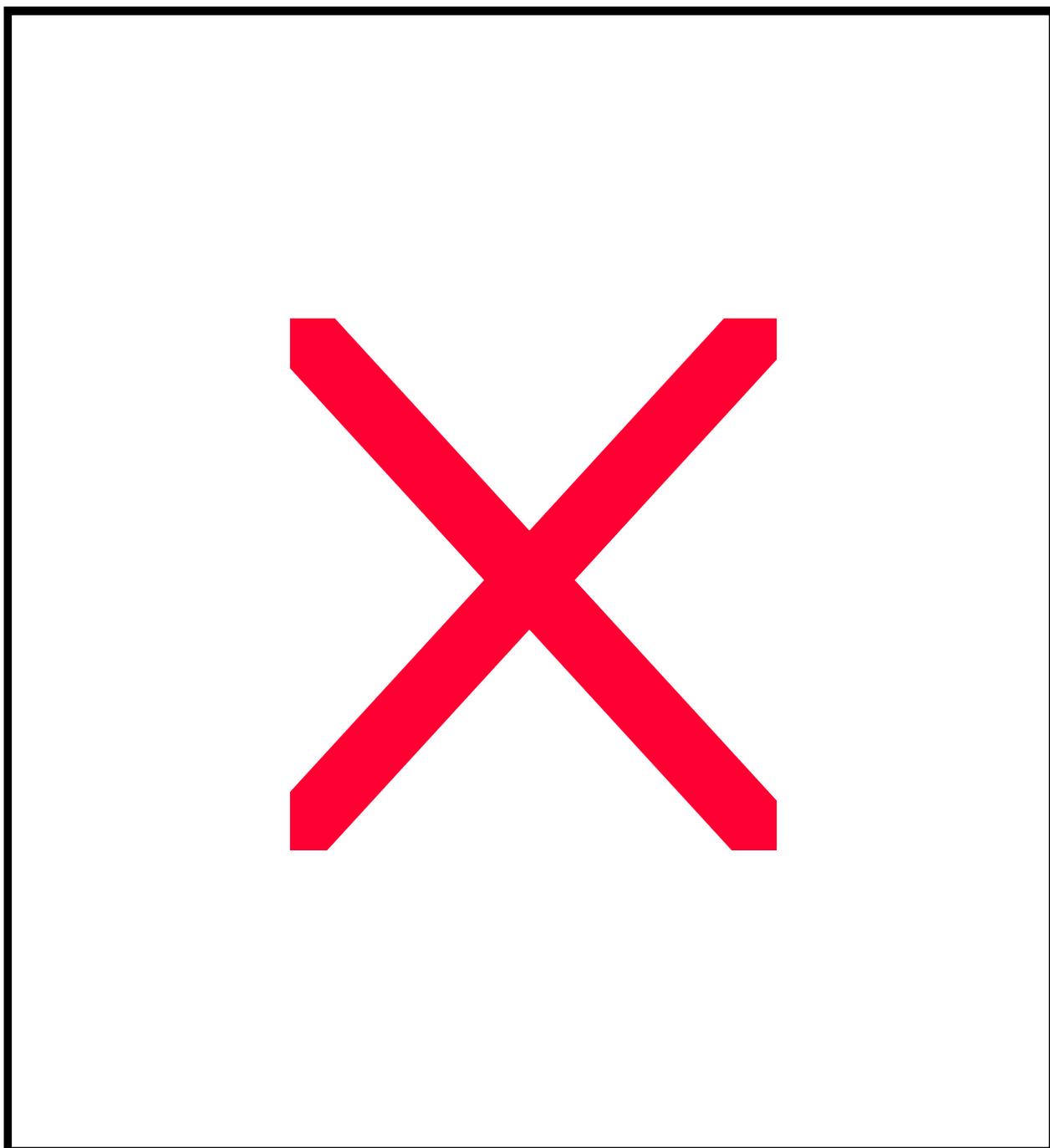
In 2003, NAP trained on CT a number of TB specialists from the RTBD and the Yerevan City TB Dispensary. Mechanisms were also established to transport blood samples to the AIDS centre for HIV testing. However, TB patients have been tested very irregularly. Meanwhile, the PLWH referred from the National Centre for AIDS to the TB dispensaries are perceived as stigmatized and do not show up for TB screening in 50% of cases. The GFATM grant does not include a number of interventions (i.e. HIV surveillance among TB patients, coordination body between programmes, revision of national policies, and communication), which are recommended for collaboration between NTP and NAP to effectively address the threat of HIV-related TB (TB/HIV).

***Recommendations:***

- NTP and NAP should establish a TB/HIV coordination body and undertake joint policy revision, HIV surveillance among TB patients, and patient education and mass communication.
- NTP and NAP should strengthen collaboration in IPT and early diagnosis of TB among PLWH by improving referral mechanisms, decentralizing services and preserving confidentiality.

*Annex 1*

MAP OF THE REPUBLIC OF ARMENIA



## Annex 2

### AGENDA OF THE MISSION

Date and time	Events
<b>Monday, 7 February</b>	
9:00 – 13:00	Debriefing, mission planning meeting
14:00 – 14:30	Meeting with the first Deputy Minister of Health Dr. Hayk Darbinyan
14:30 – 15:00	Meeting with Deputy Minister of Health (in charge of WHO country work) Dr. Tatul Akopyan
14:00 – 18:00	Meeting with NTP Central Unit
<b>Tuesday, 8 February</b>	
9:00 – 13:00	Visit to Republican TB Dispensary and National Reference Laboratory in Abovyan
11:00 – 13:00	Visit to the National AIDS Centre, project implementation unit of the GFATM grant
14:00 – 18:00	Meeting with the Chief Sanitary Doctor Dr. Vladimir Davidyants and local BTEP counterparts at the National Centre for Disease Control (NCDC) Visit to Yerevan city TB Dispensary
14:00 – 16:00	Meeting at MOH / Pharmaceuticals' Department
16:00 – 18:00	Meeting at the National Drug Regulatory Authority (NRA)
<b>Wednesday, 9 February</b>	
7:30 – 15:30	Site visit to <b>Gyumri</b> marz (Marz NTP Coordinator, TB in-patient unit, TB dispensary, general polyclinic, drug storage facility, pharmacies)
7:30 – 13:00	Site visit to <b>Dilijan</b> marz (Marz NTP Coordinator, TB cabinet, general polyclinic, drug storage facility, pharmacies)
13:00 – 18:00	Site visit to <b>Ijevan</b> marz (Marz NTP Coordinator, TB cabinet, general polyclinic, drug storage facility, pharmacies)
15:30 – 16:30	Meeting at the Ministry of Justice (Department of Penitentiary Institutions)
15:30 – 18:00	Meeting with representatives of the Ministry of Justice (Medical Service of penitentiary institutions), ICRC and site visit to Prison TB Facility
<b>Thursday, 10 February</b>	
8:00 – 18:00	Site visit to <b>Ashtarak</b> and <b>Aparan</b> marzes (Marz NTP Coordinators, TB in-patient unit (Aparan general hospital), TB cabinets, general polyclinics, drug storage facilities, pharmacies) Site visit to <b>Vanadzor</b> marz (Marz NTP Coordinator, TB in-patient unit, TB dispensary, general polyclinic, drug storage facility, pharmacies)
10:00 – 13:00	Meeting at NTP
14:00 – 16:00	Joint meeting at MOH / Financing Department and Department for organization of services and PHC
16:00 – 18:00	Meeting with the National Society of Red Cross
<b>Friday, 11 February</b>	
9:00 – 13:00	Meeting with KfW / GOPA Visit to a drug storage facility Customs / clearance department Private pharmacies, other as per GDF requirements
10:00 – 12:00	Visit to general polyclinics in Yerevan
12:00 – 13:00	Meeting with representatives of academia and trainers' team
14:00 – 18:00	Workshop with NTP – presentation of main mission's findings and planning for next steps
<b>Saturday, 12 February</b>	
11:00 – 13:00	Debriefing with the Deputy Ministers of Health Dr. Hayk Darbinyan and Dr. Tatul Akopyan
14:00 – 18:00	Mission members meetings

### *Annex 3*

#### PERSONS MET DURING THE MISSION

Haik Darbinyan	First Deputy Minister of Health
Tatul Akopyan	Deputy Minister of Health
Vladimir Davidyants	Chief State Sanitary Doctor and Head of Epidemiology Department, National Institute of Health
Vahan Pogossyan	Head of NTP Central Unit
Samvel Grigoryan	Director, National AIDS Centre
Marina Safaryan	National WHO Counterpart for TB
Marina Safaryan	Head, Department of Phtysiatry of the State Medical University, WHO National Counterpart
Hayk Grigoryan	Head, Department of International Relations, Ministry of Health
Ruslana Gevorgyan	Adviser to the Minister of Health
Vartan Daveyan	Head of Pharmaceuticals Department, Ministry of Health
Rusanna Yuzbashyan	Principal Specialist, Primary Health Care Unit, Ministry of Health
Nikolay Arustamyan	Head of Department for Judicial Reforms, Ministry of Justice
Ara Hovannessyan	TB Coordinator, Ministry of Justice
Samvel Ghazaryan	Director of Hospital for Detainees, Ministry of Justice
Emil Martirosyan	Head of TB Department at the Hospital for Detainees, Ministry of Justice
Sergey Khachatryan	Director, MOH Project Implementation Unit for the World Bank-funded project
Derenik Dumanian	Director, National Institute of Health
Narine Karakhanyan	Director, National Centre for Diseases Control
Sirak Sukiasyan	Deputy Director, National Centre for Diseases Control
Tatevik Kostanyan	Deputy Head of NTP Central Unit
Nelly Markaryan	Chief TB Specialist of MOH, member of NTP Central Unit
Naira Khachatryan	TB Specialist, member of NTP Central Unit
Laura Markosyan	TB Specialist, member of NTP Central Unit
Hasmik Martikyan	Laboratory specialist, member of NTP Central Unit
Nelly Gasparyan	Pharmacist, member of NTP Central Unit
Karina Dovlatbekyan	Marz NTP Coordinator, Health Administration, Tavush Marz
Rober Dilbaryan	Marz NTP Coordinator, Health Administration, Vanadzor Marz Marz NTP Coordinator, Health Administration, Gyumri Marz
Lilit Ghazaryan	Deputy Director, Scientific Centre for Drug and Medical Technology Expertise

Irina Jaghatpamyanyan	Principal specialist, Scientific Centre for Drug and Medical Technology Expertise
Mikael Narimanyan	Deputy Rector, State Medical University of Armenia
Liubov Nikolayanyan	Associate Professor, Department of Phtysiatry, State Medical University of Armenia
Anna Gevorkyanyan	Associate Professor, Department of Phtysiatry, State Medical University of Armenia
Gayane Minasyan	Assistant Professor, Department of Phtysiatry, State Medical University of Armenia
Sersh Stepanyan	Head Physician, Republican TB Dispensary
Alvard Mirzoyan	Head of Laboratory, Republican TB Dispensary
Gayane Nazaryan	Head of Diagnostic Department, Republican TB Dispensary
Leno Abgaryan	Head of Dispensary Department, Republican TB Dispensary
Artiusha Asatryan	Head Physician, Gyumri TB Dispensary
Lilia Karazova	Phtisiatrist, TB Cabinet, Dilijan Polyclinic
Mkrtych Mkrtychyan	Head Physician, Yerevan City TB Dispensary
Katarina Gyulbayazyan	Head of in-patient department, Yerevan City TB Dispensary
Naira Serghyeyeva	Physician, American Red Cross Society
Karina Kentenyants	Physician, American Red Cross Society
Elizabeth Danielyan	Head of WHO Country Office in Armenia
Stepan Astvatsaturyan	Programme Officer, WHO Country Office in Armenia
Anna Boshyan	TB Programme Coordinator, GTZ/Armenia
Gegham Petrosyan	Responsible for TB Programme, ICRC / Armenia
Christian Ferrier	Head of Mission in Armenia, MSF France

## *Annex 4*

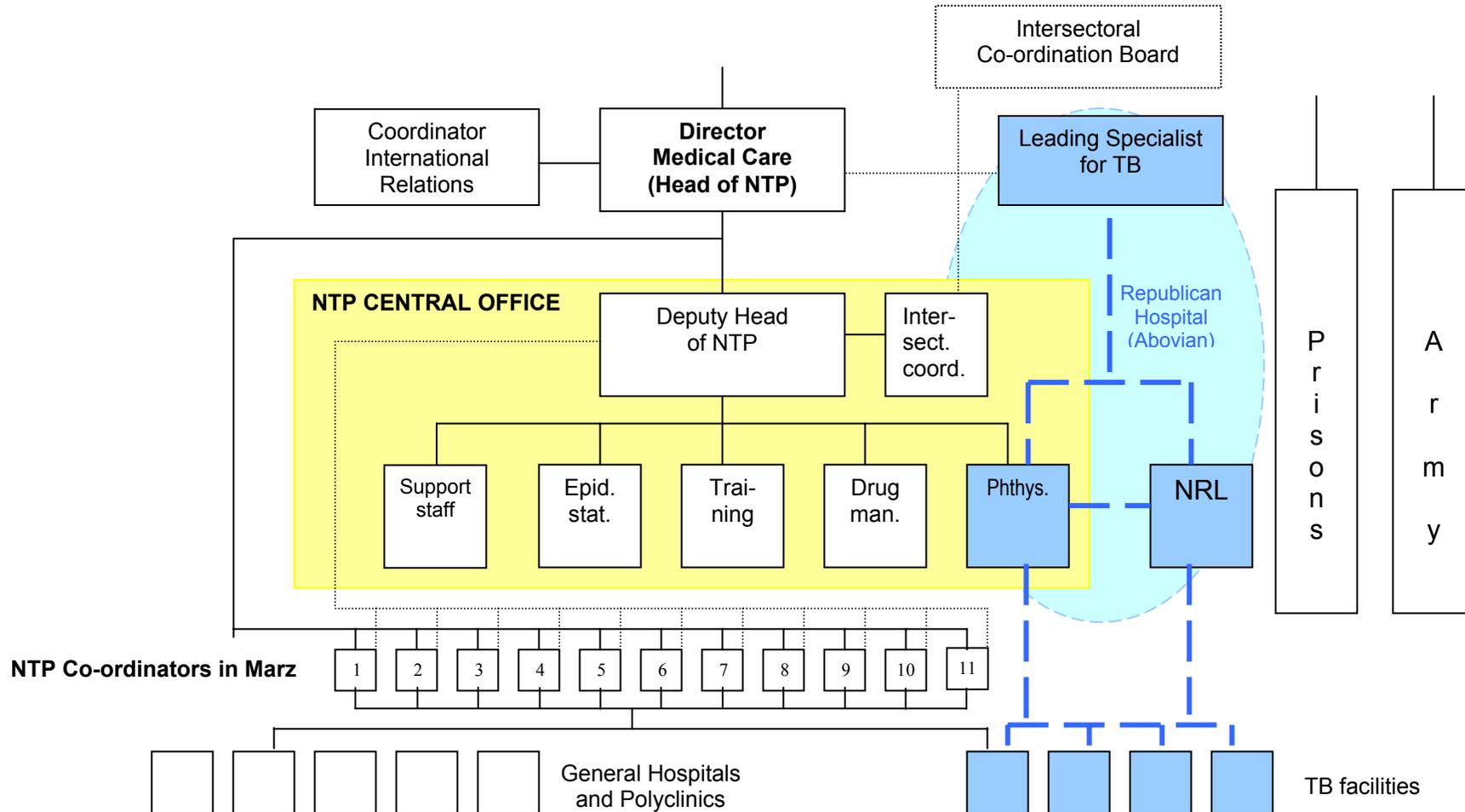
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Annex 5

ORGANIZATIONAL CHART OF THE ARMENIAN NATIONAL TB CONTROL PROGRAMME



## Annex 6

### SELECTED DATA ON TB CASE-FINDING AND TREATMENT OUTCOMES IN ARMENIA (PENITENTIARY SECTOR EXCLUDED)

Table 1: New smear positive cases reported by year and management; 1997–2003

Year	DOTS		Non DOTS		Total	
	n	%	n	%	n	%
1997	359	89.8	41	10.3	400	100.0
1998	387	81.5	88	18.5	475	100.0
1999	381	66.1	195	33.9	576	100.0
2000	456	73.4	165	26.6	621	100.0
2001	284	49.7	288	50.3	572	100.0
2002	295	57.7	216	42.3	511	100.0
2003	405	74.3	140 <sup>2</sup>	25.7	545	100.0

Table 2: DOTS detection rate of new smear-positive cases by year; 1997–2003

Year	Population (n)	TB incidence (/100K)	Cases expected (n)	Cases reported (n)	Case detection rate (CDR/100K)
1997	3 642 000	20	728	359	49.3
1998	3 537 000	20	725	387	53.4
1999	3 525 000	26	917	381	41.5
2000	3 787 000	31	1 178	456	38.7
2001	3 788 000	35	1 307	284	21.7
2002	3 072 000	35	1 062	295	27.8
2003	3 261 125	35	1 141	405	35.5

Table 3: TB cases reported under DOTS by oblast/municipality and classification; 2003

Marz / Municipality	Population (n)	PTB					ETB		Total TB		CDR (%)
		PTB positive			PTB negative		New		New	All	
		New	Relapse	New	New						
		(n)	(%)			(n)	(n)	(%)			
Armavir	299 381	44	34.1	7	67	51.9	18	14.0	129	100	42.0
Kotayk	281 441	28	22.8	6	55	44.7	40	32.5	123	100	28.4
Aragatsotn	148 744	8	28.6	2	13	46.4	7	25.0	28	100	15.4
Ararat	263 538	24	24.0	14	54	54.0	22	22.0	100	100	26.0
Shirak	295 634	36	28.6	18	46	36.5	44	34.9	126	100	34.8
Lori	278 679	34	45.3	11	26	34.7	15	20.0	75	100	34.9
Tavush	129 827	19	31.7	3	25	41.7	16	26.7	60	100	41.8
Geghargunik	251 949	5	21.7	0	15	65.2	3	13.0	23	100	5.7
Vayots Dzor	57 416	2	28.6	0	3	42.9	2	28.6	7	100	10.0
Syunik	152 516	23	24.7	10	49	52.7	21	22.6	93	100	43.1
Yerevan	1 102 000	182	46.9	32	145	37.4	61	15.7	388	100	47.2
Total	3 261 125	405	35.2	103	498	43.2	249	21.6	1 152	100	35.5

<sup>2</sup> Incomplete data for “non-DOTS”

Table 4: New smear-positive cases under DOTS by area and treatment result; 2002

Marz / Municipality	Registered (n)	Not evaluated		Cured		Treatment completed		Failure		Defaulted		Died		Transferred out	
		(n)	(%)	(n)	(%)	(n)	(%)	(n)	(%)	(n)	(%)	(n)	(%)	(n)	(%)
Armavir	34	3	8.8	25	73.5	0	0.0	1	2.9	0	0.0	2	5.9	3	8.8
Kotayk	27	2	7.4	16	59.3	6	22.2	0	0.0	1	3.7	1	3.7	1	3.7
Aragatsotn	8	2	25.0	3	37.5	1	12.5	0	0.0	0	0.0	0	0.0	2	25.0
Ararat	21	11	52.4	8	38.1	1	4.8	0	0.0	0	0.0	1	4.8	0	0.0
Shirak	26	1	3.8	22	84.6	0	0.0	1	3.8	0	0.0	1	3.8	1	3.8
Lori	24	1	4.2	20	83.3	0	0.0	1	4.2	0	0.0	0	0.0	2	8.3
Tavush	11	2	18.2	5	45.5	3	27.3	0	0.0	1	9.1	0	0.0	0	0.0
Geghargunik	6	0	0.0	5	83.3	0	0.0	0	0.0	0	0.0	1	16.7	0	0.0
Vayots Dzor	2	0	0.0	0	0.0	2	100.0	0	0.0	0	0.0	0	0.0	0	0.0
Syunik	18	6	33.3	8	44.4	1	5.6	0	0.0	0	0.0	2	11.1	1	5.6
Yerevan	124	0	0.0	106	85.5	0	0.0	7	5.6	6	4.8	4	3.2	1	0.8
Total	301	28	9.3	218	72.4	14	4.7	10	3.3	8	2.7	12	4.0	11	3.7

Table 5: Relapsed smear-positive cases under DOTS by area and treatment result; 2002

Marz / Municipality	Registered (n)	Not evaluated		Cured		Treatment completed		Failure		Defaulted		Died		Transferred out	
		(n)	(%)	(n)	(%)	(n)	(%)	(n)	(%)	(n)	(%)	(n)	(%)	(%)	(n)
Armavir	5	3	60.0	1	20.0	1	20.0	0	0.0	0	0.0	0	0.0	0	0.0
Kotayk	3	0	0.0	1	33.3	1	33.3	0	0.0	1	33.3	0	0.0	0	0.0
Aragatsotn	1	0	0.0	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Ararat	8	8	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Shirak	12	0	0.0	4	33.3	2	16.7	0	0.0	2	16.7	4	33.3	0	0.0
Lori	1	0	0.0	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Tavush	2	0	0.0	0	0.0	1	50.0	1	50.0	0	0.0	0	0.0	0	0.0
Geghargunik	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Vayots Dzor	2	2	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Syunik	12	2	16.7	3	25.0	5	41.7	0	0.0	1	8.3	1	8.3	0	0.0
Yerevan	21	0	0.0	8	38.1	4	19.0	3	14.3	4	19.0	1	4.8	1	4.8
Total	67	15	22.4	19	28.4	14	20.9	4	6.0	8	11.9	6	9.0	1	1.5

