World Health Organization

REGIONAL OFFICE FOR Europe

Extensive Review of TB Prevention, Care and Control Services in Armenia

21 April – 4 May 2011

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Mission Report

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Acknowledgements

The members of the mission would like to thank the Minister of Health of Armenia, Professor Kushkyan, for his timely request to the WHO Regional Office for Europe and for facilitating the extensive tuberculosis (TB) programme review.

The following organizations and individuals contributed their valuable time, knowledge and experience to the extensive review of TB prevention, control and care in Armenia:

- representatives of the Ministry of Health of the Republic of Armenia, acting on behalf of the Minister, Professor Kushkyan, and Deputy Minister, Dr Khachatryan;
- heads of marz (provincial) health departments and TB coordinators in Gegharkunik, Kotayk and Lory marzes (provinces);
- administration and staff of the Republican TB Dispensary, acting on behalf of Dr Marina Safaryan;
- heads and staff of health-care facilities and TB services in Yerevan, Kotayk, Gegharkunik, Lory and Aragatsotn marzes;
- heads and staff of the health-care unit of the criminal-executive department of the Ministry of Justice, criminal-executive institutions and the Central Hospital for Detainees;
- representatives of the United States Agency for International Development (USAID)/Armenia mission, the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM) and World Bank Project Implementation Unit, and Médecins Sans Frontières France.

Contents

Abbreviations

ACSM	advocacy, communication and social mobilization
AIDS	acquired immunodeficiency syndrome
APEC	AIDS Prevention, Education and Care (nongovernmental organization)
ARCS	Armenian Red Cross Society
ART	antiretroviral therapy
ARV	antiretroviral
AUA	American University of Armenia
BCG	bacillus Calmette-Guerin
BSC	biosafety cabinet
CCM	country coordination mechanism (for GFTAM grants)
CEI	criminal-executive institution (place of detention)
CPT	cotrimoxazole preventive therapy
DHS	Demographic and Health Survey
DOT	direct observation of treatment
DOTS	directly observed treatment, short-course – the basic package that underpins the WHO Stop TB Strategy
DOTS+	DOTS Plus
DRS	drug resistance surveillance/survey
DR-TB	drug-resistant TB
DST	drug susceptibility testing
EQA	external quality assurance
EQC	external quality control
FDC	fixed dose combination
FLD	first-line drugs
GDF	Global TB Drug Facility
GDP	gross domestic product
GFATM	Global Fund to Fight AIDS, Tuberculosis and Malaria
GFATM PIU	GFATM Project Implementation Unit
GLC	Green Light Committee
HIV	human immunodeficiency virus
HOTO	handover/takeover
HRD	human resources development
IC	infection control
ICRC	International Committee of the Red Cross
IDU	injecting drug user
IEC	information, education and communication
IPT	isoniazid preventative therapy
IQC	internal quality control
KAP	knowledge, attitude, practice
KfW	Kreditanstalt für Wiederaufbau – German Development Bank
KNCV	Royal Netherlands Tuberculosis Association
LPA	lymphocyte proliferation assay
M&E	monitoring and evaluation
MDR-TB	multidrug-resistant tuberculosis (resistant to, at least, isoniazid and rifampicin)
MGIT	mycobacteria growth indicator tube
MMR	mass miniature radiography
MoH	Ministry of Health
MoJ	Ministry of Justice
MSF-F	Médecins Sans Frontières – France
MSH	Management Sciences for Health (USA)
MTEF	medium-term expenditure framework
NCAP	National Centre for AIDS Prevention
NEML	National Essential Medicines List
NGO	nongovernmental organization
NRL	National Reference Laboratory for TB
NTP	National TB Control Programme
OST	opioid substitution therapy
PCR	polymerase chain reaction
PCTC	Patients' Charter for TB Care
PDR-TB	polydrug-resistant tuberculosis
PHC	primary health care
PITC	provider-initiated testing and counselling
PLHIV	people living with HIV
PMDT	programmatic management of drug-resistant tuberculosis
PPAN	Positive People Armenian Network (nongovernmental organization)
PPD	purified protein derivative
R&R	recording and reporting
RTBD	Republican TB Dispensary
SCP	sputum collection point
SLD	second-line drug

SM	smear microscopy
SNRL	supranational reference laboratory
SOP	standard operating procedure
SS-	sputum smear-negative
SS+	sputum smear-positive
SHA	Armenian State Health Agency
TB	tuberculosis
ToR	terms of reference
ToT	training of trainers
USAID	United States Agency for International Development
WB PIU	World Bank Project Implementation Unit
WHO	World Health Organization
XDR-TB	extensively drug-resistant tuberculosis
YCTBD	Yerevan City TB Dispensary

Drug abbreviations

Am	amikacin
Cm	capreomycin
E	ethambutol
Fq	fluoroquinolone
H	isoniazid
Km	kanamycin
Ofx	ofloxacin
R	rifampicin
S	streptomycin
Z	pyrazinamide

Executive summary

Tuberculosis (TB) is one of the major public health problems in Armenia. In 2009, TB incidence in Armenia was reported as high as 45.5 per 100 000 population and TB mortality was 3.9 per 100 000 population. Only 35% of estimated new sputum smear-positive pulmonary TB patients are notified annually. Of 1780 TB cases notified in 2010, only 339 patients were sputum smear-positive. The treatment success rate of new sputum smear-positive pulmonary TB patients in 2009 was 72.9%, which is below the WHO target of 85%. Poor treatment outcome is partially explained by high prevalence of drug-resistant TB forms. Armenia is among the top 10 countries with the highest prevalence rates of multidrug-resistant tuberculosis (MDR-TB). According to the 2007 drug resistance survey, MDR-TB accounted for 9.4% of cases among never treated patients and 43.2% among previously treated cases, with 4% of extensively drug-resistant tuberculosis (XDR-TB) cases. This represents an enormous public health challenge for Armenia. Early identification and effective treatment of patients with MDR-TB are crucial in order to prevent the further spread of the disease.

The National TB Control Programme of Armenia (2007-2015) (NTP) is based on the WHO Stop TB Strategy and aims to achieve the global targets for TB control. In 2010, the Minister of Health, recognizing the importance of high-level political will and commitment in ensuring expansion of the Stop TB Strategy, personally took over the management of the National TB Control Programme.

Following a request by the Minister of Health of Armenia, the WHO Regional Office for Europe, in collaboration with key partners, organized a comprehensive external review of the National TB Control Programme. The extensive review revealed that, despite the great achievements of the National TB Control Programme, there are several major gaps which require urgent action. The programme has succeeded in reducing the default rate of new sputum smear-positive pulmonary TB patients from 14% to 8% in four years and has embarked on programmatic management of drug resistance. Two projects financed by grants from the Global Fund to Fight AIDS, TB and Malaria (GFATM) are being implemented, and a close collaboration with national and international partners, particularly Médecins Sans Frontières, has been established to address MDR-TB.

To advance the achievements of the National TB Control Programme, the Ministry of Health (MoH) needs to maintain its TB control strategy. The structure, mandate and organogram of the National TB Control Programme need to be updated and endorsed by the Ministry. The excessive hospitalization of patients and TB suspects needs to be curbed by rationalizing hospitalization and revising financial mechanisms. New diagnostic methods, including Gene-Xpert MTB/RIF, need to be introduced in a phased manner to improve early diagnosis of MDR-TB. The country needs to revise its national TB strategic plan and ensure universal access to treatment of drug-resistant TB. Diagnosis of TB and MDR-TB needs to be improved by providing a one-stop service for people living with HIV. A continuum of TB treatment needs to be ensured for (ex-) prisoners, strengthening the collaborative mechanism between the civilian and penitentiary services. The programme needs to continue its collaboration with civil society organizations, focusing particularly on injecting drug users (IDU).

Key recommendations

Area	Action	Timeline	Responsible
Management	– Update the National TB Control Programme 2007-2015 (NTP) document based on recent developments and in line with Stop TB Strategy.	End 2011	NTP Central Office (NTP CO)
	– Reform financing mechanism to disincentive excessive hospitalization and promote ambulatory diagnosis and treatment.	2012	MoH/SHA
	– Rationalize excessive hospitalization by revising criteria for inpatient treatment.	End 2011	MoH/NTP
	– Establish an external governing board of Republican TB Dispensary (RTBD) (in charge of overall management of hospital).	End 2011	RTBD
	– Strengthen human resources and authority of NTP and endorse its status as the responsible body within MoH for implementation, monitoring and evaluation of National TB Control Programme.	End 2011	MoH with technical assistance from WHO and other partners
Human resources development	– Establish position of HRD officer within NTP CO, with responsibility for coordinating and evaluating in-service training, supportive supervision plans and implementation and leadership, in coordination with HRD activities of key stakeholders.	Immediately	NTP CO
	– Develop a training policy, revise training plans based on training needs assessment and prepare supportive supervision plans. Include penitentiary system.	End 2011	MoH/NTP CO
Management of TB medicines	– Develop SOP for important aspects of TB medicines management (selection, inventory control, ordering, handling of medicines, problem reporting).	End 2011	NTP CO
	– Develop a list of essential NTP medicines and commodities and apply to Scientific Centre of Drug and Medical Technology Expertise to include NTP products in the National Essential Medicines List and list of medicines liable for registration under Government orders. Maintain and regularly update the list.	End 2011	NTP CO
	– Promote legislation limiting/banning over-the-counter sales of antimicrobial medicines (including all anti-TB medicines) without prescription.	End 2011	NTP CO
	– Involve the NTP Head Pharmacist in all coordinating and decision-making mechanisms that have any relation to NTP medicines and commodities.	2011	NTP CO

Area	Action	Timeline	Responsible
TB diagnosis	– Abolish diagnostic department of RTBD and ensure diagnosis of patients on an ambulatory basis. Hospitalization of suspected TB patients shall be limited to those cases that need an overnight stay for diagnostic procedures, ensuring infection control measures to avoid nosocomial infection. The length of stay for diagnostic purposes shall be no more than six days.	2011	MoH
	– Consider ambulatory treatment of patients whose sputum results are negative.	2011	MoH
	– Enable diagnosis of sputum smear-positive pulmonary TB in TB cabinets and primary health-care facilities.	2012	NTP CO
Laboratory network	– Pilot Gene Xpert MTB/RIF in Yerevan, marzes, NRL, prisons, NCAP, YCTBD.	End 2012	NTP CO
Treatment and care services	– Expand patient-friendly models of care (including home-based care), ambulatory care and day care.	Immediately	NTP CO
	– Institute palliative care services (organized in a special centre or at home with specific measures of infection control) for patients who fail MDR-TB treatment.	End 2012	MoH, NTP
	– Work with international organizations, health authorities, the International Health Regulations mechanism and charities to ensure continuity of care for patients crossing the borders.	2011	MoH, NTP CO
	– Revise medical aspects of drug-resistant TB management, including polydrug-resistant TB (PDR-TB) for full compliance with the WHO Guidelines for the Programmatic Management of Drug-resistant Tuberculosis (2008).[1]	End 2011	NTP CO
	– Update national TB treatment guidelines, with particular focus on PDR-TB.	End 2011	NTP CO
	– Prohibit use of second-line TB drugs (SLD) for drug-susceptible patients unless there is strong evidence of close contact. Administration of SLD should be approved by DR-TB Committee.	Immediately	MoH
TB infection control	– Conduct risk assessment of TB infection control in all TB facilities, particularly at marz level.	End 2011	NTP CO

[1] World Health Organization. *Guidelines for the programmatic management of drug-resistant tuberculosis, Emergency update 2008*. Geneva, 2008 (document WHO/HTM/TB/2008.402).

Area	Action	Timeline	Responsible
Advocacy, communication and social mobilization (ACSM)	– Develop an ACSM strategy based on identified risk groups and make it part of the revised NTP document.	2011	NTP CO
TB in penitentiary system	– Strengthen infection control with administrative, environmental (improved ventilation) and respiratory protection measures. – Guarantee continuity of care (MoH and MoJ) for TB patients upon entry to a penitentiary institution and after release.	End 2011 2012	MoJ, NTP CO MoJ, NTP CO
Partnership and civil society involvement	– Finance the expansion of HIV nongovernmental organization activities to include TB aspects in their everyday work with most at-risk populations (e.g. IDU).	2012	NTP/GFATM TB Project
TB/HIV collaborative activities	– Make TB diagnosis possible at NCAP with a regularly scheduled visits by TB specialist, sputum collection for microscopic and mycobacteriological examination, provision of X-ray equipment and Gene Xpert MTB/RIF diagnostic testing.	End 2011/2012	MoH (NCAP, NTP CO)
Monitoring and Evaluation (M&E)	– Finalize a national M&E plan (beyond GFATM M&E plan) and include decentralization of the M&E to the marz coordinators. – Develop a compendium of TB programme performance indicators and facilitate their use at the marz level for decision-making.	End 2011 2012	NTP CO NTP CO

GFATM: Global Fund to Fight AIDS, TB and Malaria; HRD: human resources development; IDU: injecting drug users; MoH: Ministry of Health; MoJ: Ministry of Justice; NCAP: National Centre for AIDS Prevention; NRL: National Reference Laboratory; NTP CO: NTP Central Office; RTBD: Republican TB Dispensary; SHA: State Health Agency; SOP: standard operating procedure; YCTBD: Yerevan City TB Dispensary

Background

Tuberculosis (TB) is one of the most serious public health problems in Armenia. In 2009, the TB notification rate in Armenia was reported as high as 45.5 per 100 000 population, TB prevalence was 106.4 per 100 000 population, and TB mortality was 3.9 per 100 000 population. According to the National TB Control Programme (NTP), the highest number of patients occurs in the economically active age group (15-24 years) at a female/male ratio of 0.2/1. In 2007, the prevalence of HIV among notified TB cases with known HIV results was 16%. While Armenia reports 100% DOTS (directly observed treatment, short course) coverage for treatment of TB, the country needs to improve the quality of DOTS implementation, since until now case-detection and treatment success rates have been low. The overall treatment outcomes of smear-positive pulmonary TB cases are currently below WHO targets: in the cohort of 2008, the new-case treatment success rate was 73.3%, failure rate 5.5%, death rate 4.7%, default 9.7% and transfer-out 5.5% [NTP data]. Poor treatment outcomes are contributing to the emergence of drug-resistant (DR) TB. Armenia is among the top 10 countries with the highest prevalence rates of multidrug-resistant TB (MDR-TB).[1] According to a drug resistance survey (DRS) conducted by WHO in 2007, MDR-TB among never treated patients accounted for 9.4% of cases, while among previously treated cases it was 43.2%. Of these, 4% were extensively drug-resistant TB (XDR-TB) cases. This represents an enormous public health challenge for Armenia; early identification and effective treatment of patients with MDR-TB is crucial to prevent further spread of the disease.

The National Programme for TB Control in Armenia for 2007-2015 was developed on the basis of the WHO Stop TB Strategy with the aim of achieving the global targets for TB control in the WHO European Region. The National TB Control Programme for 2007-2015 was approved by the Government of the Republic of Armenia (Governmental decision N52 of 28 December 2006). The National TB Control Programme Central Office (NTP CO) is responsible for implementation of the Programme.

The programme has the following aims: (1) the development and implementation of and provision of State support for the National TB Control Policy; (2) improved implementation of all components of the internationally recommended DOTS strategy, which has been adopted in Armenia ; (3) provision of high-quality treatment of drug-resistant TB patients; (4) involvement of primary health care and general health-care systems in TB control infrastructures; (5) strengthening cooperation with the National HIV/AIDS Prevention Programme for better control of coinfected TB/HIV cases; (6) ensuring implementation of preventive activities, at TB foci and elsewhere; (7) coordination and implementation of high-quality TB control activities in penitentiary institutions; (8) coordination and implementation of high-quality TB control activities among military personnel; (9) raising public awareness; and (10) training medical staff to deliver TB control services at all levels of the health-care system.

Recognizing the importance of high-level political will and commitment in ensuring expansion of the DOTS approach, addressing MDR/XDR-TB and HIV-related TB, and integrating TB into general public health services while strengthening the health system, the Minister of Health personally took over the management of the National TB Control Programme. Since that time, Armenia has continuously improved the performance of the programme. Further support from WHO in this process is deemed to be crucial.

In this connection, the Ministry of Health of Armenia requested the WHO Regional Office for Europe to provide a comprehensive external evaluation of the National TB Control Programme and its achievements, and to recommend a set of coherent and prioritized actions for further improvement.

A team of international and national experts from different disciplines was accordingly set up to conduct a comprehensive review of TB prevention, care and control services in Armenia (21 April – 5 May 2011).

1 World Health Organization. *Multidrug and extensively drug-resistant TB (M/XDR-TB): 2010 global report on surveillance and response* (WHO/HTM/TB/2010.3). Geneva, 2010.

Mission objectives

- To document the progress and shortcomings of TB prevention, control and care activities, compared with the extensive programme review conducted in 2005.
- To identify legislative and structural barriers in the health system that prevent an effective response to the TB epidemic, including TB/HIV coinfection.
- To assess the role of social determinants of TB (drug dependence, HIV/AIDS, stigma, social exclusion, etc.) and the response of the health system.
- To visit TB and related health facilities, including laboratories, and report on quality of services.
- To analyse epidemiological data, accuracy of recording and reporting and the TB monitoring system.
- To assess the links, synergies and opportunities for TB control in relation to health system strengthening and other disease-specific interventions, including management of TB/HIV.
- To assess the role and involvement of civil society.
- To assess partnership, coordination and collaboration on TB control with national and international stakeholders, including the Ministry of Justice.
- To provide the Ministry of Health with a comprehensive set of recommendations and a prioritized action plan to improve TB prevention, control and care in the Republic of Armenia.

Scope of the extensive review of TB prevention, care and control

The evaluation team assessed all components of the National TB Control Programme and the Stop TB Strategy, including:

- commitment and policy (place of the TB Programme in the overall health system, TB Programme financing, organizational structure, guidelines);
- diagnosis and case detection;
- laboratory services;
- treatment (inpatient and outpatient);
- preventive activities (Bacillus Calmette-Guerin (BCG), skin tests, infection control);
- drugs and equipment;
- human resources and human resource development (HRD)
- recording and reporting (R&R);
- monitoring and evaluation (M&E)
- TB and HIV coinfection;
- MDR/XDR TB;
- TB in prisons;
- partnership and coordination;
- advocacy, communication and social mobilization (ACSM).

Methodology and sources of information for TB prevention, care and control

The mission members (brief biographies in Annex 1), representing the Ministry of Health (MoH), Management Sciences for Health (MSH), Royal Netherlands Tuberculosis Association (KNCV), Supranational Reference Laboratory (SNRL) Borstel (Germany), United States Agency for International Development (USAID) and WHO, conducted a two-week assessment between 21 April and 05 May 2011. The final timetable for the mission is reproduced in Annex 2.

The team of international and local experts assessed the achievements, strengths, shortcomings and weaknesses of the National TB Control Programme for 2007-2015, using the following approaches: review of all relevant available documents (Annex 3); site visits (to relevant institutions and facilities); and interviews (with policy-makers, health providers and beneficiaries, the general public and major national and international partners) at national level and in selected regions of Armenia (Annex 4). The TB, TB/HIV and MDR-TB country profile, statistics relating to MDR-TB cases and distribution of TB cases across the country are shown in Annexes 5-7.

Epidemiology of TB in Armenia

Armenia is one of the 18 high-priority countries of the WHO European Region's Plan to Stop TB[1] and one of the 27 countries in the world with the highest MDR-TB burden.[2] After a gradual decline in the period 1980-1991, the incidence of TB in Armenia has increased over the past 20 years, and the number of estimated new and relapsed cases has more than doubled from 1100 (range 740–1600; 32 per 100 000, range 18–48) in 1991 to 2300 (range 1800–2700; 73 per 100 000, range 59–88) in 2010 (Figure 1). The existence of a pool of prevalent TB patients in Armenia (Figure 2) is another indication of the spread of the disease: an alarming fact which shows that Armenia is far from reaching its Millennium Development Goal 6 and Stop TB partnership targets.[3,4]

Figure 1: TB estimated incidence, six-year moving average of incidence and notification rates, 1990-2015

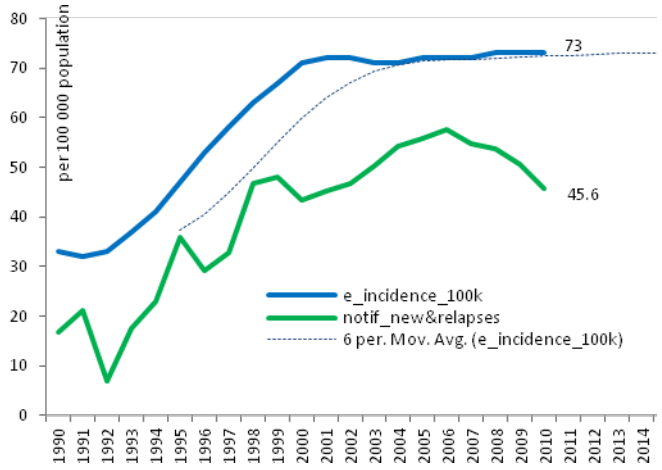
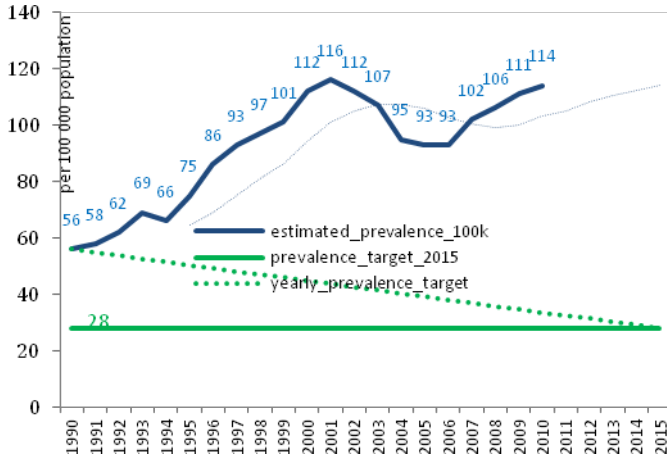


Figure 2: TB estimated prevalence and six-year moving average of prevalence, 2015 target and year-specific prevalence target, 1990-2015



According to official statistics, the notification of pulmonary smear-positive TB cases (the main sources of infection) in 2010 was 339, with only 35% of all new cases notified (Table 1). Notifications have continued to decrease since 2000. Possible contributing factors are coinfection with HIV/TB, limited use of smear examination as a diagnostic tool and poor performance of the laboratory network.

Table 1: TB case notification, 2010

New cases	n	%	Retreatment cases	n	%
Smear-positive	339	35	Relapse	81	18
Smear-negative	639	65	Treatment after failure	12	3
Smear unknown	0	0	Treatment after default	14	3
Total new pulmonary	978	74	Transfer in	0	0
			Other	344	76
Extrapulmonary	351	26			
Other	0	0			
Total new	1329		Total retreatment	451	
Total < 15 years	59	4			
			Total new and relapse	1410	79
			Total cases notified	1780	

1 World Health Organization Regional Office for Europe. *Plan to stop TB in 18 high-priority countries in the WHO European Region, 2007–2015*. Copenhagen (http://www.euro.who.int/__data/assets/pdf_file/0005/68180/E91049.pdf, accessed 6 December 2011).

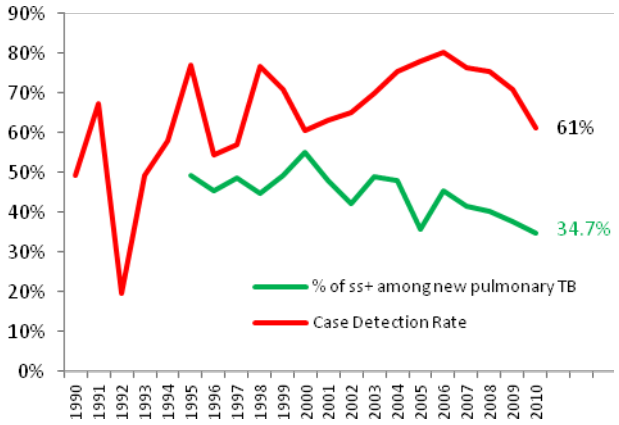
2 World Health Assembly resolution WHA 62.15. Prevention and control of multidrug-resistant tuberculosis and extensively drug-resistant tuberculosis (WHA62/2009/REC/1) (http://apps.who.int/gb/ebwha/pdf_files/WHA62-REC1/WHA62_REC1-en.pdf, accessed 6 December 2011).

3 "By 2015: reduce prevalence and death rates by 50%, compared with their levels in 1990" (http://www.stoptb.org/assets/documents/global/plan/TB_GlobalPlanToStopTB2011-2015.pdf, accessed 15 December 2011).

4 Modelling based on six-year moving average of historical trends.

The case-detection rate for new cases and relapses has decreased from 80% (range 67–100%) in 2006 to 61% (range 52–74%) in 2010 (Figure 3). The analysis of possible causes of underdetection based on the fraction of cases missed by routine TB notification have identified quantitative and qualitative gaps in the case-detection system. Trend analysis of data subcategories showed that underdetection occurs in the fifth and fourth layers of the onion module, reflecting those TB cases with access to health-care facilities who do not present for treatment and/or those presenting at health facilities but not being diagnosed.[1]

Fugure 3: Case detection rate of new TB cases and relapses, and percentage of smear-positive among new pulmonary TB cases, 1990-2010



Up to three quarters of reported cases are males. This distribution slightly increased over the last decade. Two age groups are identified as the most common among the TB patients: 25–34 years and 45–54 years. In 2010, 59 new TB cases were notified among children (nine cases per 100 000), which constitutes 4% of all TB cases notified (Figure 4; Table 1).

Figure 4: New cases by age groups and gender, 2010

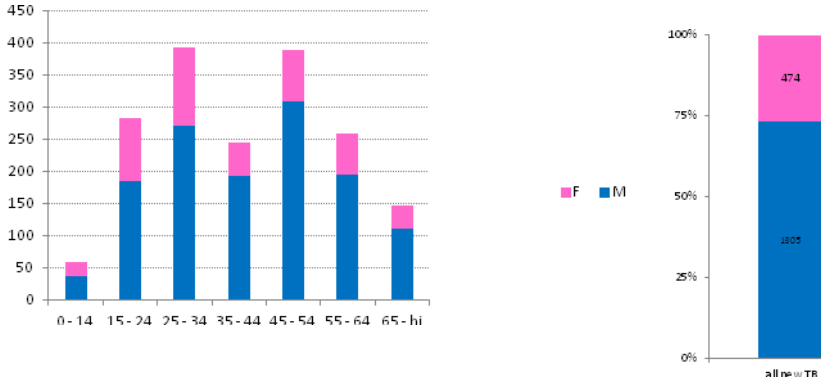
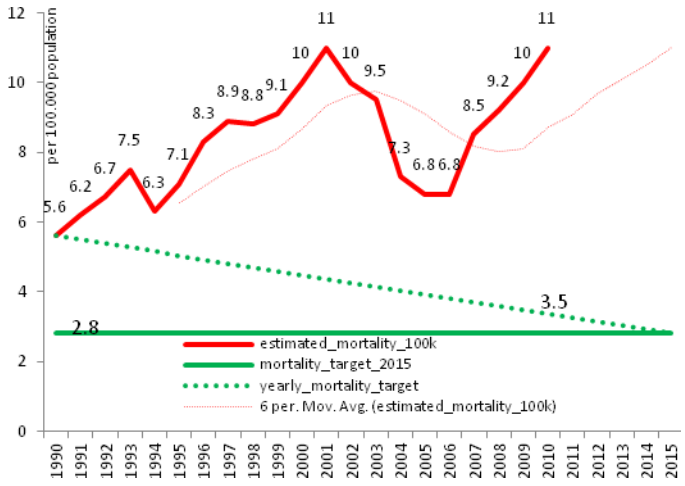


Figure 5: TB estimated mortality and six-year moving average of mortality, 2015 target and year-specific mortality target, 1990-2015

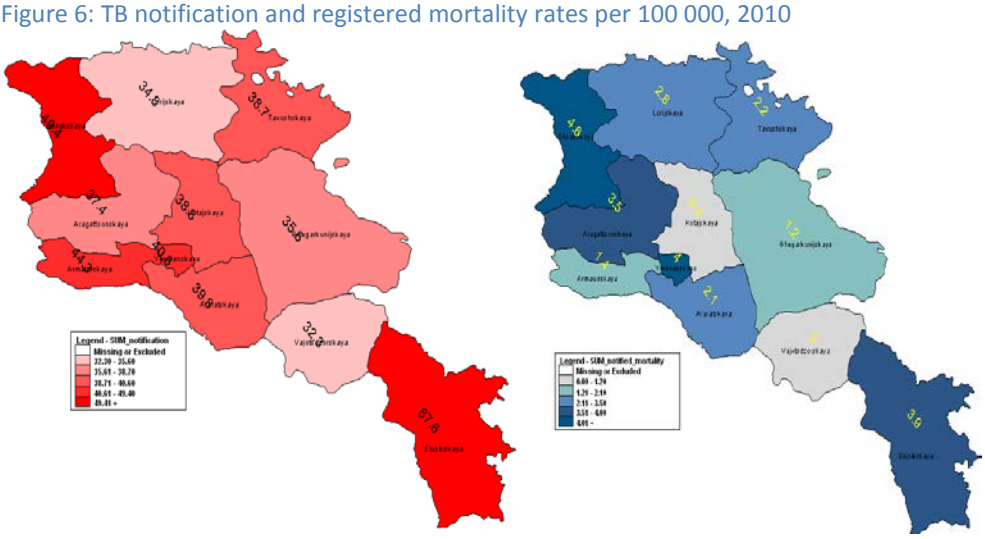


Data also indicate an increase in the mortality rate over recent years: from 5.6 (range 2.4–11) in 1990 to 11 (7–15) per 100 000 in 2010, with the drop-out increasing to 6.8 during 2005-2006 (Figure 5). The total number of TB deaths notified by NTP was 94 (3 per 100 000) which was less than one third of TB death reporting by NTP.

Both notification and mortality are noticeably higher in the north-west and south-east of the country (Figure 6).

1 The assessment of the fraction of cases being missed in routine TB notification data was conducted by a national counterpart based on the "Onion" model (Workbook of Assessment of Surveillance Data, Armenia: Bullet 2.1.8. Sudden changes in TB diagnostic capacity (for example: new laboratory facilities, training of clinical and laboratory staff, shortage of human resources, patients avoiding diagnosis because of rumours of drug shortages or stigma and discrimination, etc). Workshop on improving TB estimates: identifying the gaps and making the most of available data, Berlin, Germany, 2009.

Figure 6: TB notification and registered mortality rates per 100 000, 2010



The data also highlight that TB is much more frequent in prisoners compared with the general population: 43 notified new TB cases among prisoners amount to a notification rate of 996 per 100 000 prisoners. Moreover, 43% of previously treated TB inmates notified in the penitentiary system.

The first HIV cases in the country were registered in 1988. Since then the AIDS epidemic has advanced, and it is currently estimated that there are 1900 people with HIV/AIDS living in Armenia (range 1500–2400). The estimated HIV prevalence rate among adults in 2009 has remained below 0.1% (range 1.0-1.3).[1]

The estimated prevalence of HIV among TB patients in 2010 was 1.4% (range 0.8–2.1), with NTP notifying a 1.3% prevalence of HIV among TB cases.[2] While the notified prevalence of HIV among the TB cases came close to the estimation, the number of TB/HIV cases notified was lower than estimated: 17 versus 31 (range 17–49), which gives a 55% detection rate for TB/HIV-coinfected patients. This can be explained by a 39% underdiagnosis of new TB events (new TB cases and relapses). The number of new TB/HIV coinfected cases remains stable, even though HIV testing coverage has more than doubled (from 521 in 2009 to 1242 in 2010). This may be an indication of undernotification of TB in a hard-to-reach population where HIV is prevalent.

In 2008, the estimated MDR-TB prevalence was 9.4% (range 7.3–12.1) or 92 cases (range 68–120) among new TB cases, and 43.2% (range 38.1–48.5) or 190 cases (range 170–220) among previously treated cases.[3] This represents a detection rate of 62% – a fact which indicates undernotification of TB in areas where MDR-TB is more prevalent. It also highlights low culture confirmation: 37% among new pulmonary TB cases.

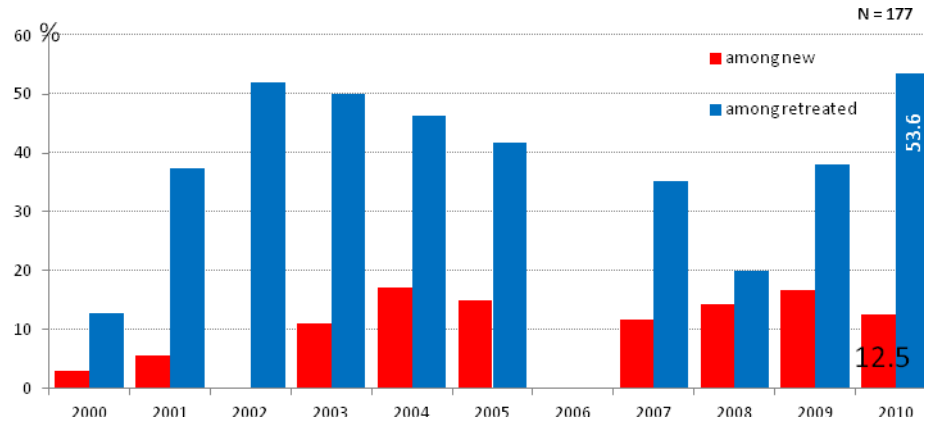
In 2010, 177 incident MDR-TB cases were identified among new and previously treated patients. Of these, 59 were new cases (12.5% of new cases) and 118 were previously treated cases (53.6% of retreatment cases) (Figure 7). About 87% of the identified MDR-TB cases (154 patients) initiated treatment with second-line drugs. This elevated MDR-TB prevalence is not prominent to the relatively low percentage of failures among new smear-positive and previously treated TB cases (3% and 4%, respectively). This was not the case in previous years, when failures in the cohorts of new smear-positive patients were reported at 10% in 2006 and 11% in 2007 and at 15% in the 2008 cohort of previously treated patients.

1 Joint United Nations Programme on HIV/AIDS (UNAIDS). *UNAIDS report on the global AIDS epidemic 2010* (document UNAIDS/10.11E|JC1958E). Geneva, 2010 (http://www.unaids.org/globalreport/default.htm, accessed 16 December 2011).

2 *WHO global TB database* (http://www.who.int/tb/country/data/download/en/index.html, accessed 16 December 2011).

3 World Health Organization. *Tuberculosis country profiles.* Geneva (http://www.who.int/tb/country/data/profiles/en/index.html, accessed 16 December 2011).

Figure 7: Percentage of MDR-TB among new and previously treated TB cases, 1990-2010

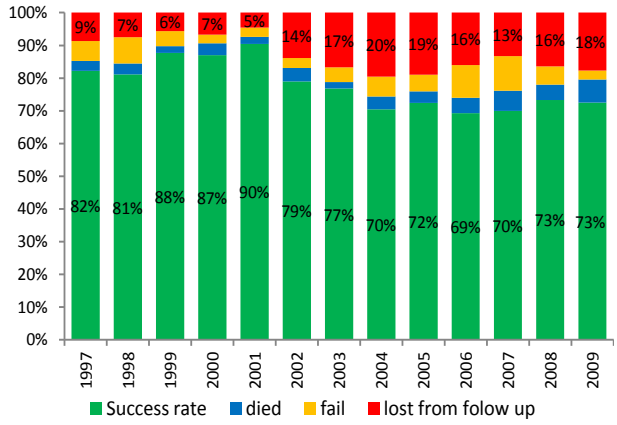


Loss from follow up, mostly due to defaulting from treatment, is often a prevalent and alarming phenomenon. In the period 2004–2009 it decreased slightly, from 20% to 18% among new smear-positive cases and in the period 2005–2009 it dropped from 40% to 25% among retreatment patients. This can be explained by the low motivation of patients to adhere to the treatment, especially in the continuation phase, when patients (mostly men) move away for work when their health improves.

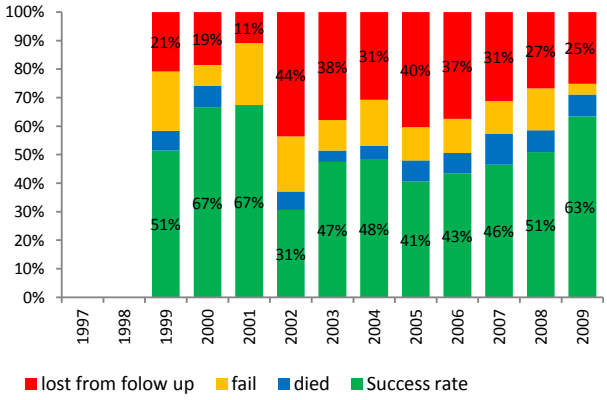
TB case mortality among new and retreatment cohorts more than doubled in the period 2003-2009, from 2% to 7% and from 4% to 8%, respectively. The treatment success rate improved from 69% to 73% in the period 2006-2009 among new smear-positive TB cases and from 41% to 63% in the period 2005–2009 among previously treated TB cases (Figure 8). However, high rates of MDR-TB and loss from follow-up will lead to a very low treatment success rate among MDR-TB cohorts in future; the 2008 MDR-TB cohort was 54.5%. The bad habit of defaulting from MDR-TB treatment, notified at 33%, may increase the prevalence of XDR-TB, which in 2010 reached 12% among MDR-TB cases.

Figure 8: Treatment outcomes

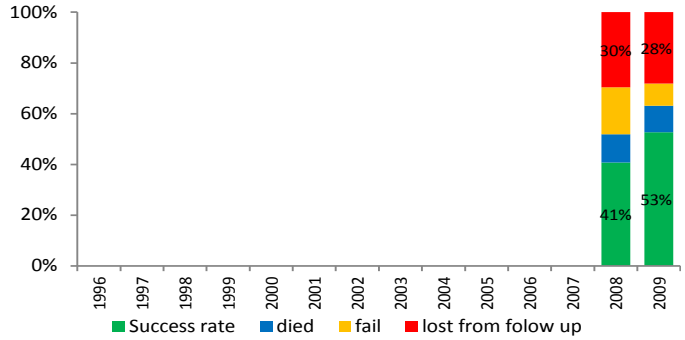
New pulmonary laboratory confirmed TB cases, 1997-2009



Previously treated cases TB cases, 1999-2009



MDR-TB cases, 2008-2009



Organization and management

Findings

Over the years, Armenia has been able to implement coordination mechanisms for organization and management of TB and MDR-TB services among public agencies, nongovernmental organizations, donors, academia and working groups for TB and HIV/AIDS. The Minister of Health is currently the Chair of the TB Country Coordination Mechanism (CCM), and the recent change in leadership at NTP has increased the potential of the programme to streamline and strengthen vital coordination among the key agencies involved in TB control. The Deputy Minister is the responsible officer coordinating the Ministry of Health's efforts to strengthen TB/MDR-TB response in the country; the State Health Agency (SHA) is in charge of provider payments, and currently interested in increasing efficiency and cost containment in service delivery; the National TB Control Programme is the entry point for the TB/MDR-TB Strategy, supported by the Global Fund. Médecins Sans Frontières France (MSF-F) is one of the key international players in addressing MDR-TB in Armenia and providing technical and material support for NTP. During the extensive review of TB prevention, care and control, all the above agencies made explicit their interest in addressing the current imbalances and inefficiencies in the organization and management of inpatient and outpatient services to ensure more effective response to the challenges of TB/MDR-TB in Armenia.

Accountability, responsibility and institutional capacity

Armenia has developed a National TB/MDR-TB Response Plan, which has been discussed and endorsed by all stakeholders, although the agencies involved in TB and MDR-TB activities have different sets of organizational goals and frameworks in mind when defining their objectives and the means to attain them. This is reflected in the fragmented activities currently pursued by them in the name of a TB/MDR-TB strategy.

Two predominant modalities compete for resources, providers and patients: the old hospital-centred model and the "new" patient-centred model. The lack of institutional capacity has prevented the health authorities from establishing clear ground rules that would convert this debilitating rivalry into a single national approach with common programmatic objectives, where each responsible agency and provider would have a clear mandate with its own attributions and responsibilities. This lack of clarity streams down the system through all levels of care right down to the TB units, where personnel refer patients for case confirmation and treatment on the basis of differing criteria.

Poor institutional capacity has undermined the health system, so that Armenia's health services cannot effectively utilize national and international resources and technical assistance to provide reliable outpatient care for TB/MDR-TB patients and ensure the quality of inpatient services. These weak health services have contributed to low-quality outpatient and inpatient care. Thanks to contributions from the donor community, continuity of drug supplies has been protected overall, but no reliable process has been set up to ensure the proper administration and use of the drugs. Lack of institutional capacity is thus one of the areas that needs to be addressed urgently in order to protect patients from erratic care and the population from infection and to prevent the drugs themselves from becoming ineffective.

There is a need to strengthen the institutional structure, which is hampering the attribution of authority, accountability and responsibility among health system agencies – NTP and RTBD – and limiting the capacity for donor and national efforts to make any progress in curbing the TB/MDR-TB trend. While the NTP Central Office (NTP CO) is the formal head of the National TB Control Programme in Armenia, the majority of TB staff interviewed saw it as a TB policy unit, but generally more associated with project implementation of the Global Fund against AIDS, TB and Malaria (GFATM). This role as a GFATM project implementation unit has been internalized by NTP CO staff as well; in the absence of a firm mandate to lead the TB/MDR-TB efforts in the country, these staff are merely passively conducting programmed training activities, distributing materials, ensuring the funding of investment and supply requests, and facilitating meetings and coordination of TB professionals led by the TB working group.

The only visible policy development exercise conducted by NTP is the annual updating and revision of the national TB and MDR-TB document that is submitted to the Ministry of Health for endorsement. The dissemination of this document among TB/MDR-TB service providers at health facilities and subnational health authorities is expected to reform TB and MDR-TB control activities, reinforce outpatient care and DOTS, step up case-finding, and actively ensure continuity of treatment. Staff cite donor-funded training activities as the other element that will contribute to this major transformation. However, in practice, the ineffective hospital-centred approach prevails under the leadership of RTBD, as the specialized centre for TB/MDR-TB in the country and the recipient of the supplies, the reliable laboratory capacity, the patient records and, until very recently, the drugs. This situation is due not only to the lack of clarity in the mandate of NTP CO and RTBD, but to the weak institutional capacity of NTP CO to take on and carry through these responsibilities. The lack of institutional capacity to coordinate active involvement of health services in outpatient care has resulted in great passivity among health service providers; despite the existence of the National TB/MDR-TB Strategy and the annually endorsed National TB Control Programme, the routine training activities and the invested resources, providers continue to regard any problem-solving or potential activity for more effective TB/MDR-TB control as being outside their responsibility. The efforts of MSF-F to embed good practice and effective MDR-TB outpatient and inpatient care within health facilities was successful during the pilot phase, with intensive support; but so far MSF-F has not succeeded in handing over the entire chain of activities needed for successful treatment to health service facilities backed by NTP CO. The causes underlying this situation need further documentation and study to to arrive at effective institutional capacity-building interventions.

Stewardship

An effective TB/MDR-TB strategy requires development of an institutional platform which will ensure accountability, establish clear responsibilities and promote active coordination among health service providers at all levels of care. Armenia has the political will to address the TB and MDR-TB challenge, and can rely on financial and technical assistance from the donor community. However, if these assets are to be converted into effective action to stop the increasing trend in TB/MDR-TB incidence, it must strengthen its capacity to make the most efficient use of these assets. The political will to face the challenge of TB/MDR-TB must be reflected in the institutional map of the health system in order to promote good governance and effective service organization and management.

Recommendations

For Ministry of Health and NTP

- ***Develop a comprehensive overall health sector strategy***, including TB care and control services.
- ***Conduct an in-depth study on the quality and coverage of DOTS+ care***. Use this to plan a more robust system for ambulatory TB care, which is needed to ensure adequate care for those TB patients who are currently still admitted unnecessarily to TB wards where they are at risk of infection.
- ***(Create) Strengthen NTP CO institutional capacity in the following areas***
  - TB/MDR-TB policy development – not merely one-off documents, but the package of policy instruments that will translate strategy into programmes and measurable performance (process) indicators.
  - TB/MDR-TB policy implementation, coordination and oversight – not one-off documents endorsed by the Ministry of Health, but coordination mechanisms for accountability, coordination, follow-up and progress evaluation among different health system agencies and authorities, levels of care, and providers.
  - Monitoring and evaluation (M&E). Set process targets that indicate institutional transformation and strengthening at different levels of care. Set the baseline and negotiate time-bound targets. Impact indicators alone will not indicate changes in health service organization.
  - Interaction, joint work and lessons learned in the dissemination of international technical assistance. It is essential to create the conditions for the Armenian health system to acquire,

disseminate and put into practice the wealth of international technical assistance it has been offered. Strengthening of the health system for more effective TB/MDR-TB control depends on NTP CO's institutional capacity to absorb international financial support and technical assistance effectively.

- ***Establish responsibility and accountability for TB/MDR-TB action implementation***. NTP CO is not an implementing agency, and depends on the regular health services for implementation. The line of authority and accountability remains under the responsibility of Ministry of Health departments and marz health authorities. Therefore, a clear and effective institutional mechanism needs to be established to provide CCM and the TB working group with a clear mandate, a working programme and sufficient staff (at NTP CO) to support the regular activities of these coordination mechanisms.
- ***Address and clarify ownership, roles and accountability between NTP CO and Ministry of Health*** (as well as with SHA). The current dissociation among these key actors is generating "business as usual" activities that maintain the status quo, instead of generating the expected change towards more effective outpatient care.
- ***Address and clarify ownership, roles and accountability between NTP CO and GFATM PIU***. As NTP CO gains in leadership and institutional capacity, the division of labour and distribution of responsibilities and attributions of the GFATM Project Implementation Unit (GFATM PIU) and NTP CO need to be revised in order to ensure that GFATM PIU works to support NTP, and not vice versa.
- ***Address and clarify ownership, roles and accountability between NTP and health providers*** at national and subnational level. The ultimate responsibility for the control of TB/MDR-TB infection in Armenia lies with the Ministry of Health, as the lead agency in the health sector. The Ministry can coordinate TB/MDR-TB services with marz health authorities and health care providers. NTP CO can develop policy instruments and guidelines, but responsibility for effective action remains with the health service organization departments of the Ministry. Accordingly, the Minister of Health has recently taken over the chairmanship of TB CCM, and has designated his deputy as the responsible officer overseeing the strengthening of the Ministry's capacity to lead the effort for more effective TB/MDR-TB control. This is an encouraging step that calls for support for immediate institutional capacity-building to make the coordination effort effective. This could take the form of institutional development of NTP CO (or a designated body within the Ministry) to serve as technical committee for policy improvement and coordination.
- ***Address and clarify ownership, roles and accountability of RTBD as a reference centre***, and its mandate in defining and coordinating the overall national strategy for TB/MDR-TB. As in all TB services, inpatient care and outpatient care are both elements of the overall system. There is sufficient international experience to specify the conditions under which a patient should follow one treatment protocol or the other. It is important to specify the role of each health-care service provider, including RTBD, on the basis of internationally recognized clinical guidelines and an evidence-based assessment of Armenia's capacity to provide inpatient and outpatient care. A reformed, internationally accredited TB dispensary has a key role to play, consistent with its own mandate and functions. It cannot, however, provide the outpatient care that needs to be offered throughout the regular health services.
- ***Create a stronger mechanism for territorial coordination with marz health authorities***. TB/MDR-TB service coordination has been decentralized to marz health authorities, mirroring the decentralization of the overall health system. However, the decentralization process has not been accompanied by clear coordination mechanisms to ensure the integration of TB/MDR-TB services into the regular health services and establishment of lines of responsibility and authority at either national or marz levels. These mechanisms must be established: routine meetings and communication with NTP CO are no substitute.

For Ministry of Health, NTP and National Centre for AIDS Prevention (NCAP)

- ***Improve national TB and HIV strategic documents*** to reflect collaborative TB/HIV actions. The country should include a full set of collaborative TB/HIV activities and references to the separate National TB/HIV Strategic Plan 2010-2014 in the National TB Control Programme and the new national HIV programme.

- As a matter of priority, ***finalize the terms of reference of the newly appointed TB/HIV coordination group***, on the basis of the National TB/HIV Strategic Plan 2010-2014, make the group operational and initiate regular meetings and joint activities. The TB/HIV coordination group should conduct a joint policy revision in order to ensure coherence between different strategic documents. It should also monitor implementation of the recommendations of this report.

For international organizations

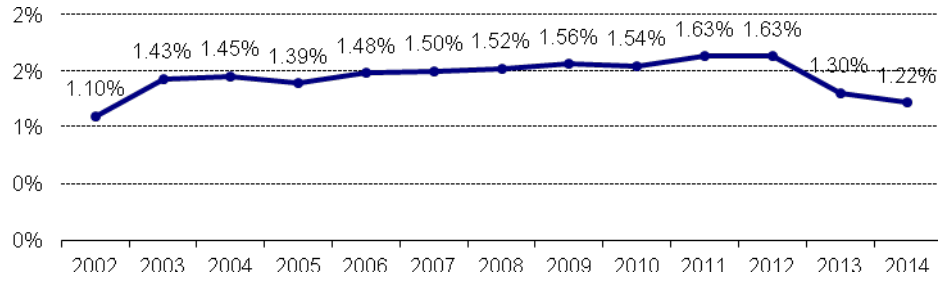
- ***Conduct a comparative study of Georgia and Armenia*** to identify good practices, health system factors and managerial processes and structures that have contributed to/hindered reforms intended to create a state-of-the-art response to ambulatory TB control, backed up by high-quality hospital services.
- It is strongly recommended that ***MSF-F continues to provide support for TB control in general***. However, more emphasis should be placed on a future exit strategy, by concentrating on developing the capacity of national and regional level TB/MDR-TB management staff.

Financing

Findings

Overall, Government expenditure on health has increased considerably over the last decade. The proportion of health expenditure to gross domestic product (GDP) remained relatively stable from 2001 to 2008. Government expenditure on health as a percentage of total Government expenditure fluctuated in the same period from around 6.6% to 9.7%. Projections indicate that the Government is intending almost to double the percentage of consolidated budget expenditure in the health sector, to 12% by 2021. In absolute terms this would mean a five-fold increase in the current budget for health. More recent figures from the Medium Term Expenditure Framework (MTEF) 2011-2013 indicate that the Government will spend about 1.5% of GDP on health in the coming years (Figure 9).

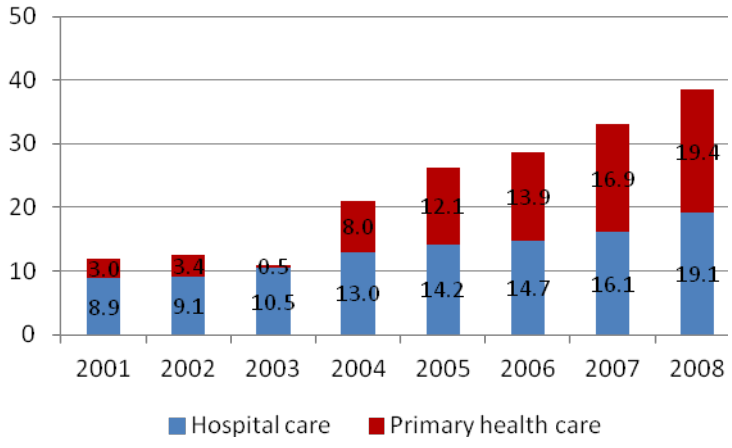
Figure 9: Public spending on health as % of GDP (Source MTEF)



Source: Medium Term Expenditure Framework 2011 - 2013

The proportion of the health budget spent on primary health care (PHC) increased relative to hospital care from roughly 25% in 2001 to 50% in 2008 (Figure 10).

Figure 10: Total Government expenditure on health by sector, in billions of drams, 2001-2008



Source: Health System Performance Assessment Report

The costs of TB services are largely covered by the Government (salaries of general staff, inpatient costs and ambulatory care). Most health expenditure goes on recurrent costs (96.7% in 2011) and only 3.3% on

capital costs. Additional external support, supplementing that provided by the Government, is available to cover programmatic aspects, such as the cost of MDR-TB medicines and support for diagnostic services.

The full range of TB care and control services is provided free of charge for all TB patients. However, costs are not always covered for certain treatments for side-effects and additional diagnostics. Although the contribution of the Government has increased proportionately over the past decade, out-of-pocket spending still remains the single biggest modality of health expenditure. On average, the population spends 12.3% of reported income on health care. The poorest quintile spends more than twice that figure (26.2%), while the richest quintile spends about 5%.[1]

The current financing mechanisms for TB control provided by SHA strongly promote inpatient care. While ambulatory care is reimbursed as a fixed amount per capita, inpatient care is reimbursed by the Government on the basis of the number of days that TB beds are occupied. As a consequence, 80% of all expenditure for TB goes on inpatient care, compared with only 20% on ambulatory care.

Recommendations

For Ministry of Health and NTP

- Make a proposal to ***scale down the excessive use and capacity of TB wards*** by tightening up the criteria for admission for TB/MDR-TB inpatient care. Include a specification of location, capacity and number of TB wards that are needed for inpatient care across the country for the coming decade or longer.
- ***Promote performance-based ambulatory care*** by setting up a performance-based incentive system using a multiplier for general and MDR-TB activities applied to the current flat-per capita remuneration or included in a composite per-capita-based PHC performance multiplier indicator.[2]

For Ministry of Health and SHA

- Revise the reimbursement mechanisms for TB care and control intended to ***reduce excessive inpatient care while promoting performance-based ambulatory TB diagnosis and care***. Excessive inpatient care can be reduced by tightening up and adhering to the admission criteria for TB patients in combination with restrictions on bed capacity.
- ***Align financing and funding flows according to NTP-established TB/MDR-TB strategy, policy objectives and action plans***, instead of by budgetary line (GFATM or Government funds). Undertake a financial flow analysis of TB and MDR-TB activities in order to realign TB and MDR-TB financing. Consider this financing realignment as a very powerful mechanism to introduce a better balance between PHC-based outpatient care and dispensary-based inpatient care. A clearer understanding of funding body and source may help clarify the role of the different agencies involved in the financing of TB/MDR-TB. The Ministry of Health, SHA and GFATM would gain significantly from this exercise in understanding of the current situation and the potential they have to progress towards more balanced outpatient and inpatient care provision.

Key recommendations

- Update the 2007-2015 National TB Control Programme document based on recent developments and in line with the Stop TB Strategy.
- Reform financing mechanism to disincentive excessive hospitalization and promote ambulatory diagnosis and treatment.
- Rationalize excessive hospitalization by revising criteria for inpatient treatment.
- Establish an external governing board of RTBD (in charge of overall management of the hospital).
- Strengthen human resources and authority of NTP and endorse the status of NTP CO as the responsible body within the Ministry of Health for implementation, monitoring and evaluation of the National TB Control Programme.

1 National Statistical Service/Ministry of Health/ORC Macro. *Armenia demographic and health survey 2005*. Calverton, MD, 2006 (http://www.armstat.am/file/article/dhs_2005e_00.pdf, accessed 16 December 2011).

2 As an alternative to the current flat-rate per capita reimbursement, one could add a composite multiplier that reflects the performance of the general PHC system. Currently, this includes delivery of maternal and child health care (immunization coverage, screening for anaemia, antenatal care) and chronic disease management (diabetes, hypertension, coronary heart disease), but not care of infectious diseases (Source: USAID Healthcare System Strengthening in Armenia (HS-STAR) project).

- ***Address the overall financing strategy of RTBD*** based on the role it plays within overall TB and MDR-TB inpatient care, and not as a separate entity. Among the issues to be considered (once the Ministry of Health establishes the role and size of RTBD) is the context of a patient-centred national TB/MDR-TB strategy which privileges minimum-length hospital stays backed by internationally recognized clinical criteria. Mission members discussed with SHA a reconsideration of the financing strategy of RTBD and establishment of a fixed budget to cover current and future running costs, which should be diminishing. "Performance payments" should be over and above the fixed budget. Criteria need to be established according to international good practice, and not per patient or per day.
- ***Address the overall financial strategy for outpatient care***, and not only incentives for health workers. Create a financial stake for polyclinics (and not just health workers) to be involved in case-finding and treatment – these are an organizational endeavour, not a matter for individual health-care providers. An extensive review of TB prevention, care and control field visits found outstandingly motivated health staff in direct contact with patients. What they seemed to lack was organizational support (logistics, information, resources, etc.) from the health facilities where they operate, and from the health system as a whole. A financial incentive mechanism needs to be developed to integrate TB/MDR-TB activities into the health system at the health-facility level.
- ***Design a payment strategy for TB/MDR-TB care to give incentives for continuity of care*** throughout the different phases of treatment, including both inpatient and outpatient treatment. International experience is readily available showing different purchasing mechanisms that have been successful in coordinating and providing incentives for cooperation among providers and levels of care, and these can be shared with the Ministry of Health, SHA and NTP for discussion.
- ***Embark on performance-based financial incentives*** in order to compensate for some discrepancies created by the per capita payment system (in outpatient facilities) and improve treatment outcomes. Incentives should be introduced alongside interventions to improve the knowledge and skills of health-care providers and control the quality of care provided.

Financial incentives at outpatient facilities

There are several types of possible incentives.

- *Patient incentives* – may be stand alone interventions or a package: travel costs (reimbursement, tokens, passes or vouchers), clothing, hygiene kits, patient monetary payment, direct payment (upon treatment completion or periodic for regular attendance), returnable deposit, food (hot meals, dry rations or food vouchers).
  - Objective: patient adherence.
  - Indicator: patient adherence – e.g. at least 80% adherence/visits or calculated per number of uninterrupted visits to DOT point.
- *Performance-based incentives* for teams, organizations and levels of government may be direct payments e.g. to facilities, earmarked for salaries.
  - Objective: to motivate teams of providers to increase the number of cases detected and people cured through cooperation, discovery and implementation of innovations at the system level that strengthen organizations and improve effectiveness, teamwork and system changes to improve outcomes.
  - Indicators: number of cases notified, new cases confirmed by microscopy, completed treatments or cured patients.

An example of a combination of different types of incentive

Inpatient facilities receive maintenance costs.

Outpatient facilities employ a combination of patient incentives and incentives for team/organization and individual provider.

Possible examples include:

- shared incentive for attendance/adherence: e.g. US$ 5 per 10 uninterrupted DOTS visits, split 50/50 between provider and patient;
- completed treatment or cured patient – lump sum at end of treatment e.g. US$ 200 shared between patient (35%), provider (35%) and health-care facility's "salaries and improvements" fund (30%). This can include a split payment to prison/civilian sector for each case successfully treated;
- concordance rate of at least 90% based on external quality assurance (EQA) report: e.g. US$ 100 paid into laboratory salaries fund based on EQA results of each quarter.

This example, based on a rough calculation of 500 SS+ TB patients and 150 MRD-TB patients (50% with a 12-month and 50% with an 18-month continuation phase) amounted to US$ 528 000 and was discussed in advance with the GFATM Portfolio Manager. This example does not contradict the recommendations of the *Assessment of financial mechanisms of TB service delivery within the health system in Armenia*, prepared by the working group.

- *Performance-based incentives for individual (health-care) workers* – may include direct payment, food packages, vouchers and other material goods.
  - Objective: to promote extension of DOTS services to ensure greater patient access and increased adherence, expand access to treatment by promoting outreach and reducing default rates, and encourage completion of treatment.
  - Indicators: patient adherence, number of new cases confirmed by microscopy, treatment success rate.

If inpatient financing is reformed by the Ministry of Health, some funds may be freed up, and these can be used by the Government to finance the incentives. Part of the incentive scheme can be financed by GFATM. The TB financing working group, headed by the Ministry's finance and accounting department, needs to propose the exact mechanism and amounts. This scheme should be acceptable and logistically feasible, and the availability of funds should be guaranteed.

To ensure that patients' views and perspectives are taken into account, it is recommended that patient focus groups and/or nongovernmental organizations representing patients should be involved in the discussion about patient incentives.

Once a performance-based incentive has been chosen, it is critical to plan implementation at all levels.

- Clear unambiguous communication with recipients.
- Control over quality of care and performance measuring, reporting and monitoring mechanisms. Capacity-building may be required for the staff who are going to implement these tasks.
- Incentive management: timely supply of funds or material goods.
- Continuous monitoring and evaluation of the incentive scheme itself: whether the desired results have been achieved, identify need for any corrective action and make changes if required.

Human resources development

A number of recommendations in the area of human resources development (HRD) made by the TB Assessment Mission of 2005 were followed up during the TB Prevention, Care and Control mission. A number of new areas for action were also identified, based on interviews with NTP CO, information gathered during field visits, visits to pre-service education providers (Armenian National Institute of Health (NIH) and Yerevan State Medical University (YSMU)) and talks with other stakeholders. All recommendations given by the TB assessment mission of 2005 in the area of human resources development have been implemented by NTP and the Ministry of Health.

Workload, salaries, training (*example of a situation from a facility in Yerevan)*

This facility serves 40% of Yerevan's population, with its official catchment area has 30 000 people. Of a total of 141 staff, the TB cabinet employs two TB doctors, five nurses and two laboratory technicians. Home-based treatment is provided for bedridden patients or (exceptionally) those who refuse to come to the DOT facility (money is available for travel by one nurse to carry out home visits). There is open enrolment – patients can choose which facility they go to.

- Workload is high: 41 MDR-TB patient (visits six days a week) and 18 TB patients in addition to about 10 suspects daily. The need for one of the nurses to collect second-line drugs from NTP CO (monthly), making several trips, while the other(s) visit patients, adds to the workload.
- Contracts act as a sort of job description and are kept in the personnel department; the staff do not appear to have copies at their workplace.
- There are no training plans. At the time of in-service training at the medical college, there was no information about DOT. After hiring, no formal in-service training on DOT was offered, but other nurses explained the work to the newly hired staff. Regular supervision is conducted by MSF-F. Training is available for staff; those mentioned included TB/HIV and counselling skills training by MSF-F.
- The minimum salary at the facility amounted to 75% of full-time equivalent (fte), which was below the minimum salary. It was possible for a "cabinet" nurse to work on Saturdays, which provided a relatively substantial extra amount (4000 drams/day, equivalent to €7.30, compared with a salary of €62/month for 0.75 fte).

Findings

With the decentralization of TB services to PHC level, a training curriculum was developed and recently (2011) revised in line with WHO recommendations. Some staff members of NTP CO provided training for trainers (ToT) in 2007 (funded by GFATM), however, NTP's involvement in the provision of training is limited at this point.

NTP CO is in the process of transformation, and the organizational structure is about to change. A number of new positions were created in the past year, and it is planned to add more. NTP CO plans to revise staff job descriptions. These changes present an opportunity to improve human resources development at NTP CO. It should be noted that preserving institutional memory and maintaining adequate documentation of activities at NTP CO are important considerations while the changes are implemented.

At the service-provision level, the monitoring system has recently been revised and marz-level monitoring teams created to supervise TB cabinets in marzes. Marz monitoring teams consist of three persons, who at present conduct two monitoring visits every month to each facility. Reports on monitoring visits are kept by the team members, and a copy is sent to the marz TB coordinator and NTP CO. A copy is not, or not systematically, left with the TB cabinet concerned. The findings of the monitoring visits are, however, discussed with a polyclinic head. Marz monitoring teams have not received any formal training in monitoring or supervision. The newly created system makes no distinction between monitoring and supervision, although the recent changes present a good opportunity to make sure that monitoring does not replace supportive supervision.

The current payment of health professionals is not linked to case-load or activity. All persons working in TB are entitled to 35 days vacation (compared with the 20 days usual in the health sector), and payments for occupational hazards add a minimum of 30% extra per hazard in addition to the base salary. A double hazard (e.g. a combination of TB and psychiatric patients, laboratory work) entitles the worker to an extra 50%. Extreme hazards, such as the work of a radiologist, also entitle the worker to an extra 50% of the base salary.

There is still a relatively high demand for training in TB medicine, for at least two reasons: postgraduate training in this specialization takes only one year, which is a relatively short time, and there are State-funded residencies. However, working as a TB doctor is not very prestigious, and medical students have a fear of getting nosocomial infections, which prevents some of them from choosing TB as their specialization.

The main providers of upgrade training pre-service education in TB are YSMU (medical education) and two basic medical colleges (nursing education). The Armenian National Institute of Health (NIH) is in charge of upgrade training. Specialists from NIH are sometimes invited by NTP CO to cofacilitate short training courses on TB. The upgrade training is a cumulative seven weeks of training for doctors and five weeks for nurses, to be completed every five years. In 2011, the curricula for in-service and upgrade training were revised at the request of the Ministry of Health (Ministry approval pending). A commission with several working groups was established to revise:

- the curriculum of a one-year postgraduate education course for family doctors (including 30 hours on TB) and the curriculum of upgrade training for family doctors, which includes two days on TB;
- the curriculum of the six-month postgraduate training in TB medicine for nurses and family nurses, including 0.5% (one day) on TB, and the curriculum for upgrade training for nurses, which includes one day on TB.

The mission was informed that the revisions of the curriculum are in line with recommendations made by the National TB Control Programme and recent developments in DR-TB, based on experiences of pilot DR-TB projects in Armenia. The current revision will include more emphasis on DOTS and programme

management of DR-TB, TB/HIV coinfection, infection control and other subjects. The revisions will be based on WHO recommendations and on materials from training courses conducted in Tomsk and Riga and by TBCARE/KNCV. The curriculum for upgrade training for nurses includes prevention of DR-TB, counselling and case-management, patient education, laboratory diagnosis, TB/HIV, infection control and TB recording and reporting (R&R) forms, so that nurses are also informed (although some of these issues, e.g. R&R, are the responsibility of doctors). The mission was informed about coordination in curriculum revision between YSMU and NIH – a unified curriculum including TB is produced centrally, but thereafter detailed curricula may differ somewhat, depending on the head of the department or medical college.

In-service training provided by NTP CO has included DOTS, TB for PHC and infection control. Some specialists at NTP CO have received ToT training. In 2011, training in DOTS for primary health care was delivered by NIH. The basis for this decision, and the reason why NTP CO was not involved in delivering training, are not clear. To facilitate the training by NIH, NTP CO provided three-day ToT training courses and attended a few training sessions for quality control (acting also as cofacilitators). NTP CO considers, and participant evaluations confirm, that the strength of its training lies in its practical experience and examples, using adult learning methods. Currently all training is put out to tender by NTP CO.

Recommendations

For the Ministry of Health and NTP

Key recommendations on HRD

- Introduce performance-based financial incentives to compensate for discrepancies created by the per capita payment system (in outpatient facilities) and improve treatment outcomes.
- Develop a training policy**,** revise training plans based on a training needs assessment and develop supportive supervision plans.
- Update job descriptions of all staff at NTP CO.
- Establish a position of HRD officer with responsibility for coordination and evaluation of in-service training, supportive supervision plans and implementation and leadership and coordination of HRD activities of key stakeholders.
- Organize TB training for medical staff at penitentiary establishments.
- Start conducting training on supportive supervision, review the list of those who should be trained and train on-the-job.
- Organize training of local trainers in programme management of DR-TB, with follow-up training. Local trainers to train remaining 60 TB doctors.

- ***Develop a training policy for in-service training***, revise training plans based on a training needs assessment and develop supportive supervision plans. A package of human resources development interventions should include education and training, based on a clear training policy for in-service training and supportive supervision to promote professional growth. Health staff at penitentiary institutions should also be involved.
- ***Update job descriptions of all staff at NTP CO***. Job descriptions of all NTP CO staff need to be updated and made more extensive (include main responsibilities and tasks, reporting lines, organizational position, scope of authority, required qualifications) based on a job analysis. It is recommended that an induction programme should be introduced for new staff members, which will ensure more cohesion between the different areas of work of NTP CO. When a replacement employee comes to fill an existing position, a "handover" period should be scheduled, in which the departing employee can introduce the new employee to the new work, inform him/her about planned activities, filing and reports, share contact details and provide any necessary on-the-job training. This will help to preserve institutional memory and strengthen continuity. For advice on HRD activities, technical assistance may be obtained from an external (human resources development or management) expert.
- ***Establish a position of HRD Officer*** (or revise job description of the Training Specialist) to take responsibility for coordination and evaluation of in-service training activities, supportive supervision plans and implementation and to take the lead in the coordination of human resources development activities of key stakeholders.
- Immediately ***start conducting training on supportive supervision***, review the list of those who should be trained and train on-the-job (NTP CO). It is recommended that training in supportive supervision should be provided for all (marz) teams involved in monitoring/supervision. MSF-F may be asked to

assist NTP CO with this training. It is not necessary to involve marz-level supervisors (e.g. deputy head of marz health department) in this training if they are not directly involved in the TB programme or the provision of supportive supervision. It should be borne in mind that monitoring is not the same as supportive supervision. The supportive supervision approach improves services by focusing on meeting staff needs for management support, logistics, training and continuing education. Guidance is provided on the technical aspects of services in the form of coaching and on-the job training, rather than control or monitoring. Supportive supervision is not linked to sanctions for poor performance. During supervision training, needs are assessed and advice is provided on the spot; further needs for formal training are identified and communicated to NTP CO. Supervision is also a time when any recent training received by TB cabinets or PHC staff can be reinforced, any training follow-up can be conducted and the impact of training, in terms of improvement in job performance, can be evaluated. The current frequency of visits by marz monitoring team may be decreased from two times a month to quarterly. Teams can then spend more time at a facility and go into more depth on more urgent subjects or follow a supervision plan based on identified needs. Supervision is an additional function for the supervisors over and above their normal jobs, so replacement staff should be appointed to take over while they are engaged in supervision so that their regular work is not disrupted.

- ***Update and make available job descriptions for staff*** at all levels of the health system. The introduction of a new incentive system is a good reason to update job descriptions. A generic job description for a particular type of position (e.g. family nurse or TB doctor) may be prepared with input from the health providers themselves (e.g. focus group of family nurses). Thereafter, generic job descriptions may be adapted by health-care facilities to fit their specific circumstances.

Management of TB medicines

Findings

Selection

Selection, procurement and distribution of first-line and second-line TB drugs (FLD/SLD) and ancillary medicines to treat side-effects is centralized and is the responsibility of NTP CO and the Ministry of Health. First-line and second-line drugs are selected by NTP CO in accordance with national treatment guidelines, which are consistent with Stop TB recommendations. Fixed-dose combinations (FDC) are widely utilized and accepted by physicians and patients; however, owing to the high incidence of drug-resistant forms of TB, NTP also requires a significant proportion of single-dose formulations to adjust regimens when drug resistance is identified or medicines must be withdrawn because of side-effects. No stock-outs of FLD for susceptible cases have been reported since 2003.

Although NTP has been using TB medicines in the formulations recommended by the Stop TB Strategy since at least 2003, these formulations have not been proposed for inclusion in the National Essential Medicines List; medicines on the list are a Government priority and must thus be made available to patients at any time. Currently on the list are the single-dose first-line medicines ethambutol (E), isoniazid (H), pyrazinamide (Z), and streptomycin (S). All FDCs listed are not in the Stop TB formulations (e.g. HR300/450; HR112.5/225; HRZ 300/450/750; HRZE 300/450/750/800 – could probably be attributed to a specific manufacturer).

There are no second-line drugs on the National Essential Medicines List. Likewise, most NTP TB medicines are not included on the list of medicines liable to registration under Government orders, i.e. a list of priority medicines for national health programmes that can be procured directly from international sources and registered using a fast-track process. This list contains the same first-line FDCs (non-Stop TB formulations), and two second-line medicines, ethionamide 125 mg and 250 mg, and P-aminosalicylic acid 500 mg oral tablet. The Armenian Scientific Centre of Drug and Medical Technology Expertise (the national drug regulatory authority) informed the mission that inclusion in both lists is based on

applications received from national health programmes. It is thus recommended that NTP requests the inclusion of its TB medicines in specific formulations in the National Essential Medicines List.

Procurement

The procurement of TB medicines is 100% donor-funded, and thus requires coordination between multiple players. In the period 2003-2009, all first-line TB medicines had been procured directly from the Global Drug Facility (GDF) by GOPA, a German technical agency, with funds provided with KfW (German Government) assistance. The last shipment arrived in Armenia in the spring of 2010 with a 100% buffer stock. It was expected that these TB medicines would be enough to sustain uninterrupted treatment through 2011, and that subsequent procurement for 2012 would be ensured by GFATM Round 5 funding, followed by GFATM Round 10 funds. These plans had to be changed owing to the expiry of a large number of first-line drugs; this was due to a combination of factors, including the unexpectedly short shelf life of the GDF medicines and the poor technical capacity of NTP CO in monitoring the inventory and enforcing NTP's own treatment guidelines, e.g. timely utilization of medicines with imminent expiry dates; full utilization of RH150/150 in the intermittent continuation phase before switching to daily regimens with RH150/75; monitoring the proportion of HRZE to (HR)ZE in drug orders by facilities, etc. NTP thus had to utilize the GFATM Round 5 funds earlier, and order medicines from GDF in November-December 2010 (by the time of this review, the medicines had not yet arrived). Because of first-line drug expiry, the buffer stock had been depleted, and the expected GDF deliveries are not likely to replenish it completely. There is thus a likelihood of a funding gap for the 2011 procurement (to cover 2012 needs); the procurement should be conducted in the end of 2011 to factor in substantial GDF lead times (at least eight months). It is thus important that after the GDF first-line drugs have arrived in the country, the new NTP CO and GFATM PIU management immediately identify the required procurement (order placement) date based on the available stock, consumption rates and expiry dates. Additionally, GFATM PIU may need to adjust the Round 8 second-phase workplan to include funds for the procurement of first-line drugs to cover 2012 needs.

Second-line TB medicines are being procured by the NTP CO, also from the GDF, with GFATM funding available for 300 patients in Round 5 and for 360 MDR-TB patients in Round 8 until 2013; additionally, € 2.5 million will be made available for second-line drugs in Round 10 (approved). The first procurements of second-line drugs made by NTP in 2009 and 2010 resulted in the expiry of a significant quantity of second-line drugs (because one bulk 24-month order had been placed instead of split six-month orders, a lower-than-planned enrolment rate, and quantification mistakes for specific medicines, e.g. kanamycin (Km)). The situation has since stabilized, and there are no shortages of second-line drugs for MDR-TB cases. During the period December 2010–February 2011, however, there were shortages of ethambutol and pyrazinamide used in DR-TB treatment at the ambulatory level; this happened because of a failure by NTP to order these medicines either through GDF as first-line drugs, or through the GDF/Green Light Committee (GLC) mechanism as second-line medicines. NTP provided fixed dose combinations of HRZE instead of the two missing medicines, which also contributed to the rapid depletion of the HRZE buffer stock. The availability of a strategic procurement plan and standard operating procedures (SOPs) for inventory management for first-line and second-line medicines could have helped to avoid such situations. It is expected that, with restructuring of NTP CO and establishment of a TB drug management department, the procurement and supply system will become more efficient.

The country's laws clearly state that any procurement using Government funds must be done through open national competitive tender. Thus, in order for NTP to continue receiving first-line drugs from GDF, an arrangement was made between GFATM PIU, the Ministry of Health and GDF for direct transfer of GFATM funds to the GDF procurement agent. The same arrangement has been made for the procurement of second-line drugs through the GLC mechanism (GFATM standard requirement).

Registration

Formal registration is not required for medicines imported/arriving as humanitarian aid: for every shipment, a special waiver is obtained through the Ministry of Health and the national drug regulatory

authority. The GDF/GLC first-line and second-line products are thus not registered in Armenia. This may pose a problem if the Government switches to procurement using its own funds, or if GFATM funds for first-line drugs are channelled through the Ministry of Health: international sources of quality-assured TB medicines will not be available to Armenia. Currently, none of the WHO prequalified or GDF quality-assured TB first-line and second-line TB medicines are registered.

It should be noted that currently there is no fast-track mechanism or any special policies for the registration of WHO-prequalified medicines or medicines registered by stringent drug regulatory authorities. Registration of a generic product may take between 60 and 180 days and will cost US$ 2000; registration of an innovative product will take longer and will cost US$ 3500. The description of the processes and lists of required documents can be found on the national drug regulatory authority web site (http://www.pham.am).

Because of intergovernmental agreements between former Soviet countries, Armenia is forced to employ a double standard when registering TB medicines: proof of good manufacturing practice and bioequivalence tests are required from western companies, but not from manufacturers based in newly independent States (which is where most of the medicines come from). Quite a number of first-line non-GDF TB medicines are registered in Armenia, mostly from eastern Europe and India; TB medicines are also available over-the-counter in retail pharmacies (mostly rifampicin and streptomycin as wide-spectrum antimicrobials, but also isoniazid and ethambutol, which may suggest that TB treatment occurs outside the NTP system).

The procurement of first-line and second-line drugs through the GDF/GLC mechanisms provides a unique chance for Armenia to improve its drug regulatory, registration, quality assurance and drug procurement practices without jeopardizing the availability of TB medicines for patients. Improvements could and should address quality assurance through registration and procurement, including fast-track registration of WHO-prequalified products and the inclusion of rigorous drug quality specifications in national standard bidding documents for the procurement of medicines.

Distribution and storage

First-line and second-line TB medicines arrive in Armenia by air and are cleared through the Customs warehouse; a special waiver is required for every shipment, and it takes about 25-30 calendar days on average, sometimes longer, to clear the medicines through Customs, which seems excessive for life-saving medicines. TB medicines are then moved to the humanitarian aid warehouse and the NTP Central Medical Store.

TB medicines are not integrated into the essential medicines programme or other health programmes; NTP is thus responsible for storage and distribution. In spring 2011, NTP CO consolidated storage of first-line and second-line medications at the NTP store, which simplified inventory management and distribution (one-stop pick-up for the district facilities).

Generally, storage conditions at NTP CO and regional facilities are adequate. Staff responsible for stock management are all aware of the first-expired/first-out principle. However, there is evidence that mistakes have been made, even at the central level, resulting in loss of medicines which have expired.

Pharmacies at health facilities keep stock records in standard ledgers (two types – one by patient and individual consumption, and the other “medicines received – medicines utilized”, by drug name). The numbers are reported quarterly to NTP, when facilities come to pick up the next quarterly supply. According to NTP guidelines, NTP must maintain a 100% buffer stock at the central level, and about a three-month stock at the facility level. In practice, the buffer stock is currently lower because of drug expiry, the need to share first-line drugs with drug-resistant cases, and sudden decisions to change treatment regimens without considering the drug formulations available in stock. Armenia is, however, a

small country with a fairly good infrastructure, and with good inventory management may not need a 100% buffer stock of first-line drugs.

It should be noted that NTP has not had technical assistance in pharmaceutical management available on a regular basis. Some ad hoc assistance was provided during the GDF missions, and NTP staff have attended regional drug management workshops, but high staff turnover has rendered this assistance inefficient (none of those trained in previous years are still with NTP). NTP is now planning to establish a drug management department staffed by three pharmacists who would develop standard operating procedures for drug management and monitor and train staff in the facilities.

Recommendations

For Ministry of Health and NTP

- Revise the GFATM Round 8 Phase 2 workplan and ***adjust (1) the number of DR-TB cases in accordance with actual enrolment and (2) the required funding for the procurement of second-line medicines*** in accordance with the changes in treatment regimens and prices of the medicines.
- There may be a funding gap for the procurement of first-line TB medicines in 2012 (money will be needed at the end of 2011). GFATM Round 5 money has already been used for 2011 procurement, there are no funds in Round 8 for first-line drugs, and the Round 10 budget is unrealistically low, especially for Year 1 (must be increased by at least 70%, or more if paediatric medicines are required). It is advised that ***options for reallocating the money in GFATM Round 8 should be identified***, or other resources sought.
- ***Involve the NTP Head Pharmacist in all coordinating and decision-making mechanisms that have any relation to NTP medicines and commodities***, e.g. the GFATM CCM to advise on medicines funding and procurement, and professional drug and therapeutic boards or committees that make decisions regarding treatment regimens: no changes in regimen should be made without the endorsement of the NTP Head Pharmacist and prior verification of the programme's capacity to ensure the availability of medicines required to support the changes. This will ensure improved TB treatment coordination (e.g. decisions on regimen change will be made taking into account availability of medicines, etc.).
- ***Develop standard operating procedures for important aspects of TB medicines management***, such as selection, inventory control, ordering, handling of medicines, etc.
- Develop a list of essential NTP medicines and commodities and apply to Armenian Scientific Centre of Drug and Medical Technology Expertise to ***include NTP products in the National Essential Medicines List*** and the list of medicines liable for registration under Government orders. Maintain and regularly update the list. At the time of assessment, NTP medicines and commodities were not on the National Essential Medicines List, and as a result, cannot benefit from Government waivers and other preferential treatment. The inclusion of NTP products in the National Essential Medicines List will also help to ensure that certain medicines are used only by NTP.

For WHO/Armenia

- ***Coordinate with GDF and the WHO Regional Office for Europe to urge GDF manufacturers to prepare drug dossiers for registration***; promote fast-track registration of GDF products (may need to identify funding sources with GFATM, or negotiate free registration).

Diagnosis

To evaluate the TB diagnosis and referral systems in Armenia, the extensive review of TB prevention, care and control mission visited TB services at primary and secondary level, conducted interviews with personnel and management at the facilities, NTP CO, the Ministry of Health, MSF-F and regional health TB coordinators. Specific findings and recommendations for each facility visited are provided in Annex 8.

Findings

Suspected TB cases are defined as patients presenting with symptoms, being a contact of a TB case, or belonging to a high-risk group. Diagnosis is based on a physical examination, laboratory results, chest X-ray, previous treatment and/or previous history of TB. Often, patients with TB-like symptoms are first put on empirical treatment for about two weeks (using a wide-spectrum antibiotic) and, if the treatment does not work, then the patient is considered a TB suspect. In addition, often only one or two sputum samples are investigated, while the protocol dictates that three samples should be investigated (WHO recommends two specimens per patient for a diagnosis). Only TB doctors can diagnose TB, and in some settings not even the TB doctor in a TB cabinet dares to take the responsibility of diagnosing the disease. Smaller centres refer sputum smear-negative (SS-) patients with active TB on X-ray to a hospital or larger TB clinic for diagnosis. Even sputum smear-positive (SS+) patients are not diagnosed at smaller centres, but are referred to a hospital for diagnosis. The main reason for this practice is the current regulation which makes the patient eligible for financial support only if the diagnosis was made in hospital.

From polyclinics and smear microscopy (SM) laboratories, SS+ samples are sent to the national reference laboratory (NRL) for culture. The doctors decide whether samples from SS- cases should also be sent, depending on the clinical presentation of the patient. In some facilities, samples of SS- patients are never sent to NRL for culture or drug susceptibility testing (DST). This results in underdiagnosis of TB patients. The detection rate using smear microscopy and culture is too low: according to official data, 30% new SS+ cases (2009) and according to NRL data, 7.8% of new SS- cases are culture-positive (2010). Case detection is also low because of the inadequate quality of the sputum; 10-60% of the samples at the various sites were actually saliva. Diagnosis is delayed because, at most sites, samples are not regularly sent to NRL for culture.

Investigation of contacts of confirmed TB cases is done by sputum investigation and Mantoux testing. In a family with SS+ cases, children receive prophylactic treatment with isoniazid (even if they are Mantoux negative). Contacts under 15 years old are assigned to preventive isoniazid therapy for three months. Afterwards the contactors undergo a tuberculin test and treatment is stopped if the results are negative. If the result is positive, the treatment course is continued for another three months. Contacts who are HIV-positive and children under four years of age are assigned to isoniazid preventive treatment (IPT) regardless of the skin test result.

Case detection

Active case-finding is conducted for military personnel and detainees. TB screening of military personnel is done at RTBD. Future military personnel (usually healthy) stay in the TB dispensary for about one week for tests to exclude possible TB infection. There are 13 criminal institutions in the country, which come under the Ministry of Justice. TB diagnosis at the Central Hospital for Detainees is based on passive and active case-finding. Active case-finding involves X-ray screening twice per year.

Intensified TB case-finding in people living with HIV

TB diagnostics in people living with HIV (PLHIV) is a weak link. The system is currently organized in such a way that all TB diagnostic procedures are performed in TB facilities. PLHIV receiving care at the National

Centre for AIDS Prevention (NCAP) are referred to TB facilities once per year as a part of the regular medical check-up, or earlier if they show TB symptoms. Those from Yerevan are referred to Yerevan City TB Dispensary (YCTBD), the rest to RTBD. However, a very low number actually get tested. In 2010, out of 423 people referred, only 175 actually reached the TB facility. Of the latter, some 33% were diagnosed with TB (57 cases). Barriers such as stigma and discrimination, especially the fear of having their HIV status exposed, prevent people with HIV from attending TB facilities. There are other barriers, such as not finding time to make a further trip to a health facility, or not being prepared to spend several days there. Those who do reach a TB facility are usually exposed to TB because of the suboptimal infection control procedures. They are hospitalized for at least five days in the facility (RTBD), usually in the same room as other cases waiting for their results, who may have active TB or MDR-TB. This system carries a very high risk of nosocomial TB or MDR-TB infection. Those referred to YCTBD are not hospitalized. There are anecdotal cases in which the TB dispensary did not diagnose TB, even though the HIV specialist had noted obvious signs of TB and referred the patient three times in a row. Only at the third referral was the TB diagnosis confirmed.

NCAP does not perform TB diagnosis and does not have the equipment to do so. An application for GFATM Round 5 funding for HIV activities included TB diagnostic equipment, but the application was unsuccessful.

The National Guidelines for Management of TB/HIV Patients (2010) indicate the need for tuberculin skin testing (Mantoux) for the discovery of latent TB, when active TB is not found in PLHIV. It also calls for preventive TB treatment with isoniazid to be started if the Mantoux test is positive. TB dispensaries do not diagnose latent TB and they do not prescribe isoniazid preventive therapy to HIV/TB coinfected people when active TB is excluded (in 2010, no TB/HIV coinfected people received IPT). Only TB dispensaries have a licence to issue isoniazid.

HIV testing and counselling in TB patients and suspects

HIV testing and counselling in Armenia has been integrated into different specialized care departments, including gynaecology, dermatovenerology, urology, antenatal, infectious diseases, TB facilities, the penitentiary system and one clinic run by a nongovernmental organization. All provide provider-initiated testing and counselling (PITC) (some 160 sites). There are no rapid tests, and only medical personnel can perform the test. Mechanisms have been established to transport blood samples to NCAP for testing and to designated laboratories in marzes when the test is performed outside Yerevan.

The provider-initiated testing and counselling system in TB facilities is well developed and well financed. NCAP has trained TB specialists from RTBD, YCTBD and TB cabinets in HIV testing and counselling. However, TB patients have not been tested regularly.

Uptake of HIV testing and counselling in TB patients is low (521, or 26%, out of 2006 patients in 2009). In addition, patients are offered testing at a later stage of their hospital stay, sometimes only in the fourth week. This delay can mean a missed opportunity for enrolment in timely HIV care (if the result is positive) and in some cases even a loss to follow-up (patient may have been released from the TB dispensary by the time the test result is available).

HIV testing has increased in recent years: 255 people were tested in 2008 (12 HIV-positive diagnoses), 521 in 2009 (17 HIV-positive diagnoses, or 3%), 1242 in 2010 (17 HIV-positive diagnoses), 260 in the first quarter of 2011 (3 HIV-positive diagnoses).

Recommendations

For the Ministry of Health and NTP

- ***Ensure samples are taken for sputum smear culture of highly TB suspects*** (whether sputum smear-positive or negative) ***as early as possible and also send sputum smear-negative samples of TB suspects to NRL for culture.***
- ***Implement the Gene-Xpert MTB/Rif assay***[1] for rapid direct detection of *M. tuberculosis* and rifampicin resistance in smear-negative sputum samples of MDR-TB suspects, HIV patients, children and TB suspects with a high probability of TB, at least at NRL and YCTBD (at YCTBD also for smear-positive cases). Despite its proximity to RTBD and NRL, it is expected that there will be enough positive cases at YCTBD.

Key recommendations on diagnostics and case detection

- Change legislation and terms of reference of polyclinic doctors to increase number of doctors who can diagnose TB.
- Stimulate collaboration between diagnosing physicians and laboratory.
- Optimize transport of specimens in some regions by supplying more funds for fuel and maintenance.
- Optimize feedback of laboratory results to minimize reporting times by installing personal computers, at least in the 28 smear microscopy laboratories/TB cabinets, to enable transmission of reports by email.
- Implement the Gene-Xpert MTB/Rif assay at NRL and YCTBD.
- Investigate the feasibility of the Gene-Xpert MTB/Rif assay at TB cabinet laboratories by implementing it in: a remote marz (Lory or Shirak), Yerevan, NCAP and a penitentiary institution.
- Develop a training and monitoring programme for sputum collection for nurses and laboratory technicians responsible for sputum collection.

- Perform a pilot study to ***investigate the feasibility of introducing the Gene-Xpert MTB/Rif assay in TB cabinet laboratories*** by implementing the system in: a TB dispensary in Yerevan and in a remote area (Lory or Shirak, because of the high number of TB/MDR-TB cases), NCAP, and a penitentiary institution. It is acknowledged that the number of samples in the penitentiary system may be low; however, considering that collaboration between the prison and civilian system is not optimal, inclusion of the penitentiary system in the pilot is recommended. It is recommended that a protocol be developed for the Gene-Xpert pilot study in Armenia, including a detailed plan for implementation of the assay, diagnostic algorithms, practical implications, procurement, management of patients, monitoring of treatment response, and training.[2]
- Change legislation and terms of reference of polyclinic doctors to ***increase number of doctors who can diagnose TB***. The mission identified several reasons why patients do not get the official TB diagnosis at the primary health care level even if they have signs of TB and smear-positive sputum and/or suspicious chest X-ray (used elsewhere in the country to diagnose TB). One reason is that sometimes the person who could diagnose the TB is not a TB doctor (and thus does not have the appropriate qualifications to give an official diagnosis) and the other reason is that patients diagnosed at the primary health care level do not get the benefits (such as financial allowances, food parcels, etc.) they would get if they were diagnosed in a TB hospital. Diagnosis of sputum smear-positive pulmonary TB should be made possible in the TB cabinets and PHC facilities by officially authorizing the doctors in these facilities to diagnose TB and ensure that TB patients get the same benefits irrespective of where they were diagnosed.
- ***Optimize the feedback of laboratory results*** to minimize reporting times by installing personal computers, at least in the 28 SM laboratories/TB cabinets, to enable transmission of reports from NRL to these 28 laboratories by email.
- ***Encourage collaboration between diagnosing physicians and laboratory.***
- ***Develop a training and monitoring programme for sputum collection*** for nurses and laboratory technicians responsible for sputum collection.

1 Practical recommendations on implementation of the Gene-Xpert MTB/Rif can be found in: World Health Organization. *Rapid implementation of the Xpert MTB/RIF diagnostic test.* Geneva, 2011 (http://whqlibdoc.who.int/publications/2011/9789241501569_eng.pdf, accessed 16 December 2011).

2 The pilot study will aim to identify cases in first-line centres. Considering the low number of sputum smear-confirmed cases in Armenia, the implementation of the Gene-Xpert assay is likely to result in detection of more TB cases. In previous studies, the use of Gene-Xpert MTB/RIF significantly increased TB case-finding when used as a replacement or add-on test with microscopy. Use of Gene-Xpert MTB/RIF as a replacement for conventional culture and DST also significantly increased MDR case-finding.

- ***Optimize transportation of specimens*** in some regions by supplying more funds for fuel and maintenance.
- ***Screening of army personnel should be done outside hospital***, e.g. by a mobile screening unit every three months.

For Ministry of Health and NCAP

- ***Expand the licence for prescribing isoniazid to HIV specialists*** and ensure full implementation of IPT in PLHIV with latent TB in accordance with the National Guidelines for Management of TB/HIV Patients (2010).
- Support TB facilities in ***scaling up implementation of provider-initiated HIV testing and counselling for TB patients***. NTP should introduce qualitative and quantitative indicators for monitoring and evaluating the service.
- ***Ensure funding for supporting, motivating and accompanying those PLHIV who still need to go through diagnostics in TB dispensaries*** (i.e. when additional and more specialized tests are needed).

Laboratory network

Findings

Optimization of the laboratory network

In 2008, a reorganization of the country-wide laboratory network in Armenia, then consisting of about 60 laboratories, was proposed to optimize the quality of laboratory services in the country. Because the workload in some laboratories was too low to ensure reliable sputum smear microscopy, it was proposed to reduce the number of laboratories performing this technique and to limit the TB diagnostic services of some laboratories to sputum collection points (SCP). To bring care closer to the patients, in some regions it was proposed to set up SCP in polyclinics, which did not offer TB diagnosis at that time. A central role was proposed for NRL to perform cultures, drug susceptibility testing and external quality control (EQC) for microscopy.

The optimization plan is currently being pursued. The progress towards the optimization of the laboratory network and establishment of EQC for laboratories in Armenia was assessed during visits to 14 laboratories of different levels and discussions with NTP CO staff.

Optimization of the laboratory network started in October 2010 and is scheduled to finish by the end of 2011. So far, 30-35 laboratories still perform SM. A detailed plan is in place documenting the number of SM laboratories and SCPs that are foreseen in each region (Annex 9). After optimization of the laboratory services, all regions will have one regional SM laboratory, which will collect all sputum samples in the region. Because of the distances involved, some regions will also have peripheral SM laboratories, which will collect samples from and perform SM for one or more SCPs. Once the optimization is finalized, the number of laboratories that perform SM will be 28 (excluding NRL) and there will be 64 SCPs.

Progress has been made in optimizing the laboratory network according to the plan in Aragatsotn, Ararat, Lory, Shirak and Yerevan. The TB laboratory at RTBD was officially appointed the National TB Reference Laboratory in May 2009. Since then, the staff of NRL have been paid by NTP CO. The NRL staff have permanent positions with renewable contracts. In general, the TB laboratories in the country function under the responsibility of NTP CO, under the Ministry of Health. MSF-F has had an important role in building up laboratory capacity in Armenia. There is good contact between the NTP laboratory manager, NRL and MSF-F. Decisions about TB diagnostic algorithms at NRL are usually agreed by discussion between these three partners. The NTP laboratory manager has regular (at least once per month) contact with NRL. NRL collaborates closely with the supranational reference laboratory (SNRL) in Borstel, Germany.

The regional laboratories in the marzes send quarterly reports to NTP CO on the number of samples tested and the positivity rate, using a standardized form. On the basis of these reports, the NTP CO manager sends the laboratory consumables, such as microscope slides. Reagents for staining microscope slides are prepared by NRL, which distributes these to the regional laboratories every quarter. This ensures the quality of the reagents used in the laboratories. Samples are collected from each region twice a week by a dedicated driver who takes the samples to NRL and brings the results of previous samples back to the regional laboratory. NTP CO (with GFATM funding) has arranged to provide a car in each region and takes care of fuel and maintenance costs.

National Reference Laboratory

All samples from TB suspects collected in the regional laboratories, YCTBD and two prison laboratories are sent to NRL for culture and DST. The polymerase chain reaction (PCR) line probe assay for identification and prediction of drug resistance to rifampicin and isoniazid is performed on samples of all smear-positive and culture-positive cases.

NRL performs a three-monthly EQC of smear microscopy for the SM laboratories in the marzes (including all peripheral SM and two prison laboratories); YCTBD performs EQC for the SM laboratories in Yerevan. There are also sample exchanges between NRL and YCTBD for EQC purposes. The number of samples to be tested for EQC is based on the number of samples the laboratories receive and the positivity rate obtained at the respective laboratories, according to WHO recommendations. The NTP laboratory manager visits the laboratories in the marzes to pick up the slides that need to be checked for quality control. Blind testing is ensured and a form has been developed for reporting of the results. The NTP laboratory manager correlates the results. The concordance between the participating laboratories and the NRL and YCTBD was exceptionally high.

Recommendations

For Ministry of Health

- Find ways to overcome practical barriers and/or local resistance to reductions in the number of laboratories and ***finalize the optimization of the laboratory network*** in Armavir, Gegharkunik, Kotayk, Syunik, Tavush and Vayots Dzor.

For Ministry of Health and NTP

- To strengthen the capacity of the regional laboratories, ***increase the staff of NRL by one person*** to perform training and site visits to supervise implementation of procedures for sputum collection and smear microscopy, including internal quality control (IQC) and waste management.
- ***Improve biosafety of some facilities*** with robust exhaust fans which create enough negative pressure to make the laboratory space safer.

Key findings on laboratory strengthening

- Find ways to overcome practical barriers and/or local resistance to reductions in the number of laboratories and finalize laboratory optimization in Armavir, Gegharkunik, Kotayk, Syunik, Tavush and Vayots Dzor marzes.
- All SM laboratories should have at least a simple extraction hood with mechanical ventilation.
- The trained local engineer at RTBD should also maintain all other BSC in the country.
- Consider upgrading the level 2a laboratory at NRL to a level 3 facility in accordance with WHO guidelines.
- The NTP laboratory officer should make an inventory of the needs of SM laboratories and prepare a list of items needed, to be financed by GFATM.
- Increase the staff of NRL by one person to perform training and site visits to supervise the implementation of procedures for sputum collection and SM.
- Hire one additional specialized laboratory technician.
- Incorporate implementation of rapid PCR line probe assays for SLD testing of MDR-TB patient samples.

- ***Ensure availability of a simple extraction hood with mechanical ventilation*** in all sputum smear microscopy laboratories to improve biosafety.
- ***Strengthen laboratory capacity for smear microscopy*** in marzes so that work continues even during staff holidays.
- ***Ensure implementation of internal quality control*** for SM at all levels.
- ***The trained local engineer at RTBD should also maintain other biosafety cabinets*** (BSC) in the country.
- ***Implement annual controls for possible TB infections in all laboratory staff*** working with TB (either by Mantoux or chest X-ray, as applicable, depending on the serum conversion status of the personnel concerned), and also a registration system.
- ***When light microscopes need replacement, consider replacing them with more sensitive fluorescent microscopes.***
- ***Monitor waste management in microscopy laboratories*** and connect the waste disposal to the general waste system in the facility.
- ***Monitor the kind of masks that are in use in the microscopy laboratories*** (masks should comply with the official recommendation and fit tightly to the face).

- Implement SLD susceptibility testing using mycobacteria growth indicator tubes (MGIT).

For Ministry of Health and NCAP

- ***Introduce a set of laboratory tests for TB that could be performed at NCAP*** in order to increase the timely TB diagnosis (both active and latent). This should include: Gene-Xpert MTB/Rif, sputum collection points, X-ray (either mobile or mass miniature radiography – MMR), Mantoux test. Equip the centre with the necessary equipment and provide funds for a TB specialist (to be agreed part-time/full-time). Once the NCAP starts performing TB diagnoses, criteria for identifying a TB suspect and methods for TB screening consistent with the National TB Control Programme protocols should be agreed.

Treatment and care services

The treatment and care services of the Armenian TB system currently include 73 TB cabinets across its 10 marzes and the capital city Yerevan. However, physicians have been trained to manage MDR-TB in only three marzes. The National MDR-TB Response Plan has been developed and endorsed; however, in view of recent developments, including expansion of MDR-TB management for marzes, the National MDR-TB Response Plan may require revision.

At the moment, treatment of TB and MDR-TB is very much segregated. TB treatment can be initiated only by a TB doctor at the marz centre and, in many cases, only by the Republican TB Dispensary in Abovian. This holds true for sputum smear-positive pulmonary TB patients as well. This may place the patient under the additional burden of self-referring to another centre and having to repeat the laboratory examination. In some rural areas, and particularly in winter, this can be particularly difficult, in addition to the risk of infecting others with TB while using public transport.

All TB patients, including retreatment patients, are put on treatment with first line drugs, pending culture and DST, which is performed for sputum smear-positive patients. As soon as a patient is diagnosed with MDR-TB, he/she is referred to a specialized centre for MDR-TB treatment. The MDR-TB treatment regimen is approved by the DR-TB Committee.

Most patients are admitted to hospital irrespective of their sputum smear results. There are small hospitals in some marzes.

The treatment of patients who are moving to the Russian Federation or other countries as migrant workers is interrupted. Some patients are infected or develop TB in other countries and move back to

Armenia for treatment; then, as soon as they get slightly better, they return to their host country to earn money for their families. These patients often come back with severe forms of TB and MDR-TB.

DOT is pursued for most inpatient and outpatient facilities. TB and MDR-TB patients receive a package of social support via the Armenian Red Cross Society (ARCS) with funding from GFATM and through MSF-F. No palliative care is available for patients who do not respond to MDR-TB treatment. It is estimated that around 20 patients per year need palliative care. Contact tracing is in place (for more details, see the Diagnosis section), which includes a registry for all family contacts examined by X-ray and purified protein derivative (PPD) tests for those below 15 years of age. Preventive treatment (with six months of isoniazid) is provided for children under the age of nine months.

Findings

Magnitude of DR-TB

Every year about 220 MDR-TB patients are diagnosed with MDR-TB in civilian services of Armenia. The number may increase in the coming years with the recommended extension of testing for susceptibility to first-line and second-line TB medicines to all new pulmonary smear-positive and retreatment cases. DST is performed at NRL, thus representative drug resistance surveillance is taking place nationwide. NRL is located at RTBD and is the only place in Armenia for culture testing and DST for first-line and second-line medicines, including Yerevan city and marzes.

Cultures and DST for first-line and second-line anti-TB medications are conducted on solid Löwenstein-Jensen or Middlebrook 7H agar media and liquid media using the BACTEC MGIT-960 System. In 2010, NRL performed 6753 culture tests on 3798 patients, with 1817 being tested for follow-up and 4935 for diagnosis.

The laboratory performs around 700 DST annually for first-line drugs (691 in 2010), of which 176 cases were confirmed with MDR-TB (59 new cases and 117 retreatment cases) – 25.4%, 78 were polydrug-resistant (PDR) (11.3%) and 99 monodrug-resistant (14.3%). A total of 304 were sensitive to first-line TB medicines (43.9%). DST data analysis requires careful analysis, since 34 DST results are missing, and do not match the total of drug-susceptible cases, nor any of the drug-resistant results, which makes the data inaccurate. The DST report for second-line drugs shows that 41.4% of cases, of all MDR-TB cases (73/176) had resistance to any second-line drug, with 11.9% confirmed XDR-TB (Table 2).

Table 2: Drug susceptibility test results (2010)

Result	New	Retreat-ment	Total
Susceptible to all drugs	259	45	304
Confirmed MDR-TB	59	117	176
MDR-TB + Km/Am/Cm	6	14	20
MDR-TB + Fq	4	17	21
MDR-TB + other SLD	4	7	11
MDR-TB + Km/Am/Cm + Fq (XDR-TB)	6	15	21

Rates of DR-TB seem to have been underestimated because not all new and retreatment sputum smear-positive and smear-negative patients are sent to NRL for culture testing. It is up to doctors to decide whether to refer the sample for culture/DST to NRL, especially from marzes. Considering national data from 2008, primary MDR-TB was present in 9.4% of cases and 43% of retreatment cases. In the 2010 DST report, the proportion of MDR-TB among new smear-positive pulmonary TB cases increased to 12.5% and to 53.2% among retreatment cases. However, this report seems to be biased (more difficult cases were likely to be diagnosed at RTBD and not all cases from marzes are tested for culture and DST). It is recommended that efforts should be intensified to achieve accurate performance of national representative DRS and perform culture and DST for first-line drugs (H, R, S, E, Z) and at least kanamycin (Km)/amikacin (Am), capreomycin (Cm) and fluoroquinolone (Fq) at all strains according to the National Guidelines for Management of DR-TB (page 9, sub-chapter 2.1 Case-finding strategy in Armenia).

Table 3: Number of patients detected with M/XDR TB during 2009-2010

Data submitted for the GLC report on the number of patients detected with M/XDR-TB in the laboratory during the last eight quarters are illustrated in Table 3.

	Q1 2009	Q2 2009	Q3 2009	Q4 2009	Q5 2010	Q6 2010	Q7 2010	Q8 2010
XDR-TB	12	6	3	5	3	5	2	1
Total MDR-TB	45	37	38	36	42	56	63	60

Management of DR-TB

NTP developed the National MDR-TB Response Plan for 2009-2013, approved by the Ministry of Health, as a strategic vision for programmatic management of DR-TB (PMDT), which covers the key aspects of DR-TB. MSF-F provided intensive technical assistance in the development of the document and supports its implementation.

Programme and medical management of DR-TB started at MSF-F sites in Yerevan City and expanded to marzes, with 251 patients on treatment as of April 2011. Armenia received three GLC approvals for treatment of DR-TB: 2006 – 90 patients (MSF-F), 2009 – 200 patients (MSF-F) and 180 patients (NTP), making a total of 470 patients. With the launch of GFATM Round 8 in September 2009, it became possible to scale up DR-TB treatment to the penitentiary sector. Starting from 2009, NTP is taking the lead in expanding the programme from Yerevan to the marzes. It has made significant structural changes in TB and DR-TB care delivery by integrating vertical TB care down to the PHC level (TB cabinets).

Rapid expansion of PMDT to new marzes in 2010 has brought into question the quality of DOT during the continuation phase, especially in remote areas. The expansion was forced by improper drug order placed by NTP for 180 patients and arrived at in early 2010. Since NTP CO is taking the lead on DR-TB patient enrolment, there is a desperate need for a clear enrolment plan that matches the National MDR-TB Response Plan. No explanation was given to show whether PDR-TB patients are included in the GLC-approved cohort of 300 MDR-TB patients under the GFATM Round 8 grant.

NTP CO, with technical support from MSF-F, developed and adopted the National Guidelines for the Management of DR-TB, which regulate all medical and programmatic aspects, with minor exceptions relating to regimens for PDR-TB and monodrug-resistant cases.

Case definitions are consistent with WHO recommendations and are based on the status of the disease, prior treatment history and type of drug resistance. The type of treatment is also included in case definitions, stratifying for empirical and individualized regimens. Indications for empirical regimens include close contact with an MDR-TB case, Category II failure, and other, unspecified reasons. The DR-TB Committee should clearly define indications for empirical regimens and start them only if representative yearly DST surveys indicate a very high probability of MDR-TB for certain cases. Individualized regimens are designed according to drug resistance pattern and history of previous treatments.

The DR-TB Committee is responsible for coordination of medical management of DR-TB patients, with the presence of experts from MSF-F, and covers both civilian and prison services. Patients with monodrug-resistance, PDR-TB and M/XDR-TB from Yerevan city and marzes are presented to the committee (usually once a week) for diagnosis, treatment initiation, change of regimen, and mode of treatment delivery (inpatient vs. outpatient, transfers from/to prison, etc.).

At the inpatient and outpatient facilities visited, the regimens and dosages are adequately determined by the DR-TB Committee, in accordance with the National Guidelines on Programmatic Management of DR-TB and WHO recommendations. MSF-F has clinical experts at the majority of treatment sites and coordinates medical management of DR-TB for all patients in Yerevan city and those marzes which recently started DOTS+ treatment. The criteria for the intensive phase and entire duration of treatment match the requirements of the WHO Guidelines for the Programmatic Management of Drug-resistant Tuberculosis (2008). Dosages of levofloxacin are 750 mg in majority of cases observed, even for those

patients over 71 kg in weight. Moxifloxacin is commonly used instead of levofloxacin in regimens for patients susceptible to Fq (diabetes mellitus, HIV coinfection, mass pulmonary damage). With DST susceptible for Km/Am, some of the regimens included Cm, possibly due to the shortage of aminoglycosides. Km/Am should be the choice of an injectable agent if susceptible, as they are more potent agents than Cm. Drug shortages of E and Z during a three-month period (December 2010–February 2011) led to the use of a fixed-dose combination of drugs, including HREZ, in regimens for DR-TB patients (mostly PDR-TB).

Treatment cards were reviewed at inpatient and outpatient sites (RTBD, TB cabinet and PHC point in Kotayk marz, Shengavit polyclinic in Yerevan). Regimens for PDR-TB are determined by the DR-TB Committee, and are largely consistent with the WHO guidelines (Chapter 8, Table 8.1), with four types of regimens in use (A, B, C, D). Regimens are designed in direct accordance with DST pattern and history of previous use of first-line and second-line medications. Slight differences in regimen design and duration of treatment towards prolongation was noticed, especially for patients with HE and HES resistance, as the most common DST pattern. Guidelines for DR-TB management also include step-by-step algorithms for PDR-TB medical tactics if patient remains SS+ after first three months of treatment, when an empirical MDR-TB regimen is often initiated. Regimen D for patients with RE or RES resistance seems to be weak, and thus requires revision by the DR-TB Committee to include other SLD in case of massive pulmonary damage or initiation of an empirical Category IV regimen.

Clinical monitoring of patients is performed adequately, with narrow specialists available at RTBD and at PHC level. Requirements for clinical and bacteriological monitoring during the treatment are clear and match the WHO Guidelines for the Programmatic Management of Drug-resistant Tuberculosis (2008). Side-effects are managed adequately; monitoring forms are available, but not recorded properly at all treatment sites visited. Regular monitoring of side-effects is performed mostly at sites where MSF-F has established a permanent presence or regular monitoring, except for the prison sector. However, regular capacity-building of medical personnel, especially in TB cabinets and PHC providers in rural areas, is essential to increase the effectiveness of programme implementation.

Types of social support and patient-centred approach

- Travel costs reimbursed (200 AMD per day per patient);
- Food baskets and hygiene packages for NTP patients (once a month) through ARCS (GFATM Round 8 grant).
- Coupons for food – distributed bimonthly, 5 500 AMD each for MSF-F patients.
- Polyvalent counselling team – psychologist, social worker, nurse.
- Home visits from TB cabinet nurses for those patients who are not able to come to the polyclinic .

Treatment is directly observed in inpatient and outpatient settings. The majority of patients come for treatment to TB cabinets at selected polyclinics in Yerevan city, TB cabinets in marz centres and rural medical ambulatories run by specialized DOT nurses. Options for home-based treatment are also available in Yerevan city for patients with disabilities, elderly people and children. Delegated DOT nurses visit patients at their homes, using either public transport or MSF-F vehicles. When using public transport, travel costs are reimbursed. As one of the patient-centred approach mechanisms and options for increasing access to care, MSF-F is also implementing the "Sputnik Initiative" as an option to increase adherence to treatment for those DR-TB patients abandoning treatment due to behavioural and social challenges.[1] It does not cover patients with drug-susceptible TB and operates only in Yerevan. At he time of the mission, there were seven patients on the Sputnik Initiative. At Yerevan Shengavit polyclinic, the level of social support and its organization is impressive compared with other programmes. MSF-F provides continuous technical and financial assistance for the system of intense DOT and sociopsychological support, as well as defaulter tracing mechanisms. Use of various types of incentives and enablers led to a relatively low level of defaulted patients among the DR-TB cohort in Shengavit polyclinic with 10.5% in 2010.

1 The Sputnik ("Fellow Traveller") Initiative, first developed and implemented in Tomsk, Russian Federation, was very effective for a limited number of patients suffering from severe alcoholism who had sociobehavioural constraints affecting their treatment. A team of two nurses, a social worker and a driver deliver intensive home-based care to patients close to abandoning their treatment. At the time of the mission, there were seven patients on the Sputnik Initiative in Armenia (none of them suffering from alcoholism or drug addiction).

The quality of DOT is a challenge in the Central Hospital for Detainees in the penitentiary sector, as there is only one TB nurse responsible for treatment of patients in DR-TB infectious and noninfectious units. There is a desperate need for capacity-building in PMDT for all TB personnel (intensive training).

Cohort analysis of treatment outcomes of Category IV patients (MDR-TB only) is not yet complete, as some patients, even from the 2008 cohort, are still on treatment, and there are both MSF-F and NTP CO cohorts of patients (Annex 10). Transferred-in patients were excluded from the analysis. Four patients from the 2010 cohort were considered as cured and one as treatment-completed, making the duration of treatment less than the minimum of 18 months post-culture-conversion. Preliminary analysis of the 2008 cohort shows 56.0% of treatment success (cured + completed treatment – still on treatment), 10.6% of treatment failures, 29.3% of defaulted patients, 2.6% of deaths and 1.3% of transferred-out. The number of patients defaulting was also high in the 2009 and 2010 cohorts, even with resources available for social and psychological support of patients. A full analysis of the reasons for treatment default is essential and will benefit programme implementation. The quality of DOT, especially in new marzes, should be prioritized by NTP, and support is required from MSF-F and ARCS.

A cohort analysis of treatment outcomes for PDR-TB patients is also available for both NTP and MSF-F cohorts. PDR-TB patients transferred in and those who received only first-line TB medicines were excluded from the analysis. PDR-TB patients with laboratory-confirmed PDR-TB were identified as patients receiving regimens A, B, C and D. Detailed analysis of outcomes based on four types of PDR-TB regimens would benefit NTP and provide justification for PDR-TB treatment regimens when submitted for approval to the regional GLC-Europe Initiative.

Management of TB/HIV coinfected patients

The Ministry of Health approved the National Guidelines for Management of TB/HIV Patients in a decree dated 29 July 2010. The guidelines are comprehensive and follow the latest international recommendations. However, their implementation remains a considerable challenge.

There are currently 278 PLHIV who receive antiretroviral (ARV) therapy in Armenia. The criteria for starting therapy are a CD4 count of less than 350, clinical stage 3 or 4, active TB (irrespective of CD4 count), hepatitis B. All those with known HIV status in need of treatment are currently receiving it. The number of late diagnoses is considerable. In the period 2007-2010, one third (33%) of PLHIV received their HIV diagnosis with a CD4 count of less than 200; 13% with a CD4 count of 200-349; 12% with a CD4 count of 350-499; and 18% with a CD4 count above 500. In 20% of cases, the CD4 count at the time of the HIV diagnosis was not known, because of an interruption in the supply of CD4 tests.

According to NCAP, 78% of those with known HIV status were seen in care in 2010 and 82.9% are still on ARV after 12 months of initiation (data for October 2009–September 2010). Those who interrupt their treatment are mostly migrants who leave the country.

NCAP has six departments: prevention, epidemiological and surveillance, laboratory diagnostics, psychosocial counselling and medical care. There are six doctors in the medical care department, who also form a mobile unit that visits TB dispensaries, prison hospitals and other places where PLHIV are hospitalized (home-based care, in marzes) and provides ARV treatment and monitoring.

HIV treatment and care is fully under the supervision of NCAP. Inpatient care is provided in infectious disease clinics, including the Nork infectious disease clinic, Armenicum clinic (for opportunistic infections other than TB; patients with active TB are not admitted to Armenicum clinic). Ambulatory care is based at NCAP, including all laboratory tests for treatment monitoring (CD4, viral load). There are no tests for HIV drug resistance.

The mobile unit visits TB facilities to prescribe treatment and monitoring and perform laboratory tests. PLHIV are supportive of this approach and appreciate the presence of specialized doctors whom they know and trust. Patients are given ARV sufficient for one month at a time, which they keep and

administer themselves. TB clinicians have no clinical experience of the management of HIV and opportunistic infections, and are not involved in ARV therapy. There are recent reports that the nurses in TB facilities are taking away ARV from patients in order to administer them with other medications; however, this was not agreed with NCAP and there was no special training.

Only 47% (nine people out of 17 TB/HIV coinfected) received cotrimoxazole preventive therapy (CPT) in 2009. There is no information on how many eligible people (CD4 count less than 200 or clinical stage 3 or 4) have received CPT. The low number was explained as being due to contraindications and side-effects.

Management of drug dependence

The national methadone programme (started end of 2009) is an important drug dependence treatment option for injecting drug users, and also an essential HIV prevention activity. It currently covers 124 people, but has the potential to expand, given that the estimated drug user population is around 5000. The criteria for enrolment in the programme are several failed attempts to get treated for drug dependence through detoxification and age over 18 years. The programme gives priority to people with HIV, TB or hepatitis. The programme is not anonymous. There is currently no provision of methadone in TB inpatient facilities.

This programme has the potential to increase uptake of TB diagnosis and improve treatment outcomes in active IDU, as it could serve as an entry point to diagnostics. While hospitalized in TB dispensaries, IDU could be provided with methadone for their drug dependence. This would increase their adherence and reduce the drop-out rate due to drug use.

Recommendations

For Ministry of Health

- ***Continue improving models of care and treatment success rate to avoid further emergence of drug-resistant TB.***
- Allow registered physicians who are trained and coached in TB ***start TB treatment for sputum smear-positive pulmonary TB patients*** while they schedule a visit by a specialist during the intensive phase of treatment (as early as possible).

For Ministry of Health and NTP

- ***Consider ambulatory treatment of patients whose sputum results are negative.*** Discharge from hospital and ambulatory treatment is recommended for patients whose sputum results are negative. Because sputum smear-negative patients are not infectious, they should ideally be sent home directly after their sputum has been found to be smear-negative. These patients do not pose a threat to their direct contacts and are at unnecessary risk of reinfection during their stay in hospital because of suboptimal infection control in most TB care facilities.
- ***Ensure diagnosis of patients in ambulatory or half-day admission.***
- ***Examine all retreatment patients with a rapid diagnostic method*** (lymphocyte proliferation assay (LPA) and, in future, Gene-Xpert MTB/Rif) in order to diagnose MDR-TB as early as possible.
- ***Explore the possibility of treating TB and MDR-TB patients in the same centre*** (to be discussed with NTP and MSF-F on integration of TB and MDR-TB services).
- ***Plan and implement scale-up of PMDT to new marzes after intense evaluation*** of the preparedness of each marz to manage DR-TB patients properly during ambulatory treatment. Fast expansion puts in jeopardy the successful implementation of the NTP, can lead to poor programme and treatment outcomes and may increase the risk of further spread of drug resistance due to poor DOT. Regular M&E visits by NTP should be conducted at all treatment sites according to plan, with technical assistance from MSF-F. Intense training in PMDT should be provided for TB and PHC providers in all settings, especially prior to expansion to new marzes, including all aspects of diagnosis and treatment, infection control and M&E.
- ***Consider palliative care services*** for patients who fail MDR-TB treatment by end 2012. Palliative care can be organized in a special centre or at home with specific measures of infection control. The

authorities may consider compassionate use of drugs for eligible patients after review by the national ethics committee.

- ***Consider as a last-hope treatment the compassionate use of new drugs*** for management of patients with extensive drug resistance and no clinical dynamics. This may contribute to a positive outcome in patients suffering from severe disease. New drugs should be used according to Annex 5 of the WHO Guidelines for the Programmatic Management of Drug-resistant Tuberculosis (2008) and do not constitute palliative treatment. The possible, but unproven, benefits of experimental treatment must be weighed against the risks. Experimental treatment should be approved by the national ethics committee and the Ministry of Health of Armenia. Patients should be informed in advance of the possible benefits and risks, as well as the unproven efficacy of experimental treatment, and sign an informed consent form. Drug procurement issues, including Customs clearance, should be set up in advance to avoid possible failures of supply and interruptions of treatment.
- ***Intensify efforts to achieve accurate national representative drug resistance surveillance, and conduct culture*** and ***DST as a minimum for first-line drugs (H, R, S, E, Z) and Km/Am, Cm and Fq at all strains.***
- ***Ensure that medical aspects of DR-TB management, including PDR-TB, are fully consistent with the WHO Guidelines for the Programmatic Management of Drug-resistant Tuberculosis (2008).*** Indications for empirical regimens have to be clearly stated, assigned only by the DR-TB Committee and used temporarily for MDR-TB suspects with further adjustment when the DST results become available. The DR-TB Committee should clearly define indications for empirical regimens and start them only if representative yearly DST surveys indicate a very high probability of MDR-TB. Moxifloxacin should be used for patients with laboratory-confirmed resistance to any injectable agent (Km/Am/Cm) and Fq together (XDR-TB) as well as for resistance to Fq. Levofloxacin should be the first choice of fluoroquinolones for the majority of regimens, unless laboratory-confirmed resistance to ofloxacin (ofx) is detected. Km and Am are recommended as first-choice injectables. Adjunctive therapy is recommended for consideration for all patients; surgical management should be considered as a complementary option for patients with XDR-TB and a wide drug resistance pattern after at least two months of therapy.
- ***Consider obtaining approval for PDR-TB regimens A, B, C and D from the regional GLC-Europe Initiative.*** Coordinate with other GLC-approved programmes (Tomsk, Mary El, Novosibirsk, Latvia, etc.) for experiences of design and management of PDR-TB regimen. A detailed analysis of outcomes, based on four types of PDR-TB regimen, would benefit NTP and provide justification for PDR-TB treatment regimens when submitted for approval to the regional GLC-Europe Initiative.
- ***Prohibit use of SLD for drug-susceptible TB patients***, unless there is strong evidence of close contact. All administration of SLD should be approved by the DR-TB Committee.
- ***Record and monitor side-effects regularly, with ancillary medicines and outcomes of adverse reactions registered at all treatment sites.***
- Prioritizing a ***full analysis of reasons for treatment default*** is essential and will benefit programme implementation and quality of DOT, especially in new marzes (with support from MSF-F and ARCS).
- ***Establish a centre of excellence for DR-TB management in Shengavit TB cabinet*** for other polyclinics in Yerevan city (PMDT, including social support), with rotation of doctors and nurses from other polyclinics, including specialists from marzes. DR-TB management should be expanded to other polyclinics in Yerevan (although not to all), or the quality of DOT at the Shengavit TB cabinet will suffer from covering the majority of patients in Yerevan city. Mapping of TB and DR-TB patients in Yerevan city is needed to rationalize DR-TB management among the polyclinics. Improvements in default tracing are essential to avoid treatment interruption and further development of drug resistance in drug-sensitive TB patients and amplification of drug-resistance in DR-TB patients.
- ***Ensure implementation of the National Guidelines for Management of TB/HIV Patients (2010)*** at all HIV and TB facilities.
- ***Produce an operational manual for the TB/HIV coordination group*** that clearly describes the procedures and roles of different facilities and specialists in implementing activities related to TB/HIV prevention, diagnosis, treatment and care and is reflected in the National TB/HIV Strategic Plan 2010-2014 and the National Guidelines for Management of TB/HIV Patients (2010).

- ***Before introducing a different mechanism for dispensing ARV within TB hospitals*** (e.g. by nurses, along with TB medications) ***agree the procedures with NCAP and HIV specialists***. TB medical staff should be trained in relevant issues (i.e. how to dispense ARV).
- Collaborate with international organizations, health authorities, the International Health Regulation mechanism and charitable organizations to ***improve continuity of care for patients who leave the country***.

For NTP and GFATM TB project

- ***Consider financing a mobile methadone team that would provide support and methadone treatment for active IDU hospitalized in TB facilities.*** This will improve adherence and TB treatment outcomes.
- ***Consider a patient-centred approach at all treatment sites, with comprehensive social and psychological support available***. Alternatives to forced treatment, such as the patient-centred approach and community-based treatment with comprehensive social and psychological support, should be addressed at Government level. The coupon system used by MSF-F is recommended for consideration as an option for all NTP patients, as there is an opportunity to include the incentive in Phase 2 of the GFATM Round 8 grant. ARCS should avoid delays and gaps in delivering social support to NTP patients on treatment. Home-based treatment and the "Sputnik Initiative" should also be considered for patients with drug-susceptible and PDR-TB.

For international organizations

- Provide continuous technical assistance to ***support improvement of PMDT at all treatment sites*** (by MSF-F).

Infection control

Findings

TB infection control (IC) measures are conducted according to the "Tuberculosis Epidemiological Control in the Republic of Armenia SR 3.1.-010-08 Sanitary Epidemiological Regulations and Norms" according to Ministry of Health Decree N-21-N of 20 October 2008, which have recently been revised by the national working group on infection control, with technical assistance from invited infection control experts. In 2010, NTP developed an Infection Control Activities Organization Plan for step-by-step implementation of the WHO Policy on TB Infection Control in Health Care Facilities (2009). In addition to implementing the sanitary norms on infection control, a national TB-IC action plan has been developed by the national working group on infection control, with the support of the United States Agency for International Development (USAID) TB Control Assistance Programme (TB CAP). With the technical assistance of MSF-F, health facilities involved in MDR-TB treatment are developing a facility TB-IC plan.

During the previous GLC visit, the consultant found suspected TB patients admitted for long periods (up to two months) with almost no infection control measures in place. In the meantime, the situation at the diagnostic department of RTBD has improved significantly; however, up to two or three months ago, some TB suspects were admitted for 40-60 days, even though most examinations can be performed on an ambulatory basis.

Infection control in regional TB facilities

There are still no infection control plans in some of the TB facilities in marzes (particularly recently established inpatient facilities).

In some regional facilities with TB inpatient units, sputum smear-positive, new and retreatment patients, extrapulmonary TB and sputum smear-negative patients are admitted to the same department (although in different rooms).

Environmental measures

Some departments of RTBD were renovated two years ago, but the problem of incorrect airflow and low air-change rate per hour has not yet been corrected.

Some of the TB inpatient facilities in the marzes have received continuous upper-air radiation lamps (ultraviolet germicidal irradiation (UVGI) lamps) but have not yet installed them.

Personal protection

Respirators are available (FFPII/N95 certified) for staff. NTP CO has procured respirator fit testing kits. Some staff prefers to use types of respirators other than the round one, as they are concerned about the fit.

The national infection control strategy has indications for keeping patients hospitalized for treatment and diagnostic purposes, administrative separation of infectious patients, and environmental and personal protection.

For treatment initiation, all patients are placed in the recently renovated DR-TB unit at RTBD, with a ventilation system installed and administrative separation of patients according to their bacteriological status (DST pattern and smear/culture conversion). The recently installed ventilation system in specialized MDR-TB wards is still not functioning properly (achieving less than 6-12 air changes per hour). With donor assistance, specialized wards have been equipped with UVGIs working properly in patients' presence: this significantly decreases the risks of nosocomial transmission of infection. Certain criteria for hospitalization in the DR-TB Unit are clear, with patients remaining on the ward until they achieve smear conversion (two consecutive smears) and positive clinical dynamics. Discharge from hospital to the ambulatory sector is well coordinated with the marzes and assisted by MSF-F and ARCS.

Keeping suspects in hospital with unconfirmed DR status and keeping them in the RTBD diagnostic unit for diagnostic purposes with poor infection control may increase the risk of nosocomial transmission of DR-TB strains. Although adequate management of DR-TB in the early stages of treatment is available for all DR-TB patients at RTBD, alternatives for intensive-phase treatment in the ambulatory sector should be considered.

Yerevan City TB Dispensary manages drug-sensitive patients and those hospitalized for diagnostic purposes. Drug-sensitive TB patients with limited pulmonary damage are separated from similar patients with massive pulmonary disease and hospitalized for a minimum of 50 days. The administrative separation of infectious from noninfectious patients is inadequate, with all patients on the same floor, although they can occupy separate rooms. UVGI lamps are available, but were not used at the time of the visit.

The Central Hospital for Detainees in the penitentiary sector hosts patients with DR-TB in a specialized TB unit in a separate building. Isolation of infectious patients from those who are smear/culture-converted is adequate, except in one part of the building, where smear-/culture-positive drug-susceptible and drug-resistant TB patients are not separated adequately. UVGI lamps are available and installed in corridors and patients' rooms, but were not used properly, being turned off at the time of the visit. Health personnel do not use respirators and none of the patients in the infectious unit were wearing surgical masks.

The Armenian Parliament is currently discussing the State law on compulsory treatment of infectious TB patients who refuse treatment; however, owing to the lack of closed inpatient facilities, this seems impossible to implement. Alternatives to forced treatment, such as the patient-centred approach and community-based treatment with comprehensive social and psychological support, should be addressed at Government level.

Recommendations

For Ministry of Health and NTP

- ***Revise the national infection control strategy*** to match the WHO Policy on TB Infection Control in Health-Care Facilities (2009).
- Close down the diagnostic department of RTBD and ***ensure TB suspects are examined on an ambulatory basis***. Admission of suspected TB patients shall be limited to those cases that need an overnight stay for diagnostic procedures, provided that infection control measures are ensured to avoid nosocomial infection. The length of stay for diagnostic purposes shall be no more than six days.
- Conduct respirator fit testing for all staff using different respirators and ***order the most suitable respirators for average Armenian health workers***.
- ***Finalize the TB-IC risk assessment.***

For inpatient TB facilities

- ***Improve the ventilation system to increase air changes up to 12/hour at least in smear/culture-positive wards at RTBD.***
- ***Consider alternative ways of treating smear/culture-converted drug-susceptible patients in the ambulatory sector*** instead of keeping them hospitalized for 50-60 days at YCTBD.
- Administrative measures for ***separating smear/culture-positive drug-susceptible patients from smear/culture-positive drug-resistant patients are essential***, especially at the Central Hospital for Detainees.
- ***It is recommended that patients be discharged from the inpatient facility for treatment continuation after achieving two consecutive negative smears and positive clinical dynamics***, and when there is evidence for adequate DOT in the ambulatory phase.
- ***Ensure that health personnel in the presence of any infectious patient at all treatment sites wear respirators and that patients at all inpatient sites wear surgical masks, as a minimum.***
- ***Use UVGI lamps in patients' presence in all inpatient facilities***, ***as a minimum,*** including the penitentiary sector (wards, corridors, procedure rooms, DOT points).

Advocacy, communication and social mobilization

Objective 9 and the related strategy of the strategic plan of the Armenian TB Control Programme (2007-2015) aims at the enhancement of TB awareness and reduction of stigma and discrimination towards patients and their family members.

Findings

In accordance with recommendation (No. 3) of the 2005 TB assessment mission, an advocacy, communication and social mobilization (ACSM) group was established under CCM in September 2010, following USAID-organized training on ACSM. Members of the ACSM group are ARCS, MSF-F, a representative of GFATM and NTP CO.

At NTP CO there is a staff position of public relations specialist, whose responsibilities also include information, education and communication (IEC) activities. Recommended IEC activities are implemented: patient education sessions at TB cabinets, production and distribution of calendars, posters and leaflets showing that TB is curable and giving information about free TB diagnosis and care and common misconceptions about TB, a map of DOT cabinets and information about MDR-TB. Most of the above-mentioned visual materials were used at the facilities visited by the mission. However, the mission saw no obvious strategy for the IEC component involving impact indicators (e.g. for addressing gender differences and stigma). Information about risk groups is not aggregated for analysis (by ARCS or at

NTP CO). MSF-F has information available from patient assessment sheets and a default study is underway, but it will not take into account all the information in the assessment sheets.

A TB knowledge, attitude and practice (KAP) survey was undertaken in 2010 by the independent sociological centre "Sociometer" (the previous TB KAP survey was part of the 2005 Armenia Demographic and Health Survey). It is not clear how the results of the 2010 KAP Survey results have been disseminated and whether and how the information obtained from KAP survey(s) was used in designing IEC interventions. The quality of the 2010 KAP survey requires verification.

The results of the 2010 KAP Survey and 2005 Armenia Demographic and Health Survey are not easily comparable. Nevertheless, as an illustration, 50% of women and 60% of men in 2005, compared with 50% overall in 2010, know that TB is curable. Around 55% in 2005, compared with 30% in 2010, know that TB is transmitted by air/coughing, which may indicate a decrease in knowledge about transmission. The 2010 survey also points out the "low level of awareness" about TB symptoms.

Advocacy and social mobilization

The mission did not observe any structured advocacy efforts by civil society organizations to ensure that the Government remains strongly committed to implementing TB control policies, or to influence policy-makers or funding or international decision-making bodies.

Involving volunteers is an example of social mobilization. At ARCS there are 35 social workers (mostly nurses) whose travel costs are reimbursed when they visit patients at home. They are volunteers, and their motivation is increased by learning opportunities (sometimes from foreign specialists), which enables them to get better jobs in the future. Volunteers can get refresher training (psychosocial work and counselling skills, MDR-TB, TB/HIV, side-effects – six courses of three days' training each), which also acts as a nonfinancial incentive. Volunteers do not carry out DOT, but they trace patients' contacts and inform doctors about side-effects.

Recommendations

Key Recommendations on ACSM

- Develop an ACSM strategy based on identified risk groups and make it part of the revised NTP document.
- Study the 2010 KAP survey to determine its quality and whether its information can be put to use.
- Recruit a qualified ACSM specialist at NTP CO who can take the lead in improving coordination of ACSM activities between different stakeholders.
- Translate and print copies of of the Patients' Charter for Tuberculosis Care, outlining patients' rights and responsibilities.
- Use the existing networks, partnerships and structures already built up by other civil society organizations to support TB prevention, diagnosis, treatment and care among their beneficiaries.

For Ministry of Health and NTP

- ***Develop an ACSM strategy based*** on identified risk groups and make it part of the revised National TB Control Programme document. The 2010 KAP Survey should be studied by NTP CO to determine its quality and whether its information can be put to use. If necessary, external technical assistance may be used. During the update of the national TB strategic plan, the ACSM strategy should be clearly formulated with identification of special risk groups, related objectives, and more targeted activities, preferably based on information from a (new) KAP survey. Alternatively, a KAP survey may be planned as one of the ACSM activities, particularly aiming to improve the quality of behaviour change communication interventions (key messages, information channels, target groups, etc.). To ensure close cooperation between different stakeholders, the ACSM strategy should be formulated with the involvement of civil society organizations and the ACSM group of the CCM. Measuring outcome and impact is a prerequisite, and it is important to develop a set of indicators and monitor all interventions. To evaluate long-term effects, it is imperative to conduct a second KAP at the end of the project.[1] The ACSM strategy should be translated into a costed annual plan.

1 Frequency of KAP studies - measuring behavioural change is every 3-5 years, depending on the project cycle and available budget.

- Immediately ***recruit a qualified ACSM specialist at NTP CO*** who can take the lead in improving coordination of ACSM activities between different stakeholders. ACSM training is essential for the person with the responsibilities of an ACSM focal point, and should form part of induction training, together with an introduction to the focal points of civil society organizations working in TB and their activities. It is best if this specialist can be recruited before the formulation of the ACSM strategy so that he/she can take an active part in this activity. The specialist should cooperate closely with civil society organizations and be part of the ACSM group. The job description for this position needs to be revised to reflect a broader number of ACSM tasks, going beyond IEC tasks. External technical assistance is available to assist with ACSM-related activities or help to design a KAP survey. The format, content and methods of dissemination of the printed materials and activities may need to be re-evaluated, based on the identified risk groups. For example, migrant workers can be targeted with materials posted in airport waiting areas, and other at-risk or vulnerable groups can be effectively reached with messages about TB via organizations of PLHIV, IDU, rural women's organizations and others. At the stage of developing the materials, they all should always be validated with the target audience and adapted to specific groups according to their needs.
- ***Translate and print copies of the Patients' Charter for TB Care*** (PCTC) outlining patients' rights and responsibilities. This charter should be adapted to the existing laws and regulations of Armenia. The launch of the Charter should be preceded by training for staff on its use (e.g. integrating information about PCTC into training on patient counselling). PCTC is a key element of the WHO Stop TB Strategy, and was launched in 2006. In order to promote empowerment and involvement of patients, it is recommended that the promotion of PCTC should be included on the agenda of the ACSM group of CCM. It is recommended that PCTC should be adapted, translated intot Armenian and printed. It would also be possible to set up a patient forum to discuss the quality of services, and exchange ideas between patients and TB services.

For MSF-F and ARCS

- ***Make copies of the Patients' Charter (adapted if necessary) available to patients at inpatient and outpatient facilities***. It is recommended that ARCS and MSF-F include the Charter as an annex in social assistance contracts signed by MDR-TB patients and provide information about it in patient education sessions.

Penitentiary system

Findings

The penitentiary system in Armenia comes under the responsibility of the Ministry of Justice. There are 13 penitentiary institutions, of which 12 are currently in use. One of the institutions (Nubarashen) is a pretrial institution, and approximately 95% of all offenders await their court decision there. The other 11 institutions are intended for convicted prisoners, although some of them in the remote areas include small pretrial facilities as well.

The responsibility for prison health lies with the Ministry of Justice. The Health Unit of the Criminal Executive Department of the Ministry of Justice has a health-care plan for prisons for 2006-2015.

In recent years, a number of international organizations have supported the strengthening of the prison health system in Armenia. In the period 1998-2008, the International Committee of the Red Cross (ICRC) supported the prison system, with a particular emphasis on the TB control programme. In 2008, an extensive review of the programme took place, when ICRC withdrew its support. A handover/takeover (HOTO) report was submitted to the Ministries of Health and Justice. The report included recommendations for the TB control programme and the overall prison health system. The report stressed that management of TB cases within Armenian prisons remains challenging because of the generally poor prison health system.

In 2001, Armenia adopted the European Prison Rules of the Council of Europe, and the Ministry of Justice endorsed the corresponding standards on prison health care. These standards include:

- giving prisoners access to the same quality and range of health-care services as the general public receives from the national health service;
- integrating prison health policy with national health policy, and linking the administration of public health with the health services administered in prisons;
- ensuring equivalent professional independence for health-care staff working in penitentiary institutions with their professional colleagues working in the community.

The prison population in Armenia has almost doubled since 2008, mainly because of changes in the criminal justice system, e.g. stricter rules regarding early release from prison. The prison population numbered 3965 in 2008 and increased to 5142 in 2010. The current prison population is almost 6000. The rapid increase in the number of prisoners has led to overcrowding in most institutions. This is currently the main problem facing the prison system, and also presents the prison health system with enormous challenges.

There are 179 full-time positions for health-care staff in penitentiary institutions, of which approximately 25% are vacant. The majority of prison health staff are currently working as Ministry of Justice officers. However, there are discussions of abolishing the health staff's officer status. If prison health staff had civilian status, it might increase their approachability and prisoners' trust in them and increase their professional independence.

A new structural division for alternative types of punishment ("administrative sentences") was created in 2008. Approximately 120 persons are currently serving their sentence in a special institution. Also, sentencing persons to alternatives to imprisonment is now possible by law, which should enable the country to reduce the number of detainees in penitentiary institutions in future. However, these alternative sentences have not been widely used up to now.

As detainees are listed as a vulnerable group in Armenia, they all have access to free health care. Detainees primarily receive health care from doctors working for the institution where they are detained. At the request of the prison doctor, various health specialists from the penitentiary system and, if necessary, from the civilian system, conduct on-site consultations for detainees.

NACP has conducted HIV-related activities in prisons since 2004. Voluntary HIV testing and counselling is available for detainees in all institutions. Antiretroviral therapy is provided by NCAP at the Central Hospital for Detainees. Information material on HIV/AIDS is developed by NCAP and distributed in all institutions.

Owing to improvements in medicines management and the supply system at the Ministry of Justice, all essential medicines are currently available in prison health units.

TB Control Programme of the Ministry of Justice

The Ministry of Justice TB control programme in prisons is part of the national Ministry of Health TB Control Programme. After the official withdrawal of the International Committee of Red Cross (ICRC) from the Ministry of Justice TB control programme in 2009, ICRC supported completion of a joint ICRC/NTP/Ministry of Justice manual on TB control in prisons. Furthermore, ICRC provided support for the Ministry of Justice in the development of a TB infection control plan for prison settings, which is currently available in draft form.

Since 2002, active and passive case-finding methods have been used to detect TB among prisoners. Screening of prisoners takes place using MMR every six months on a voluntary basis. The majority of prisoners participate in the biannual screening. For example, in the Kosh institution between 22 and 24 September 2010, 648 prisoners participated in the screening, out of a total prison population of 750 at

that time (currently 951). Twelve TB suspects were identified during the screening and were moved to the Central Hospital for Detainees the same day. Three of them were confirmed as TB cases and enrolled in treatment in the Hospital for Detainees.

As part of the six-monthly screening, all prison staff may be screened for TB by MMR as well. In Nubarashen pretrial institution, detainees are also screened using MMR on arrival, as a standard practice.

Within the penitentiary system, there are two institutions where TB patients are treated, receiving full-course treatment. These institutions are the pretrial institution Nubarashen and the Central Hospital for Detainees. Detailed observations on the TB facilities of the penitentiary system are presented in Annex 11. The Central Hospital for Detainees is the only institution that treats DR-TB, currently supported by MSF-F and gradually to be taken over by NTP.

All those suspected after MMR examination (upon entry or by six-monthly screening) or questionnaire upon entry, will undergo sputum smear examination. There are two TB microscopy laboratory facilities within the penitentiary system, at Nubarashen and the Central Hospital for Detainees, where sputum is sent for analysis. If required, culture and DST are carried out by NRL. Suspected cases of TB within all penitentiary institutions are transferred to the Central Hospital for Detainees for confirmation of the diagnosis. NTP regularly (every three months) monitors TB treatment practices at the Central Hospital for Detainees and Nubarashen and sends a monitoring visit report to the authorities of the Ministry of Justice Criminal Executive Department.

Health information system – continuity of care

Data on TB patients from medical units in penitentiary institutions are reported to TB facilities in the civilian sector, but the system could be strengthened. Every three months the Ministry of Justice reports on TB to NTP, using quarterly, handwritten DOTS forms (TB01). NTP integrates the data into the national TB database. The introduction of an integrated, advanced information system is currently being discussed by the Ministry of Justice and NTP.

Adequate communication of data on TB patients between penitentiary institutions and the civilian sector is also essential in ensuring continuity of care for the detainee upon release from the penitentiary institution. Currently there is an exchange of information between the penitentiary and NTP/civilian facilities, but information flows need to be strengthened. Before a detained TB patient is released, the Ministry of Justice TB unit sends the detainee's medical data (TB09 and TB01 forms) to NTP, which contacts the civilian TB facility in the detainee's region within two weeks, to ensure his/her registration and continuation of treatment after release from the penitentiary institution. If necessary, the Ministry of Justice TB unit provides the patient with TB drugs for 10 days after release to avoid any interruption of treatment. However, too often the TB staff working in the prison are not aware of the patient's imminent release, so that the information is sent only after the detainee has been released and continuity of care is not adequately achieved. Data on treatment outcomes for ex-detainees are sent by NTP to the Ministry of Justice, and these show that only 30% of ex-detainees continue their treatment in the civilian sector after their release. In 2008, 10 prisoners on TB treatment were released from the penitentiary system; in 2009, the number was 6 and in 2010, it was 11.

Key recommendations on TB control in penitentiary institutions

- Strengthen infection control with administrative, environmental (e.g. improved ventilation) and respiratory protection measures.
- Improve early TB case detection by piloting Gene-Xpert MTB/Rif.
- Guarantee continuity of care for TB patients upon entry to a penitentiary institution and after release.
- Introduce IEC and Patients' Charter for TB Care.
- Increase the involvement of NTP in all aspects of TB prevention, control and care in penitentiary institutions, not only treatment.

Recommendations

For the Ministry of Justice

- Allocate funds to ***finalize construction of a new pretrial institution*** and close down Nubarashen pretrial institution because of the very poor conditions prevailing there.

- ***Improve infection control in penitentiary institutions***, taking a "whole-prison" approach. Adequate measures must be in place in the entire penitentiary institution for treatment of TB and other health conditions to be effective:
  - improved ventilation in TB wards and cells;
  - preventing contact between sputum smear-negative and sputum smear-positive TB patients, and between TB and non-TB patients;
  - encourage mask-wearing by staff, patients and family members, if necessary.
- ***Increase the involvement of NTP in the TB programme*** in penitentiary institutions, including all aspects of TB prevention, control and care, not only treatment.
- ***Electronically record and analyse the data on TB cases submitted to NTP*** (for their own records, even though an integrated database is not yet established).
- Improve early case detection in all penitentiary institutions, by consistently using the TB questionnaire included in the medical cards of detainees and by ***introducing a Gene-Xpert MTB/Rif*** pilot. Also, diagnosis confirmation should be reconsidered, i.e. whether it should be organized in the penitentiary institution where the detainee with suspected TB is being held, or in the Central Hospital for Detainees, in order to make the process of diagnosis as timely, safe and cost-effective as possible. This does not apply to the penitentiary institutions where diagnosis confirmation is done by the closest civilian TB laboratory.
- ***Revise the benefit package for (TB) health staff in the penitentiary system***, to make conditions and benefits more attractive for them.
- ***Develop a human resources plan for health staff working in penitentiary institutions,*** to reassess the number and type of staff positions needed, as well as the need to fill current vacant positions. For instance, there is only one nurse at the Central Hospital for Detainees providing DOT for sputum smear-positive and sputum smear-negative regular TB cases, who cannot be replaced by any other staff member.
- ***Develop a human resources development plan*** and collaborate with Ministry of Health and NIH for ***provision of essential postgraduate education and training for prison health staff***.
- ***Intensify HIV prevention activities.*** Prison authorities should expand access to condoms and water-based lubricants in various places in prisons, not only in family meeting rooms. Prison authorities should evaluate the reasons for the low uptake of clean needles and syringes and adjust the implementation and delivery of these programmes accordingly.
- ***Optimize delivery of ARV and opioid substitution therapy (OST)*** so it does not limit uptake and the scale of implementation. Removing implementation from the hospital system and incorporating it into the health services provided in all prisons (wherever conditions, especially the prisoner's health status, allow) is possible and could contribute to wider access and uptake. However, special attention should be given to respecting confidentiality and preventing stigma and discrimination against prisoners who are treated in regular prisons.

For the Ministry of Justice and Ministry of Health/NTP

- ***Strengthen the collaboration between the Ministry of Justice and Ministry of Health with regard to prison health.***
  - More funds (Government and donor-supported) should be allocated for strengthening the prison health system.
  - A joint assessment of the health and health needs of prisoners should be conducted within the next year.
  - Health-care services in prisons should be further developed in line with national health strategies, health-care sector reforms and quality assurance systems.
  - An integrated electronic health information system should be developed, in which health indicators used in the civilian sector are also applied to the penitentiary sector.
  - A network needs to be established between the different prison health units and between the prison health units and health facilities in the civilian sector to facilitate contacts and exchange of medical data (phone, Internet).

- ***Intensify collaboration and coordination, in order to agree on responsibilities and practicalities regarding TB management in penitentiary institutions***. The following points need to be specifically addressed.
  - Discuss the need to strengthen TB education, including specific education for all prison staff, detainees, TB patients and family members. Currently, only information brochures are developed and available within the penitentiary system, but a more integrated TB education programme needs to be established.
  - Set up an advanced, integrated TB information system, to be used by both NTP and the penitentiary system.
  - Increase regular monitoring functions and include not only Nubarashen and the Central Hospital for Detainees, but also other penitentiary institutions to monitor case detection, management of suspected cases, etc.
  - Ensure availability and use of FFP2 or N95 respirators by all prison staff who may be exposed to TB.

Partnership and civil society involvement

Findings

Information provided by Mission East Armenia, ARCS, "Protect Children from TB" Foundation, Real World Real People, AIDS Prevention, Education and Care (APEC) and NTP CO was used to review existing partnerships and civil society involvement and opportunities for the future.

Civil society organizations and patient involvement

ARCS and MSF-France are the two key civil society organizations in Armenia that work with TB patients. Psychosocial assistance and IEC activities provided by them are described elsewhere in this report. Involvement of patients and ex-patients in patient education was piloted by ARCS at one polyclinic, where three ex-patients provided information during the training session (the observations show that (ex-)TB patients are not willing to be involved in social activities, owing to a fear of being stigmatized). MSF-F has not carried out regular peer support activities, but it developed and made available a list of patients who are willing to provide education and communicate health messages to other TB patients. Peer support activities need a planned approach supported by a detailed budget. This will produce better trained peers and improve their motivation.

Stigma is a major problem for TB patients and PLHIV. An example of overcoming stigma from Armenian HIV nongovernmental organizations is a programme to empower PLHIV by increasing their self-confidence and organizing a study tour to meet peers in Ukraine (nongovernmental organization alliance). One outcome of this initiative was the establishment of self-help groups for PLHIV in 2005, and involvement of its members in joint advocacy and psychosocial support. This experience can be replicated for TB.

The "Sputnik" programme, proven to be successful in the Russian Federation, was designed to provide access to treatment at patients' convenience (outside TB cabinet working hours). A similar initiative is due to be launched shortly by MSF-F in Armenia. Patient adherence to treatment is a problem, and good education and counselling have been identified as a solution. MSF-F nurses and counsellors have been trained in patient education. Together with other components of the psychosocial support programme, in 2010 it resulted in an improvement in patient treatment outcomes: out of 210 patients in Yerevan, only seven defaulted (compared with a 21-25% default rate at the start of the programme). A translation of an MSF-F counsellors' guide was shared with NTP.

In 2010, less complicated home-based care patients were taken over by the Ministry of Health. Prior to this, nurses were trained to conduct home-based care visits. They will get a small incentive to be part of the Sputnik Initiative. The Ministry will be involved in the MSF-F Sputnik programme from the start. Possibly ARCS or NTP CO could take it over shortly after the launch of the programme.

Most TB patients in the country are unemployed and in need of good counselling and education. Training of nurses in patient education and counselling is required, and this should not be a haphazard process. A routine detailed assessment of a patient before and during enrolment in the programme, in order to prepare him/her for treatment and encourage compliance later on, is a component of the psychosocial programme that needs strengthening. MSF-F is available to provide hands-on training for the Ministry of Health/NTP, but is not in a position to build capacity on a large scale. To improve staff motivation, those Ministry nurses, who qualify for reimbursement of travel costs and Saturday-working incentives, should be paid regularly and without delay. At present, ambulatory nurses who work on Saturdays do not receive incentives.

HIV nongovernmental organizations work with vulnerable populations, such as injecting drug users. The nongovernmental organization "AIDS Prevention, Education and Care" provides outreach services for IDU (distribution of clean needles and syringes) and also accompanies clients to the user-friendly clinic. This user-friendly clinic for the most at-risk populations is run by the Armenian National AIDS Foundation. Currently it provides testing and counselling for HIV and other sexually transmitted infections and some additional health services, such as ultrasound examination. Nongovernmental organizations such as Real World, Real People and the Positive People Armenian Network (PPAN) provide psychosocial support and organize self-help groups for PLHIV. None of these organizations works with TB issues or communicates about TB patient referral to diagnostic services.

Recommendations

For Ministry of Health and NTP

- ***Use the networks, partnerships and structures already built up by other civil society organizations*** (HIV/AIDS, IDU, etc.) ***to support TB prevention, diagnosis, treatment and care among their beneficiaries***. This activity can be part of the ACSM strategy.
- Practical ***patient empowerment*** (long-term). Patient empowerment starts by involving patients and ex-patients practically in identifying their own needs, joint strategy development, planning of activities and implementation and evaluation of results. An important step is the identification of (ex)TB patients who can act as leaders. They can be identified in collaboration with HIV/AIDS nongovernmental organizations, or they can be ex-patients who already cooperate with MSF-F, ARCS or "Protect Children from TB". A particular subject, such as patients' incentives, can be taken for a discussion with a group of (ex-)patients. At the same time, they can be informed about the Patients' Charter. Seed funding for activities of the group, should it decide to continue its meetings, should be foreseen in the ACSM budget of NTP. The group can be kept informal in the beginning. It will need an opportunity to meet with other nongovernmental organizations and the Open Society Institute, which, this mission was informed, works on patients' rights. (Ex-)patients will feel empowered when they are treated as resource persons, are not patronized and are given training and the possibility to participate in activities of existing nongovernmental organizations (e.g. ARCS) or given organizational support and seed funding if they want to form their own organization.

For GFATM TB Project and NTP

- Finance the expansion of HIV nongovernmental organization activities to ***include TB aspects in their everyday work with the most at-risk populations, such as injecting drug users***. HIV organizations should use their potential to expand their services to provide TB education and referral to diagnosis. Nongovernmental organizations that provide outreach services to IDU (e.g. APEC) could serve as a link between their clients and TB services, by distributing information, recognizing symptoms and referring (and physically accompanying) clients to TB diagnostic services. Those that plan to provide

some health services for IDU should include (some aspects of) TB diagnostics, e.g. sputum collection, using different options, such as a part-time TB clinician or fixed visits from a TB specialist. If this option is not possible, one TB cabinet, with medical staff trained and sensitized to the special needs of this population, could be identified for specialized work with IDU.

It is recommended that existing local civil society mechanisms should be used to reach risk groups, create synergies and learn from the experience of other Armenian civil society organizations.

Monitoring and evaluation

Monitoring and evaluation (M&E) of TB programme performance depends on a cascade-structured system of data management (collection, quality assurance, input, aggregation, analysis and feedback). Data management requires a proper recording and reporting (R&R) system that may be paper-based or electronically structured.

Quality assurance must be achieved through supervision visits in the field, analysis of data management in each facility and, where needed, on-the-job training provided as part of support during supervision.

Findings

Monitoring and evaluation (M&E) of National TB Control Programme performance is a responsibility of NTP CO, which monitors and evaluates the performance of the National TB Control Programme by means of regular: (a) data management (collection, quality supervision, aggregation, analysis, interpretation and reporting); (b) local capacity-building for NTP implementation; (c) field supervision and outreach; and (d) cooperation with national counterparts – NACP, the State Hygiene and Anti-Epidemic Inspectorate (SHAEI), the National Centre for Disease Control (NCDC),[1] GFATM PIU and international partners, such as WHO, MSF-F, ICRC and others.

The national M&E outreach team is composed of four members of NTP CO, each responsible for and coordinating a specific technical area: epidemiology, clinical management, laboratory network strengthening and pharmaceutical management. The SOPs for field monitoring of programme performance and outreach are defined in the relevant NTP training module. Epidemiological monitoring is performed by a group made up of two medical officers (statistician and epidemiologist) and one assistant/data management clerk. The M&E unit has insufficient technical capacity in electronic tool development for data management and database maintenance, as well as a lack of funding for outreach visits.

The main directive document for the unit is the National Monitoring and Evaluation Plan 2010-2015.[2] The M&E plan describes the approach, methods, systems and resources needed to monitor and evaluate the National TB Control Programme in Armenia. Supervisory reports are not shared promptly with the facilities visited.

The plan includes a performance framework that is organised based on the major service areas of interventions/service delivery of the National TB Control Programme. Each area is related to a national programme objective, and includes one or more indicators. Each indicator identifies baseline values and specific targets that will be achieved on a quarterly or yearly time-periods. The indicators, targets and

1 SHAEI and NCDC are two separate agencies that share responsibility for conducting surveillance for the majority of notifiable diseases in Armenia. SHAEI provides supervision and management of its subnational offices and the associated Expertise Centres, while NCDC receives, manages and analyses surveillance data submitted from the SHAEI subnational offices.

2 Approved by the Ministry of Health in December 2009. This document was a collaborative effort by NTP CO, GFATM PIU, participants in the TB M&E systems-strengthening workshop, members of the TB M&E working group, and the USAID Grant Management Solutions Project.

timescales covered in the performance framework reflect the set of targets outlined in the National TB Control Programme 2007-2015. The performance framework should be used by programme managers to monitor and evaluate the programme's progress against key indicators within specific time periods.

In addition, overall health indicators are collected by the National Health Information Analytical Centre at the National Institute of Health (www.healthinfo.am). Its terms of reference and structure are shown in Annex 12. The Centre issues several annual publications. Health and health care in Armenia is one of its key publications, monitoring 147 health indicators. Before 2010, TB was reflected by five indicators, but from 2011, 11 core indicators will be monitored. All these indicators are fully in line with the NTP M&E plan 2010-2015.

Recommendations

For Ministry of Health and NTP

- ***Discontinue monitoring of the case-detection rate of new pulmonary smear-positive TB cases and replace it with case detection of new cases and relapses.*** In 2010, WHO stopped reporting on the case-detection rate for smear-positive TB. This decision is based on the lack of certainty about its true value (the denominator) and the difficulty of measuring it directly.[1]
- ***Include an indicator that reflects implementation of new techniques in diagnosis,*** such as Gene-Xpert MTB/Rif.
- ***Revise the targets for the indicators of the TB performance framework*** based on the specific comments and recommendations made (see Annex 13).
- Improve communication with the vital registration system in order to ***increase death detection rates*** (death notified by TB service and TB deaths notified by vital registration system).
- ***Develop a compendium of TB programme performance indicators*** and encourage its use for decision-making at the marz and regional level.
- ***Decentralize the use of TB indicators at the marz level***, by organizing an annual meeting of marz TB coordinators, regional TB doctors, the TB officer from the regional SHAEI and the heads of the marz health-care departments (the latter should emphasize NTP activities with the regional administration by involving local stakeholders) at the marz level. This should take place every quarter in prisons and led by NTP CO in close cooperation with prison authorities and prison TB doctors.
- ***Case-finding indicators should be appropriately interpreted, and actions to increase the susceptibility and specificity of the case-detection system should be undertaken jointly by PHC, NTP and SHAEI.***
- ***Provide a supervisory log book or add a summary of observations and recommendations*** in the TB registry, dated and signed by supervisors. This will ensure that immediate feedback is provided for the staff of the visited facility.

Data collection and reporting

Findings

Data on TB services in Armenia are collected by public health-care facilities, the penitentiary sector and nongovernmental organizations. At the national level, the data are aggregated and analysed by NTP CO and GFATM PIU.

The main sources for information management under the National TB Control Programme are routine case notification, monitoring of treatment outcomes and operational research.

1 For details, refer to the following: World Health Organization. *Estimates of the burden of disease caused by TB and phasing out the publication of estimates of the case-detection rate for smear-positive TB*. Geneva (http://www.who.int/tb/publications/global_report/2010/gbtr10_sp_cdr_faq.pdf, accessed 16 December 2011).

The system of routine reporting and recording of TB case notification and treatment outcome monitoring is logically designed and includes the standard set of WHO recommended reporting and recording forms.[1] The system also fully incorporates the conventional Soviet-type recording and reporting forms, identifying a specific complementary role. Until electronic surveillance (hosted by a centralized database with remote access for data management) is fully implemented in the field, the conventional Soviet reporting and recording forms should remain an integral part of the system. The system is managed by NTP and primary data entry/management is performed at marz TB offices. It is considered as the main TB surveillance and treatment monitoring system in the country. The standard set of TB data recording and reporting forms for drug-resistance notification and case-treatment outcome monitoring is in place. A set of data management forms for pharmaceutical management is also in place.

The entire data collection and reporting process, by type of facility (outpatient and inpatient in the civilian sector, and penitentiary facilities) is summarized graphically in Annex 14.

The content of the forms requires updating for consistency with the latest WHO recommendations.

Data from the marz TB registries are entered on the electronic database managed by NTP CO and are updated quarterly. Data quality is ensured by a check code included in the application.

The marz-level TB case logbooks are also sent quarterly to NTP CO, where the individual case data are entered in an Epi Info database. The database contains 25 core variables, sufficient for simple cohort analysis, and does not store culture, DST or HIV test results. The data are used to monitor the main NTP indicators, which are specified in the cohort analysis methodology and are reported to WHO. The database includes all TB cases registered since 1995, although the best-validated data can be found from 2007. There is no electronic registry for drug-resistant TB cases.

Drug resistance surveillance is performed at NRL. Drug susceptibility testing is performed for all TB patients detected, followed/confirmed by culture. DST is performed for the first-line drugs, and people identified with multidrug resistance are tested for extensive drug resistance. Results are sent back to the TB doctor who sent the sample. DST data are managed electronically in a Microsoft Access database. The national electronic registry is not linked to the national DST database.

In addition to the above-mentioned data collection system, there is a parallel reporting system managed by SHAEI and NCDC. The roles of the two institutions are not well defined on paper, but appear to have been developed through practice. SHAEI provides oversight and management of its subnational offices and the associated expertise centres (through its regional/marz offices), while NCDC receives, manages and analyses surveillance data submitted from the SHAEI marz offices. Each confirmed TB case is reported to the district level SHAEI office by urgent notification (form 058u) by the local TB officer(s). This notification includes limited information. The marz SHAEI office is expected to investigate each TB case to perform contact tracing, health education, vaccination, preventive treatment and environmental disinfection. However, resources for these investigations appear to be limited, and it is unclear how often and how completely they are performed. It has been observed that SHAEI inspectors unofficially require reporting of all TB suspects going through a diagnosis process performed by the marz TB officer. This increases the amount of work for TB doctors and leads to discrepancies in the data managed by NCDC and NTP CO. The main role of SHAEI in the field is to assist TB doctors in case-finding among contacts (contact investigation).

1 World Health Organization. *Revised TB recording and reporting forms – version 2006* (document WHO/HTM/TB/2006.373). Geneva, 2006 (http://whqlibdoc.who.int/hq/2006/WHO_HTM_TB_2006.373_eng.pdf, accessed 16 December 2011).

Recommendations

For Ministry of Health and SHAEI

- ***Discontinue unofficial reporting of TB suspects to SHAEI: they should be managed by PHC services and the TB service jointly.***

For Ministry of Health and NTP

- ***Link the national electronic registry with the national DST registry on a quarterly basis in order to monitor drug resistance and verify data in the marz TB registry.***
- ***Speed up the implementation of the eTB manager in cooperation with MSH.*** Share access to the data with SHAEI and NCAP to synchronize specific activities for case-finding and management.
- ***Upgrade the core set of TB recording and reporting forms (TB01 and TB03) for treatment Category I and II*** by including the HIV section from the DR-TB recording and reporting forms, as well as DST results.
- ***Implement the quarterly reporting of DST results from the marz to the national level.*** The latest guidelines on DST reporting are recommended.[1]

For Ministry of Health/NTP and NCAP

- ***TB and HIV programmes should collect and publish data on issues that are not covered within the regular surveillance system***, such as vulnerability to TB in specific groups, migration and TB/HIV, TB-related mortality in PLHIV, etc.
- ***Update the HIV data reporting form*** used for national surveillance to reflect information about TB status (diagnosis, treatment, treatment outcomes).

1 World Health Organization. *Guidelines for surveillance of drug resistance in tuberculosis* (document WHO/HTM/TB/2009.422). Geneva, 2009 (http://whqlibdoc.who.int/publications/2009/9789241598675_eng.pdf, accessed 16 December 2011).

Annexes

Annex 1: Biography of review mission members

Dr Masoud Dara (Team leader, regular and MDR-TB)

Dr Masoud Dara works as Team Leader and Manager of the TB and MDR-TB Programme in the Division of Health Systems and Public Health of the WHO Regional Office for Europe. Dr Dara is a physician and public health expert from Belgium. In addition to his medical degree, he has completed various courses and periods of postgraduate study, including courses at the London School of Hygiene and Tropical Medicine and the Harvard School of Public Health. Dr Dara's professional career began as a clinician responsible for diagnosing and treating tuberculosis and implementing DOTS in rural and urban areas of the Islamic Republic of Iran. Since 1998, Dr Dara has worked with multiple national and international organizations implementing TB control programmes. From 1998 to 2001, he worked as the Médecins Sans Frontières programme manager and medical coordinator of several TB control projects in Central Asia. From 2001 to 2003, Dr Dara worked as a WHO Medical Officer in the Russian Federation, providing technical assistance to national health authorities and TB control services across the country. From 2003 to 2010, Dr Dara worked as a senior consultant for KNCV TB Foundation in different countries, mainly in the fields of MDR-TB, TB/HIV and TB infection control. Since 2008, Dr Dara has been the Chair of the TB Control in Prisons Working Group of the International Union Against Tuberculosis and Lung Disease. In the last six years, Dr Dara has provided technical assistance to different countries as a senior consultant and MDR-TB and TB-IC trainer. Since September 2010, Dr Dara has worked for the WHO Regional Office for Europe, coordinating WHO technical assistance to Member States in prevention and control of drug-resistant TB. Dr Dara speaks English, French, Russian, Persian and Dutch.

Dr Andrei Dadu (TB surveillance)

Dr Andrei Dadu, MD (Epidemiology), Technical Officer (TB surveillance) in the TB & M/XDR-TB control programme of the Division of Communicable Diseases and Environment of the WHO Regional Office for Europe. As a medical doctor trained in epidemiology, Dr Dadu has experience in the field of TB surveillance, monitoring and evaluation of TB control programmes and field supervision. He has been involved in the implementation of several field projects on TB, HIV/AIDS and viral hepatitis in several of the newly independent States (Republic of Moldova, Kazakhstan, Kyrgyzstan, Uzbekistan, Tajikistan, Turkmenistan, Russian Federation, Ukraine). Since July 2007, Dr Dadu has been the officer responsible for managing the TB surveillance network in the WHO European Region.

Smiljka de Lussigny (TB/HIV and other coinfections)

Smiljka de Lussigny, MPharm, MPH, is the Technical and Advocacy Officer of the HIV/AIDS, STIs and Viral Hepatitis Programme of the WHO Regional Office for Europe. Her major area of responsibility includes the development of the European Action Plan on HIV/AIDS for 2011-2015; she is also the focal point for TB/HIV coinfection, HIV prevention and treatment among men who have sex with men and transgender people, as well as for partnerships with civil society. Prior to joining WHO, she worked as the Executive Director of the European AIDS Treatment Group, a pan-European network based in Brussels, where she also spent four years on the Board of Directors. She was closely involved in the process of organizational development, including strategic planning, as well as leading fundraising and staffing efforts. She studied pharmacy at the Moscow Medical Academy and has been involved in the HIV field since 1999, focusing her work on issues such as access to HIV prevention and treatment, especially in the eastern European and central Asian regions. As a coordinator of an International Planned Parenthood European Network (IPPF EN) project, she has also been involved in design and implementation of HIV prevention programmes and sexual and reproductive health and rights interventions for vulnerable youth and men who have sex with men at national level in her home country of Serbia.

Brenda van den Bergh (TB in prisons)

Brenda van den Bergh, MSc in Economics, expects to obtain her MSc in Public Health from the London School of Hygiene and Tropical Medicine in 2012. She started her career in 2003 as a policy-maker with the Dutch National Agency of Correctional Institutions in the Netherlands. In 2007, she started in her

current position as Technical Officer for Prison Health at the WHO Regional Office for Europe. She supports Member States of the WHO European Region in improving public health by addressing health and health care in prisons and by giving technical advice on prison health system development and on a number of technical issues relating to communicable diseases, especially TB, HIV/AIDS, hepatitis, illicit drug use including substitution therapy and harm reduction, and mental health in prisons. She has focused particularly on issues related to women's health and health care in prison.

Dr Alejandra Gonzalez Rossetti (TB health systems)
Dr Alejandra Gonzalez Rossetti is a Senior Adviser on Health Policy at the WHO Regional Office for Europe, Division of Health Systems and Public Health, Barcelona Office. She has extensive experience in the field of health systems reform. She has acted as advisor to governments in both the European and the central Asian region, as well as in Latin America. Dr Gonzalez Rossetti has supported multilateral operations addressing institutional capacity-building for health policy development. Her work has focused on structuring financial and institutional incentives to increase health systems' capacity to ensure equitable access to high-quality health care. She has taught in Mexico, the United Kingdom and Brazil, and publishes on the political economy of State reform in the health and social sectors.

Dr Bert Schreuder (TB health systems)
Dr Bert Schreuder, MPH (International Health Development), MD, is senior consultant at KNCV TB Foundation, specializing in health systems development and epidemiology. The combined experience he gained both in health systems development (human resources, health sector reforms, sector-wide approaches, health financing, decentralization) on the one hand and in disease control programmes (TB, Expanded Programme on Immunization, leprosy) on the other gives him the broad view needed for results-based sustainable health-care development.

Dr Askar Yedilbayev (GLC consultant, MDR-TB)
Dr Askar Yedilbayev, MD, MPH, works as Programme Director for Kazakhstan and Medical Officer for the Russian Federation at "Partners In Health" (PIH), with practical experience in medical and programmatic management of DR-TB (PDR, MDR, XDR) and coinfection with HIV gained in the Russian Federation, Kazakhstan and Lesotho. He is a WHO consultant in a series of GLC monitoring missions in the European Region and an international trainer in related fields.

Dr Doris Hillemann (Laboratory management)
Dr Doris Hillemann, PhD. – Senior Scientist, Supranational Reference Laboratory for Mycobacteria, Research Centre Borstel, Borstel, Germany, has long-standing experience in all fields of laboratory tuberculosis diagnostics. She has acted as advisor for different organizations in the European and Asian regions to build up, assess and improve laboratory capacity. She has conducted training in new laboratory methods in Viet Nam, Peru, Brazil, and India, implemented a quality control system in Bosnia and Herzegovina, and publishes on various TB research topics, TB diagnostics and resistance mechanisms.

Dr Kristin Kremer (Laboratory management)
Kristin Kremer has worked as a laboratory expert in the TB and M/XDR-TB programme at the WHO Regional Office for Europe since April 2011. Before that, she worked for over 17 years at the TB Reference Laboratory of the Centre for Infectious Disease Control at the National Institute for Public Health and the Environment in the Netherlands. She specializes in the molecular epidemiology of TB, the laboratory diagnosis of mycobacteria, the development and implementation of DNA typing techniques and molecular diagnostics, and capacity-building.

Kristin was project manager of various large European projects on the molecular epidemiology of TB, including one on the molecular surveillance of MDR-TB, and coordinator of an EU-supported project on the adaptation of *M. tuberculosis* to anti-tuberculosis drugs and BCG vaccination. She has organized international studies on the reproducibility and discriminatory power of various genetic markers for typing of *M. tuberculosis* complex strains and has conducted research in the field of molecular epidemiology, population genetics and evolution of the *M. tuberculosis* complex. Her research has been

published in 117 articles in peer-reviewed journals and books. Kristin has organized international scientific meetings and practical workshops. She has over 16 years of experience in training visitors from many countries of Europe, Asia, Africa and South America in the molecular epidemiology of TB and working at biosafety level (BSL) 3, mainly at the National Institute for Public Health and the Environment and occasionally on-site. She has been supervisor and evaluator of numerous BSc students and a number of PhD students.

Dr Nonna Turusbekova (ACSM, civil society participation, HRD)
Dr Nonna Turusbekova, PhD, is a senior consultant at KNCV specializing in three areas: human resources for health, advocacy, communication and social mobilization and TB infection control. Dr Turusbekova has a number of years of experience in programme management and development work in the former Soviet Union, with an emphasis on marginalized population groups. She has conducted research in the area of human resources management and organization studies, focusing on performance management. Currently she provides technical assistance in developing policy, formulating strategic plans, improving motivation and performance, effective training design and social mobilization for TB control programmes internationally.

Mr Andre Zagorski (Drug management)
Andre Zagorski is Senior Technical Manager for TB for the Strengthening Pharmaceutical Systems (SPS) Programme based in Arlington, VA, United States of America. He has over 15 years of global TB and essential medicines project management experience, in regions including eastern Europe, central Asia and Africa. He manages core TB activities for SPS, including collaborative efforts with WHO, GFATM, GDF, GLC, StopTB partners and field programmes aimed at strengthening pharmaceutical management systems. His technical areas of expertise include project management, implementation and evaluation; health reform and drug policy; supply chain management, development of pharmaceutical management tools and use of tools developed by Management Sciences for Health; management information systems; monitoring and evaluation; and development of training courses and capacity development programmes. He holds a Master's degree in education and training, and has completed fellowships in psychology.

Annex 2: Timetable for the review

Preparation of health system assessment of Armenian National TB Control Programme
21 April – 22 April 2011

Time	Activity	Place	Participants
	21 April, Thursday		
12:00 – 13:00	Briefing at the WHO CO Armenia	WHO country office	B. Schreuder G. Ghukasyan
13:00 - 14:00	***Lunch***		
14:00 – 18:00	Working meetings with the National TB Programme (NTP) – Programme management – Surveillance, monitoring and evaluation – Laboratory services – Treatment – Pharmacy – Continuous education/trainings	NTP Markaryan 6/2	B. Schreuder H. Karapetyan (translator) All NTP staff
	22 April, Friday		
10:00 – 11:30	Meeting with monitoring and evaluation specialist of the WB Project Implementation Unit (Dr Edward Elibekyan)	WB PIU Shirvanzade 17	B. Schreuder H. Karapetyan (translator)
11:45 – 13:30	National Institute of Health (NIH) (research) (Dr Vladimir Davidiants)	NIH Komitas 49/4	B. Schreuder H. Karapetyan (translator)
13:30 - 14:30	***Lunch***		
15:00 – 16:30	Meeting with Deputy Chief of Party USAID|HS-STAR Project (Gayane Gharagebakyan)	USAID|HS-STAR Project Sundukian 14	B. Schreuder
	25 April , Monday		
10:00 – 13:00	Meetings at the MSF-F	MSF-F office Aygedzor 53 B	A. Gonzalez Rossetti B. Schreuder A. Yedilbayev N. Angmo (MSF-F) J. Price (MSF-F) N. Khacharyan (MSF-F) G. Mezhlumyan (MSF-F) S. Islam (MSF-F)
13:00 - 14:00	***Lunch***		
14:00 – 16:00	Meeting at the American University of Armenia (AUA) (Dr Byron Crape and Dr Varduhi Petrosyan)	AUA Baghramian 40	A. Gonzalez Rossetti B. Schreuder
16:00 – 18:00	Two mission members' debriefing	As convenient	A. Gonzalez Rossetti B. Schreuder

Extensive Review of TB Prevention, Care and Control

25 April - 05 May 2011

Time	Activity	Place	Participants
	26 April, Tuesday		
10:00 – 13:00	Preparatory work by the mission members at the WHO country office Mission internal briefing	AUA Business Centre (AUA BC), room 210	All team members WHO country office
13:00 – 14:00	***Lunch***		
14:30 – 17:00	Initial briefing by the mission – round table with Ministry of Health, NTP and other national and international partners	AUA BC, room 502	All team members Ministry of Health, NTP, MSF-F, other stakeholders V. Petrosyan (translator)
17:00 – 18:00	Meeting with the Deputy Minister of Health responsible for international collaboration (Dr Sergey Khachatryan)	AUA BC, room 211	All team members
	27 April, Wednesday		
10:00 – 11:00	Meeting with Head of the Medical Care Organization Department, Ministry of Health (Dr Karen Kostanyan)	Ministry of Health, Government building 3	M. Dara G. Ghukasyan N. Turusbekova K. Kremer A. Gonzalez Rossetti B. Schreuder D. Hillemann A. Dadu S. de Lussigny H. Karapetyan (translator)
11:00 – 12:00	Meeting with the Head of Staff of the Ministry of Health (Mr Suren Krmoyan)	Ministry of Health, Government building 3	M. Dara G. Ghukasyan N. Turusbekova H. Karapetyan (translator)
09:30 – 11:30	Meeting with NTP pharmaceuticals team	Moskovian 15	A. Yedilbaev A. Zagorski
12:00 – 13:30	Meeting with the Team Leader of the GFATM PIU (Dr Hasmik Harutyunyan)	Ministry of Health, Government building 3	M. Dara G. Ghukasyan A. Gonzalez Rossetti B. Schreuder D. Hillemann N. Turusbekova A. Yedilbaev A. Zagorski N. Mezhlumyan (NTP)
10:00 – 11:00	Meeting with the Ministry of Health Focal Point for health in prisons (Dr Tamara Ghukasyan)	Ministry of Health, Government building 3	B. van den Bergh D. Atadjanian R. Grigoryan (translator)

Time	Activity	Place	Participants
11:30 – 13:00	Meeting with head of health-care unit of the Criminal-Executive Department of the Ministry of Justice (Dr Alexandr Sarkisov) and with TB Coordinator of the Criminal-Executive Department of the Ministry of Justice (Dr Ara Hovhannisyan)	Central Hospital for Detainees Arshakuniats 2	B. van den Bergh D. Atadjanian T. Ghukasyan A. Dadu K. Kremer S. de Lussigny R. Grigoryan (translator)
13:30 – 14:30	***Lunch***		
14:30 – 18:00	Meetings at NTP – Programme management – Treatment – Surveillance, monitoring and evaluation – Laboratory services – Pharmacy – Continuing education/training	NTP Markaryan 6/2	M. Dara G. Ghukasyan A. Dadu A. Gonzalez Rossetti K. Kremer N. Turusbekova A. Zagorski NTP staff V. Petrosyan (translator)
14:30 – 18:00	Visits to the TB wards of the Central Hospital for Detainees	Central Hospital for Detainees Arshakuniats 2	B. van den Bergh D. Atadjanian S. de Lussigny D. Hillemann A. Yedilbaev B. Schreuder R. Grigoryan (translator)
	28 April, Thursday		
9:30 – 13:00	Visits to polyclinics and pharmacies in Yerevan – Shengavit; St. Astvatsamair Medical Centre; Polyclinic #18 (MDR-TB cabinet) – Malatia Polyclinic #15 (regular TB cabinet) – Pharmacies	 Arshakuniats 43 Sebastia 9	M. Dara A. Yedilbayev N. Turusbekova A. Zagorski K. Kremer A. Martirosyan (NTP) S. Islam (MSF-F) G. Mezhlumyan (MSF-F) H. Karapetyan (translator)
9:30 – 13:00	Visits to polyclinics and pharmacies in Yerevan – Avan Polyclinic #12 (MDR-TB cabinet) – Arabkir Polyclinic #8 (regular TB cabinet) – Pharmacies	 – Khudiakov 153 – Baghramian 51	A. Gonzalez Rossetti B. Schreuder D. Hillemann N. Hovhannisyan (NTP) N. Khachatryan (MSF-F) V. Petrosyan (translator)
9:30 – 12:00	Meetings at the National Centre for AIDS Prevention Samvel Grigoryan, Director	Acharian 2	G. Ghukasyan A. Dadu S. de Lussigny N. Dolyan (translator)
12:00 – 13:00	Meetings at the Narcological Clinic Acting Director Seda Jamalyan	Acharian 2	
9:30 – 13:00	Visit to the Nubarashen Criminal-Executive Institution	Nubarashen	B. van den Bergh D. Atadjanian A. Hayrapetyan (NTP) R. Grigoryan (translator)

Time	Activity	Place	Participants
13:00 – 14:00	***Lunch***		
14:00 – 18:00	Visiting Yerevan City TB Dispensary – Laboratory department – Diagnostic department – Pharmacy/drug store – Dispensary department – Inpatient department	Rubinyants back-street 7	A. Yedilbayev D. Hillemann K. Kremer K. Gharagyozyan (NTP) B. Schreuder A. Dadu N. Turusbekova A. Hayrapetyan (NTP) H. Margaryan (NTP) H. Karapetyan (translator)
14:30 – 16:00	Meeting with the Health Team, USAID Sangita Patel, Head of Health and Social Reforms office Ruben Jamalyan, Health Project Management specialist	American Ave. 1	M. Dara G. Ghukasyan A. Zagorski
16:30 – 18:00	Meeting with the State Health Agency (SHA) - purchaser of health services in Armenia Dr Ara Ter-Grigoryan, Head of the SHA	Gevorg Hovsepyan St., 10	M. Dara G. Ghukasyan A. Gonzalez Rossetti A. Zagorski N. Dolyan (translator)
14:30 – 18:00	Visit to the “Erebuni” Criminal-Executive Institution	Erebuni CEI Yerevan	B. van den Bergh D. Atadjanian S. de Lussigny N. Hovhannisyan (NTP) R. Grigoryan (translator)
	29 April, Friday		
08:30 – 13:00	Visiting TB sites in regions (joint NTP/MSF-F) – Meeting with regional health department TB coordinator – TB dispensary/TB unit of regional hospital (Abovian Medical Centre) – Polyclinic/TB cabinet (Hrazdan Polyclinic) – Rural medical ambulatory (Dzoraghbiur Medical Ambulatory)	Kotayk region	A. Gonzalez Rossetti B. Schreuder A. Yedilbayev S. de Lussigny D. Hillemann K. Kremer A. Matirosyan (NTP) N. Khachatryan (MSF-F) A. Serobyan (MSF-F) V. Petrosyan (translator)
09:30 – 13:00	Work in the NTP office on TB surveillance, continuing education/training and pharmaceuticals issues	NTP Office, Markaryan 6/2	A. Dadu A. Zagogrski N. Turuzbekova N. Mezhlumyan (NTP)
13:00 – 14:00	***Lunch***		

Time	Activity	Place	Participants
14:30 – 18:00	Visit to the Republican TB Dispensary – Laboratory department – Diagnostic department – Dispensary department – Inpatient department – Central Pharmacy of NTP and Republican TB Dispensary – National Reference Laboratory	Abovian Kotayk region	M. Dara A. Dadu A. Yedilbayev D. Hillemann K. Kremer N. Turusbekova A. Zagorski A. Hayrapetyan (NTP) H. Margaryan (NTP) N. Hovhannisyan (NTP) A. Matirosyan (NTP) K. Gharagyozyan (NTP) V. Petrosyan (translator) H. Karapetyan (translator)
09:00 – 18:00	Visit to the "Kosh" Criminal-Executive Institution	Kosh CEI, Aragasotn region	B. van den Bergh D. Atadjanian M. Hovhannisyan (NTP) R. Grigoryan (translator)
18:30 – 20:00	Meeting with Gayane Tovmasyan, GFATM PIU Team Leader (NGO PR)	Congress Hotel	S. de Lussigny N. Turusbekova
	30 April, Saturday		
09:30 – 11:00	Meeting at the Armenian Red Cross Society Narine Matevosyan, Health Sector Coordinator	Paronian 21	S. de Lussigny A. Yedilbayev N. Turusbekova H. Karapetyan (translator)
11:00 – 14:00	Home care visits with MSF-F		A. Yedilbayev
11:30 – 13:00	Meeting with "Real World Real People" nongovernmental organization (Elina Azaryan)	Minas Avetisyan 4, building 33	S. de Lussigny N. Turusbekova H. Karapetyan (translator)
11:30 – 12:30	Meeting with the Head of the National Information Analytical Centre of the Armenian National Institute of Health (NIH) (Dr Vladimir Davidyants)	NIH, Komitas 49/4	A. Dadu
13:00 – 14:00	***Lunch***		
14:00 – 16:00	Outreach with "AIDS Prevention, Education and Care" nongovernmental organization (Artak Musheghyan)	Nansen 3	S. de Lussigny N. Turusbekova H. Karapetyan (translator)
17:00 – 18:00	National Centre for AIDS Prevention	Acharian 2	M. Dara G. Ghukasyan S. de Lussigny H. Karapetyan (translator)

Time	Activity	Place	Participants
	2 May, Monday		
08:30 – 18:00	Visiting TB sites in regions (established by the MSF-F) – TB units of Aparan Medical Centre (Aparan) – Meeting with regional health department TB coordinator (in Vanadzor) – TB dispensary/TB unit of regional hospital (Vanadzor) – Polyclinic/TB cabinet (Vanadzor Polyclinic #1; Stepanavan polyclinic)	Lory region	M. Dara A. Dadu K. Kremer N. Khachatryan (MSF-F) P. Balikagala (MSF-F) N. Khachatryan (MSF-F) R. Grigoryan (translator)
08:30 – 18:00	Visiting TB sites in regions (NTP site) – Meeting with regional health department TB coordinator (Gavar) – Polyclinic/TB cabinet (Gavar polyclinic, Martuni polyclinic) – Rural medical ambulatory (Lichq Medical Ambulatory)	Gegarkunik region	D. Hillemann N. Turusbekova A. Martirosyan (NTP) N. Hovhannisyan (NTP) H. Karapetyan (translator)
10:00 – 12:00	Meeting with NTP Manager on prison health issues (Dr Armen Hayrapetyan)	NTP Office, Markaryan 6/2	B. van den Bergh D. Atadjanian S. Irbe N. Dolyan (translator)
	3 May, Tuesday		
	Work on report/preparation for the exit debriefing	WHO country office	All team members
10:00 – 11:00	Meeting with Vice-Rector for Educational Reforms, Yerevan State Medical University, YSMU (Dr Mikayel Narimanyan)	YSMU Koryun 2	N. Turusbekova K. Kremer H. Karapetyan (translator)
11:30 – 13:00	Meeting with Acting Director of the National Institute of Health (NIH) (Dr Mkrtich Avagyan)	NIH, Komitas 49/4	
10:00 – 12:30	Visit to MSF-F office	MSF-F office Aygedzor 53 B	M. Dara A. Dadu G. Ghukasyan D. Hillemann S. Irbe N. Angmo (MSF-F) L. Hovhannisyan (MSF-F) I. Oganezova (MSF-F) N. Khachatryan (MSF-F)
13:00 – 14:00	***Lunch***		
14:30 – 16:00	Meeting with the Head (Dr Artavazd Vanyan) and senior staff of the State Hygiene and Anti-Epidemic Inspectorate (SHAEI)	Nork, Gevorg Hovsepyan St., 10	A. Dadu N. Turusbekova K. Kremer D. Hillemann S. Irbe H. Karapetyan (translator)

Time	Activity	Place	Participants
	4 May, Wednesday		
09:00 – 13:00	Work on report/preparation for the exit debriefing Internal debriefing in the WHO country office	WHO country office	M. Dara D. Hillemann K. Kremer N. Turusbekova
12:00 – 13:00	Meeting with the Minister of Health	Ministry of Health, Government bld. 3	M. Dara E. Danielyan G. Ghukasyan H. Karapetyan (translator)
13:00 – 14:00	***Lunch***		
14:00 – 15:00	Debriefing with NTP office staff	American University of Armenia, room 502	M. Dara D. Hillemann K. Kremer N. Turusbekova G. Ghukasyan A. Hayrapetyan (NTP) K. Gharagyozyan (NTP) N. Mezhlumyan (NTP) N. Hovhannisyan (NTP)
15:00 – 17:30	Exit debriefing of the mission – round table with Ministry of Health, NTP and other national and international partners	American University of Armenia, room 502	All stakeholders V. Petrosyan (translator)

Annex 3: Background documents

1. Country TB profile
2. Previous TB Programme Assessment Mission Report (February 2005)
3. National TB Control Programme for 2007-2015
4. Two-Year Action Plan of the National TB Control Programme of Armenia, 2009-2010
5. National TB Monitoring and Evaluation Plan for 2010-2015
6. National MDR-TB Response Plan in Armenia, 2009-2013
7. Norms and Regulations for the Implementation of State-funded Tuberculosis Activities in Armenia, 2009
8. TB Team Technical Assistance to the National TB Control Programme of Armenia in the Area of Laboratory Strengthening, mission report, January 2011
9. TB Control Programme in Prisons: ICRC Handover/Takeover (HOTO) Report, December 2008
10. Analysis of the TB Control System in Armenia in both the Civilian and Penitentiary Sectors, September 2008
11. Anonymous Survey on Knowledge, Attitude and Practice towards TB among prisoners and prison staff in Armenia, 2006
12. TB Infection Control consultancy visit (TBCAP, USAID-funded project, KNCV TB Foundation) by Arch. Thea Zuccotti, Nestan Tukvadze, October 2009
13. TB Infection Control consultancy visit (TBCAP, USAID-funded project, KNCV TB Foundation) by Johannes Mulder, Nestani Tukvadze, July 2010
14. Framework for Reorganization (Optimization) of the TB Laboratory System in Armenia, 2008
15. Pay for Performance Scheme for Ambulatory TB in Armenia, 2009, by Michael Borowitz
16. Short policy paper on TB in Armenia, 2009, by Michael Borowitz
17. Assessment of Financial Mechanisms of TB Services within the Health System in Armenia, 2009
18. National Programme on the Response to the HIV Epidemic in the Republic of Armenia for 2007-2011, including:
    - Action Plan for Implementation of the National Programme on the Response to the HIV Epidemic
    - Financial Resources Required for the Implementation of the National Programme on the Response to the HIV Epidemic
    - Monitoring and Evaluation Indicators and Timeframe for Monitoring and Evaluation of the National Programme on the Response to the HIV Epidemic
19. National Guidelines for Management of TB/HIV Patients, approved by the Ministry of Health on 29 July 2010 (Google translation into English available)
20. Protocols for Organization of Voluntary HIV Testing and Counselling in Primary Health Care Facilities, approved by the Ministry of Health on 22 April 2004 (Google translation into English available)
21. Voluntary HIV Testing and Counselling (National Guidelines), approved by the Ministry of Health on 11 December 2002 (Google translation into English available)
22. Provider-Initiated Counselling and Testing in Primary Health Care Facilities, approved by the Ministry of Health on 22 May 2008 (Google translation into English available)
23. National TB/HIV Strategic Plan, 2010-2014
24. Report on TB laboratory assessment, by Kiebooms Ludo, December 2009
25. Effectiveness of the "Social Assistance and Information for TB Patients" project in Abovian, Armenia: a pilot study, by Karine Kentenyants, October 2007
26. Predictors of time to sputum culture conversion in MDR-TB patients enrolled into second-line TB treatment programme in Armenia: Analysis of dataset, Master's thesis project by Arax Hovhannisyan, September 2010
27. Assessment of DR-TB unit ventilation system and proposal for its improvement, by MSF-F
28. Programmatic Management of Drug Resistant TB, GLC Monitoring Report, September 2009
29. Programmatic Management of Drug Resistant TB, GLC Monitoring Report, May 2010

30. Mission report on clinical case management of patients with HIV/AIDS, by Heiko Karcher, October 2007
31. Mission report on clinical case management of patients with HIV/AIDS, by Heiko Karcher, February 2009
32. Final report on sociological survey “Regarding the knowledge, attitude and behaviour of population of Armenia towards tuberculosis disease”
33. Armenia Demographic and Health Survey 2005

Annex 4: People interviewed[1]

#	Name	Position, Organization
1.	Sergey Khachatryan	Deputy Minister of Health, Ministry of Health
2.	Suren Krmoyan	Head of Staff, Ministry of Health
3.	Ara Ter-Grigoryan	Head, State Health Agency
4.	Artavazd Vanyan	Head, State Hygiene and Anti-Epidemic Inspectorate
5.	Karen Kostanyan	Head, Medical Care Organization Department, Ministry of Health
6.	Marina Safaryan	Chief Doctor, Republican TB Dispensary
7.	Norayr Mkrtchyan	Deputy Chief Doctor, Republican TB Dispensary
8.	Mkrtich Mkrtchyan	Chief Doctor, Yerevan City TB Dispensary
9.	Samvel Grigoryan	Head, National Centre for AIDS Prevention
10.	Vladimir Davidyants	Head, National Information Analytical Centre, National Institute of Health
11.	Seda Jamalyan	Acting Director, Republican Narcological Clinic
12.	Armen Hayrapetyan	Manager, National TB Control Programme, Central Office
13.	Karen Gharagyozyan	Pharmacist, National TB Control Programme, Central Office
14.	Narine Hovhannisyan	Epidemiologist, National TB Control Programme, Central Office
15.	Hasmik Margaryan	Laboratory Expert, National TB Control Programme, Central Office
16.	Narine Mezhlumyan	Statistician, National TB Control Programme, Central Office
17.	Marjik Hovhannisyan	TB doctor, National TB Control Programme, Central Office
18.	Anna Martirosyan	TB doctor, National TB Control Programme, Central Office
19.	Alla Mirzoyan	National Reference Laboratory, National TB Control Programme, Central Office
20.	Hasmik Harutyunyan	Team Leader, Global Fund To Fight AIDS, TB and Malaria Project Implementation Unit, Ministry of Health
21.	Yelena Amirkhanyan	Project Coordinator, Global Fund To Fight AIDS, TB and Malaria Project Implementation Unit, Ministry of Health
22.	Maya Simonyan	Health System Strengthening Project Coordinator, Global Fund To Fight AIDS, TB and Malaria Project Implementation Unit, Ministry of Health
23.	Yervand Elibekyan	Monitoring and Evaluation Specialist, World Bank Project Implementation Unit, Ministry of Health
24.	Gayane Tovmasyan	GFATM PIU Team Leader (NGO PR)
25.	Mikayel Narimanyan	Vice-Rector for Educational Reforms, Yerevan State Medical University
26.	Mkrtich Avagyan	Acting Director, National Institute of Health
27.	Gayane Martirosyan	TB Coordinator, Marz Health Department, Kotayk
28.	Samvel Lambaryan	TB Coordinator, Marz Health Department, Lory
29.	Gurgen Davtyan	TB Coordinator, Marz Health Department, Gegharkunik
30.	Ruzanna Petrosyan	Doctor, TB Unit of Abovian Medical Centre
31.	Marine Yenokyan	Doctor, TB Unit of Aparan Medical Centre
32.	Marina Loris-Russo	Doctor, TB Unit of Vanadzor Medical Centre
33.	Melanya Khachatryan	Doctor, TB Cabinet of Hrazdan Medical Centre
34.	Marina Loris-Russo	Doctor, TB Cabinet of Vanadzor Polyclinic #1
35.	Hasmik Grigoryan	Doctor, TB Cabinet of Stepanavan Medical Centre
36.	Valentina Lavrova	Doctor, TB Cabinet of Gavar Medical Centre
37.	Gayane Knyazyan	Doctor, TB Cabinet of Martini Medical Centre
38.	Mosoyan Gayane	Doctor, TB Cabinet of Yerevan Polyclinic #8
39.	Armen Bardumyan	Chief Doctor, Yerevan Polyclinic #12
40.	Nazik Ghukasyan	Doctor, TB Cabinet of Yerevan Polyclinic #12
41.	Hakob Harutyunyan	Chief Doctor, Yerevan Polyclinic #15
42.	Hasmik Aivazyan	Doctor, TB Cabinet of Yerevan Polyclinic #15
43.	Gagik Petrosyan	Chief Doctor, Yerevan Polyclinic #18

1 This is not an exhaustive list and gives the names of people interviewed as provided by mission members to the editors of the report. TB patients and detainees in some of the criminal-executive facilities visited were also interviewed in this review.

#	Name	Position, Organization
44.	Hakob Ajemyan	Doctor, TB Cabinet of Yerevan Polyclinic #18
45.	Jivan Fidoyan	Head, Lichq Rural Medical Ambulatory
46.	Narine Khurshudyan	Doctor, Lichq Rural Medical Ambulatory
47.	Lyudmila Khoyantsyan	Head, Dzoraghbuir Rural Medical Ambulatory
48.	Gayane Gorgyan	Doctor, Dzoraghbuir Rural Medical Ambulatory
49.	Ella Hayrapetyan	Nurse, Dzoraghbuir Rural Medical Ambulatory
50.	Tamara Ghukasyan	Ministry of Health Focal Point for “Health in Prisons”
51.	Ara Hovhannisyan	Deputy Head of Health Unit, TB Coordinator, Criminal-Executive Department, Ministry of Justice
52.	Aram Khachatryan	Director, Central Hospital for Detainees
53.	Rafik Mikaelyan	Deputy Director, Central Hospital for Detainees
54.	Emil Martirosyan	Head of TB Department, Central Hospital for Detainees
55.	Samvel Samvelyan	TB Doctor, Central Hospital for Detainees
56.	David Harutyunyan	TB Doctor, Central Hospital for Detainees
57.	Astghik Zakaryan	TB Laboratory Specialist, Central Hospital for Detainees
58.	Diana Avetisyan	TB Laboratory Specialist, Central Hospital for Detainees
59.	Ruben Dolmazyan	Radiologist, Central Hospital for Detainees
60.	TIgran Navasardyan	Director, “Nubarashen” Criminal-Executive Institution
61.	Gor Khachatryan	Head of Health Unit, “Nubarashen” Criminal-Executive Institution
62.	Anaida Kirakosyan	TB doctor, “Nubarashen” Criminal-Executive Institution
63.	Arthur Aghabekyan	TB feldsher, “Nubarashen” Criminal-Executive Institution
64.	Hovik Petrosyan	Director, “Erebuni” Criminal-Executive Institution
65.	Hayk Harutyunyan	Head of Health Unit, “Erebuni” Criminal-Executive Institution
66.	Lyova Bagdasaryan	Director, “Kosh” Criminal-Executive Institution
67.	Samvel Gurjanyan	Deputy Director, “Kosh” Criminal-Executive Institution
68.	Arthur Kostanyan	Head of Health Unit, “Kosh” Criminal-Executive Institution
69.	Nilza Angmo	Medical Coordinator/Head of Mission, MSF-F
70.	Janti Price	Project Coordinator, Yerevan, MSF-F
71.	Phoebe Balikagala	Project Coordinator, Marzes, MSF-F
72.	Shahid ul Islam	Doctor Manager, Yerevan, MSF-F
73.	Naira Khachatryan	Assistant Medical Coordinator, MSF-F
74.	Lana Hovhannisyan	Database Manager, MSF-F
75.	Izabella Oganezova	Laboratory Supervisor, Yerevan, MSF-F
76.	Armenie Serobyan	Medical Doctor, Kotayk, MSF-F
77.	Sangita Patel	Head, Health and Social Reforms Office, USAID Armenia
78.	Ruben Jamalyan	Health Project Management Specialist, USAID Armenia
79.	Gayane Gharagebakyan	Deputy Chief of Party, USAID HS-STAR Project
80.	Davit Khachatryan	Health Information Adviser, USAID HS-STAR Project
81.	Varduhi Petrosyan	Director, Centre for Health Services Research and Development, American University of Armenia
82.	Byron Crape	Technical Consultant, Centre for Health Services Research and Development, American University of Armenia
83.	Mariam Sianozova	Regional Director, Europe/Eurasia, Project Hope
84.	Narine Matevosyan	Health Sector Coordinator, Armenian Red Cross Society
85.	Elina Azaryan	“Real World Real People” NGO
86.	Artak Musheghyan	“AIDS Prevention, Education and Care” NGO

Annex 5: TB, TB/HIV and MDR-TB country profile

Armenia

Tuberculosis profile

| High MDR-TB burden |

Population 2010 (millions) 3

Estimates of burden * 2010	Number (thousands)	Rate (per 100 000 pop)
Mortality (excluding HIV)	0.33 (0.22–0.47)	11 (7–15)
Prevalence (incl HIV)	3.5 (1.5–5.9)	114 (48–189)
Incidence (incl HIV)	2.3 (1.9–2.7)	73 (60–87)
Incidence (HIV-positive)	0.031 (0.017–0.049)	1 (0.55–1.6)
Case detection, all forms (%)	61 (52–74)	

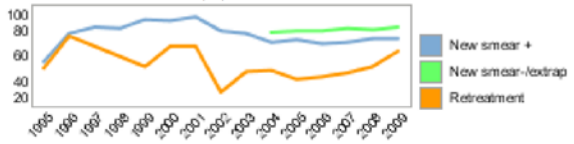
Case notifications 2010				
New cases		(%) Retreatment cases		(%)
Smear-positive	339	(26) Relapse	81	(18)
Smear-negative	639	(48) Treatment after failure	12	(3)
Smear unknown	0	(0) Treatment after default	14	(3)
Extrapulmonary	351	(26) Other	344	(76)
Other	0	(0)		
Total new	1 329	Total retreatment	451	
Total < 15 years	59			

Total new and relapse	1 410	(79% of total)
Total cases notified	1 780	

Drug regimens	
Rifampicin used throughout treatment	Yes
% of patients treated with fixed-dose combinations (FDCs)	85
Paediatric formulations procured	No

Treatment success rate 2009 (%)	
New smear-positive	73
New smear-negative/extrapulmonary	82
Retreatment	63

Treatment success rate (%)



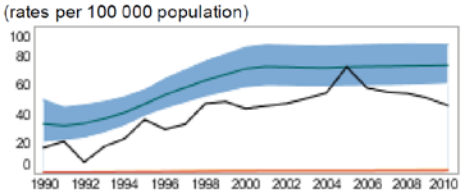
MDR-TB, Estimates among notified cases *	
% of new TB cases with MDR-TB	9.4 (7.0–12)
% of retreatment TB cases with MDR-TB	43 (38–49)
Estimated MDR-TB cases among new pulmonary TB cases notified in 2010	92 (68–120)
Estimated MDR-TB cases among retreated pulmonary TB cases notified in 2010	190 (170–220)

MDR-TB reported cases 2010	New	Retreat-ment	Total
Cases tested for MDR-TB	471	220	691
% of notified tested for MDR-TB	35	49	39
Confirmed cases of MDR-TB	59	118	177
MDR-TB patients started treatment			154

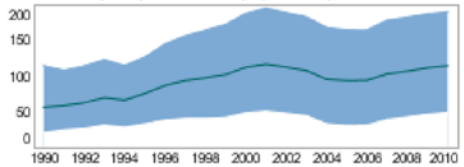
Laboratories	2009	2010	2011
Smear (per 100 000 population)	1.8	1.4	0.9
Culture (per 5 million population)	1.6	1.6	1.6
DST (per 5 million population)	1.6	1.6	1.6

Second-line DST available	In country
National Reference Laboratory	Yes

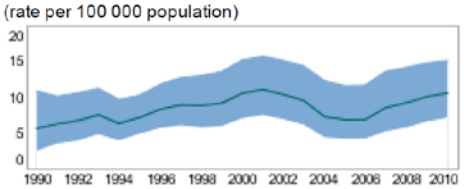
Incidence (HIV+TB in orange), notifications (black)
(rates per 100 000 population)



Prevalence (rate per 100 000 population)

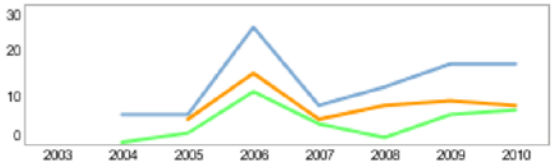


Mortality excluding HIV
(rate per 100 000 population)



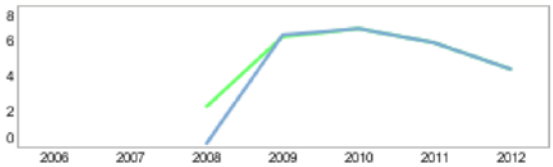
TB/HIV 2010	
TB patients with known HIV status	1 242
% of TB patients with known HIV status	70
TB patients that are HIV-positive	17
% of tested TB patients that are HIV-positive	1
% HIV-positive TB patients started on CPT	47
% HIV-positive TB patients started on ART	41
HIV-positive people screened for TB	89
HIV-positive people provided with IPT	

CPT (orange) and ART (green) for HIV-positive TB patients (blue)



Financing	2011	2012
Total budget (US$ millions)	6	4
Available funding (US$ millions)	6	4
% of budget funded	100	100
% available funding from domestic sources	69	6
% available funding from Global Fund	31	94

NTP Budget (blue) and available funding (green) (US$ millions)



** Ranges represent uncertainty intervals*

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Armenia

| High MDR-TB burden |

Tuberculosis finance profile

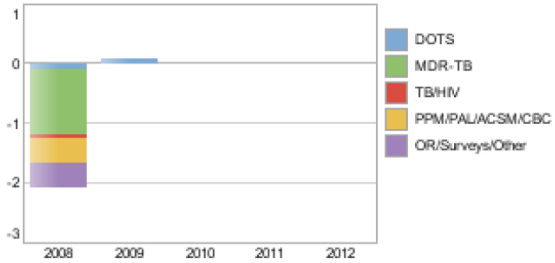
WHO TB planning and budgeting tool used: Yes (2010)

Total National TB Programme (NTP) budget, available funding and expenditure

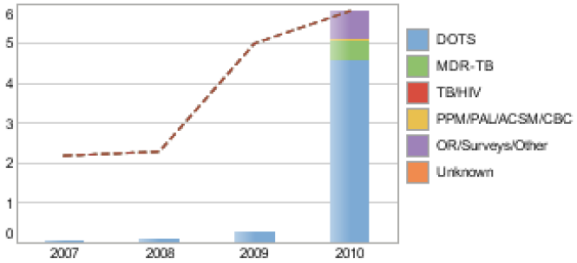
Funding by source (US$ millions)

Funding by line item (US$ millions)

Funding gap by line item (US$ millions)



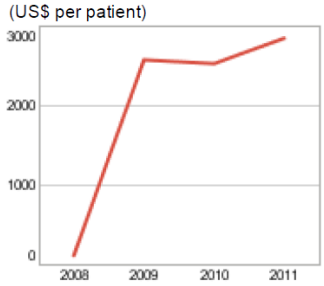
Received funding (dotted line) and actual expenditure by line item (bar) (US$ millions)



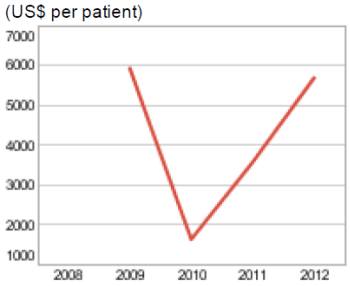
* *ACSM: Advocacy, Communication and Social Mobilization; CBC: Community-based TB Care; PAL: Practical Approach to Lung Health; PPM: Public-Private Mix; OR: Operational Research*

Per-patient budget

DOTS budget required per TB patient to be treated (US$ per patient)

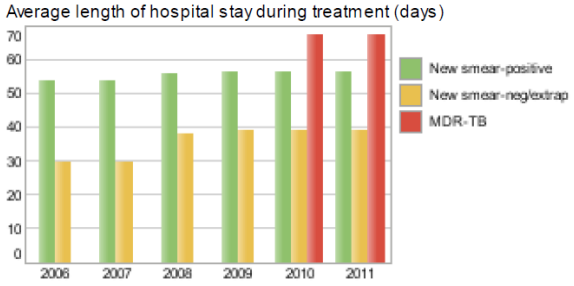


MDR-TB budget required per MDR-TB patient to be treated (US$ per patient)

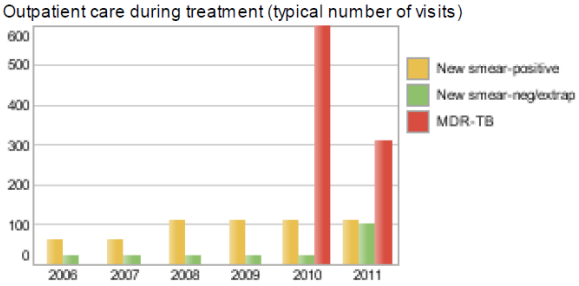


Use of general health services

Average length of hospital stay during treatment (days)



Outpatient care during treatment (typical number of visits)



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Annex 6: MDR-TB cases estimated, notified, enrolled on treatment and expected to be treated

27 high-MDR-TB-burden countries and WHO regions

	ESTIMATED % OF ALL NEW TB CASES WITH MDR-TB[a]			ESTIMATED % OF ALL RETREATED TB CASES WITH MDR-TB[a]			TOTAL NUMBER OF ESTIMATED CASES OF MDR-TB IN 2008[a] (THOUSANDS)			ESTIMATED CASES OF MDR-TB AMONG NOTIFIED CASES OF PULMONARY TB IN 2009[b] (A) (THOUSANDS)			NOTIFIED CASES OF MDR-TB IN 2009 (B)	NOTIFIED CASES OF MDR-TB AS % OF ESTIMATED CASES OF MDR-TB AMONG ALL NOTIFIED CASES OF PULMONARY TB (B/A)[c]	CASES OF MDR-TB ENROLLED ON TREAT-MENT IN 2009	EXPECTED NUMBER OF CASES OF MDR-TB TO BE TREATED	
	BEST[d]	LOW	HIGH	BEST	LOW	HIGH	BEST	LOW	HIGH	BEST	LOW	HIGH				2010	2011
Armenia	9.4	7.3	12	43	38	49	0.5	0.4	0.6	0.17	0.14	0.19	156	92	–	380	160
Azerbaijan	22	19	26	56	52	60	4.0	3.3	4.7	–	–	–	–	–	–	–	–
Bangladesh	2.2	0	5.6	15	0	40	9.8	1.0	19	3.2	0.8	7.5	–	–	468	1 119	776
Belarus	12	0	25	42	12	72	0.8	0.3	1.3	0.8	0.4	1.4	–	–	–	–	–
Bulgaria	12	0	25	42	12	72	0.5	0.1	0.8	–	–	–	–	–	–	–	–
China	5.7	5.0	6.6	26	23	28	100	79	120	59	53	66	474	1	458	3 291	6 706
DR Congo	1.8	0	4.3	7.7	0	18	5.6	0.5	11	2.0	0.7	4.2	91	5	352	–	–
Estonia	15	12	20	43	32	54	0.09	0.07	0.12	–	–	–	–	–	–	80	80
Ethiopia	1.6	0.9	2.7	12	6.4	21	5.2	2.4	8.0	1.8	1.1	2.7	233	13	88	539	746
Georgia	6.8	5.2	8.7	27	24	31	0.7	0.6	0.8	0.34	0.29	0.40	–	–	–	–	–
India	2.3	1.8	2.8	17	15	20	99	79	120	66	59	73	1 660	3	1 136	8 000	15 000
Indonesia	2.0	0.5	6.9	15	0	40	9.3	0	21	5.8	1.0	16	–	–	20	250	1 000
Kazakhstan	14	11	18	56	51	62	8.1	6.4	9.7	6.5	5.9	7.2	3 644	56	135	5 163	4 215
Kyrgyzstan	12	0	25	42	12	72	1.4	0.4	2.4	0.7	0.3	1.3	–	–	545	220	210
Latvia	12	9.9	15	32	25	40	0.17	0.14	0.20	–	–	–	–	–	–	135	140
Lithuania	9.0	7.5	11	48	43	52	0.33	0.27	0.39	–	–	–	–	–	–	300	–
Myanmar	4.2	3.2	5.6	10	7.1	14	9.3	6.4	12	4.4	3.4	5.4	815	19	64	125	200
Nigeria	1.8	0	4.3	7.7	0	18	11	1.3	20	1.9	0.6	3.9	28	1	–	80	350
Pakistan	2.9	0	8.0	35	0	75	15	1.2	29	9.8	2.7	22	49	1	368	400	1 100
Philippines	4.0	3.0	5.5	21	15	29	13	8.9	17	6.8	5.3	8.5	1 073	16	491	1 494	2 004
Republic of Moldova	19	17	22	51	49	53	2.1	1.7	2.4	1.3	1.3	1.4	924	71	–	–	–
Russian Federation	16	12	20	42	38	47	38	30	45	30	26	34	7 062	24	8 143	12 000	–
South Africa	1.8	1.5	2.3	6.7	5.5	8.1	13	10	16	6.6	5.5	7.7	7 343	111	4 143	7 301	8 642
Tajikistan	17	11	24	62	53	70	4.0	2.9	5.1	0.9	0.7	1.2	319	35	52	–	–
Ukraine	16	14	18	44	40	49	8.7	6.8	11	6.4	5.8	7.1	808	13	–	–	–
Uzbekistan	14	10	18	50	36	64	8.7	6.5	11	2.6	2.1	3.1	654	25	464	720	1 010
Viet Nam	2.7	2.0	3.6	19	15	25	5.9	3.8	8.1	3.1	2.5	3.8	217	7	307	650	910
High MDR-TB burden countries	**3.9**	**3.5**	**4.3**	**23**	**21**	**24**	**380**	**330**	**450**	**220**	**200**	**240**	**25 550**	**12**	**17 234**	**42 247**	**43 249**
AFR	1.5	1.3	1.8	6.8	5.7	8.1	69	53	110	22	19	26	8 798	40	6 194	9 323	11 382
AMR	2.1	1.8	2.4	12	11	14	8.2	7.3	9.3	5.3	4.8	5.8	2 865	54	3 128	3 205	3 651
EMR	2.5	0.9	5.7	29	14	49	24	11	81	13	6.3	26	496	4	707	1 156	2 063
EUR	12	10	13	41	38	44	81	73	90	50	46	54	13 816	28	9 568	20 354	7 176
SEAR	2.3	1.8	3.1	17	15	19	130	110	170	85	75	99	2 560	3	2 156	9 833	17 309
WPR	4.8	4.2	5.4	23	21	26	120	100	140	71	65	79	2 000	3	1 412	5 729	9 933
Global	**3.3**	**3.0**	**3.6**	**21**	**19**	**22**	**440**	**390**	**510**	**250**	**230**	**270**	**30 535**	**12**	**23 165**	**49 600**	**51 514**

- Indicates data not available.

[a] See Multidrug and extensively drug-resistant TB [M/XDR-TB]: 2010 global report on surveillance and response. WHO/HTM/TB/2010.3.

[b] Calculated by applying the best estimate of MDR to the notified cases of pulmonary TB (a multiplier of 0.9 is used to determine the number of pulmonary cases expected to be culture-positive if tested).

[c] Percentage may exceed 100% as a result of conservative estimates of MDR-TB and/or notification of cases of MDR from a previous year.

[d] Best, low and high indicate the point estimate and lower and upper bounds of the 95% uncertainty interval.

Annex 7: Distribution of TB cases notified in 2010 per marz

Marz	Population x 1000**	Number of SS+		Number of SC+		Number of DST (first-line) provided		Number of MDR-TB cases		MDR-TB prevalence	
		New cases	Prev treat*	New cases	Prev treat*	New cases	Prev treat*	New cases	Prev treat*	New cases (%)	Prev treat* (%)
Aragatsotn	141.7	17	5	23	5	18	5	2	4	**11.1**	**80.0**
Ararat	278.8	27	21	35	23	32	21	5	9	**15.6**	**42.9**
Armavir	284.1	28	22	45	23	39	20	5	11	**12.8**	**55.0**
Gegharkunik	241.5	20	8	29	9	26	8	3	2	**11.5**	**25.0**
Kotayk	280.6	32	23	32	21	30	19	4	11	**13.3**	**57.9**
Lori	281.6	29	34	35	38	34	33	5	23	**14.7**	**69.7**
Shirak	281.5	45	14	62	18	58	15	8	12	**13.8**	**80.0**
Syunik	152.9	14	5	19	5	19	5	3	1	**15.8**	**20.0**
Tavush	134.4	19	5	23	4	22	4	3	2	**13.6**	**50.0**
Vayots Dzor	55.8	3	3	4	4	3	4	0	2	**0.0**	**50.0**
Yerevan	1116.6	135	219	183	89	167	75	17	37	**10.2**	**49.3**
Other		17	12	27	9	23	11	2	5	**8.7**	**45.5**
Total	**3249.5**	**386**	**371**	**517**	**248**	**471**	**220**	**57**	**119**	**12.1**	**54.1**

* Includes observations with missing data on history of previous treatment

** Source: http://www.armstat.am; National Reference Laboratory

Annex 8: Findings and recommendations for laboratory facilities visited

Central Hospital for Detainees, Yerevan (visited on 27 April 2011)
The laboratory in the Central Hospital for Detainees provides laboratory services for detainees. It was supported until 2009 by the International Committee of the Red Cross (ICRC). One doctor and one technician work in the laboratory (Diana Avetisyan and Astghik Zakaryan). In 2009, 2010 and 2011 until now around 500, 435 and 141 slides, respectively, were tested. Out of these 20, 14 patients were smear-positive and 121 (76 patients) were smear-negative. The laboratory is equipped with two microscopes in good condition. External quality control (EQC) and staining materials are organized by the National Reference Laboratory (NRL). The laboratory supervises the laboratory in Nubarashen. The last training for staff took place in 2008, and the last visit of the head of the NRL in 2009. The laboratory sends all positive specimens and specimens from all new and all MDR cases to the NRL for culture.

Recommendations
- To perform internal quality control (IQC) (as discussed with the staff) with a positive and a negative slide on a weekly basis, not only when new staining materials arrive.
- To organize a faster system to get culture results from NRL.
- To post standard operating procedures (SOPs) on the walls of the rooms where smears are prepared and reading is performed.

Avan Polyclinic #12, Yerevan (visited on 28 April 2011)
The laboratory of the Avan Polyclinic is supported by MSF-F. Last supervision was in February 2011. One doctor and one technician work in the laboratory (Sona Papoyan and Emma Lazaryan). The laboratory is in good condition; it is equipped with a homemade biosafety cabinet (BSC), a microscope in good condition (Boeco), and an autoclave. A safe workflow is realized, and SOPs are available. To date in 2011, 165 slides have been tested. Of these, two patients were smear-positive/culture-negative and two smear-positive/culture-positive. Staining materials are provided by the Yerevan City TB Dispensary.

External quality control is organized by YCTBD, but the laboratory has not yet received feedback on the results.

Recommendations
- To perform IQC (as discussed with the staff) with a positive and a negative slide on a weekly basis, not only when new staining materials arrive.
- To organize feedback on EQC results proactively from the YCTBD.

Arabkir Polyclinic #8, Yerevan (visited on 28 April 2011)
The diagnostic service in the polyclinic is based on X-ray, anamnesis and laboratory results. In 2010, out of 55 suspects, 22 TB patients were identified (of these two were smear-positive). To date in 2011, five of 10 suspects have been identified (one of these was smear-positive).

Recommendations
- To replace the old X-ray machine (from 1967?) with a new one.
- To send the specimens to the laboratory for investigation rather than the patient in person; a sputum collection point should be established.

Shengavit: St Astvatsamair Medical Centre, Polyclinic #18, Yerevan (visited on 28 April 2011)
The first TB cabinet in the country was established at this medical centre, in 2005. The centre serves 40% of Yerevan TB patients. The centre's laboratory was established by, and is still supported by, MSF-F. The laboratory is very clean and well-maintained, with equipment in good condition. It has separate rooms for preparation of slides (with a biosafety cabinet (BSC) and a sink for staining), microscopy and changing of laboratory clothing. Waste management is in order, staff follow protocols, reagents are changed

quarterly. The laboratory receives 5-20 samples per day and has about 3-4 SS+ samples per month. Twice a week, samples are sent to the Republican TB Dispensary (RTBD) by car under cooled conditions. The laboratory usually receives feedback about culture results from RTBD after two months.

Recommendation

- Increase the time spent examining stained slides to 15 minutes.

Malatia Polyclinic #15, Yerevan (visited on 28 April 2011)

This is one of the oldest polyclinics in the country, established in 1936. Both the building and the equipment of the laboratory at this polyclinic were in poor condition. Even though the polyclinic has a regular TB cabinet, this laboratory offers no TB diagnostic services, but serves as a general microbiological laboratory. TB suspects are referred to Polyclinic #19. The director of the facility was not aware of this arrangement.

Recommendations

- Serious renovation of the building is needed.
- The biosafety cabinet should be repaired.
- Some equipment should be replaced, starting with the X-ray machine and X-ray film developing facilities.
- Training should be offered to laboratory staff free of charge.
- The workload of laboratory staff should be reduced.

Yerevan City TB Dispensary (YCTBD) (visited on 28 April 2011)

The laboratory in the City TB Dispensary has three rooms and is well-equipped, with a microscope in good condition (Boeco), two autoclaves (for sterilization and for waste) and a functioning BSC. The laboratory stopped carrying out cultures in 2009. One doctor and two technicians work in the laboratory (Armenuhi Jakimova, Gayane Bagdasareyan, and Hasmik Hayreapetyan). In 2010, 1107 smears were performed (211 for follow-up and 896 for diagnosis). Of these, 96 were smear-positive and 1011 were smear-negative. Of 1107 specimens, 258 were categorized as saliva. To date in 2011, 624 specimens were performed. External quality control and staining materials are organized by NRL. The laboratory supervises five polyclinics and performs external quality assurance (EQA) for them. The last staff training took place in 2008, and the last visit by the head of NRL was 2009. They send specimens from all smear-positive cases, all new cases, and all MDR-TB cases to NRL for culture. Culture results arrive promptly.

Recommendations

- To perform IQC (as discussed with the staff) with a positive and a negative slide on a weekly basis, not only when new staining materials arrive.
- Training of staff to increase sputum quality. Proactive attitude of staff during the sputum collection process; if patients produce saliva instead of sputum, the staff should assist and/or supervise the patient in obtaining good quality sputum.
- To organize maintenance of the existing BSC proactively (last maintenance was in 2005).

Dzoraghbiur Medical Ambulatory, Kotayk region (visited on 29 April 2011)

No TB laboratory diagnostic services. TB suspects are referred to RTBD.

Hrazdan Medical Centre, Kotayk region (visited on 29 April 2011)

The laboratory in Hrazdan has been renovated with the support of the World Bank. The laboratory has a ventilation system which is connected to the hospital system (it is unknown where the air goes). Only one technician works in the laboratory (Anna Agadjanyan) and she is responsible for sputum collection, smear preparation, microscopy and administration. No biosafety cabinet is in place. Her last training took place in 2008 (certificate from GFATM). Two rooms are available, one for staining and one for microscopy (Boeco).

In 2010, 300 smears were performed (115 for follow-up and 185 for diagnosis). Of these, seven were smear-positive and 293 were smear-negative. Of 300 specimens, 201 were categorized as saliva. In 2010, no specimens were sent to the NRL for culture.

External quality control and staining materials are organized by the NRL. In 2009, there was no feedback from NRL to the laboratory on the EQA results. In 2010 no EQA was performed, but in 2011 some slides were sent.

Recommendations

- Maintenance of the microscope.
- Waste disposal should be connected to the hospital disposal system.
- To reduce unnecessary infection risk while disposing of waste, sputum containers should remain closed after smear preparation and not be poured into the chloride container.
- Training of staff to increase sputum quality. Proactive attitude of staff during the sputum collection process; if patients produce saliva instead of sputum, the staff should assist and/or supervise the patient in obtaining good quality sputum.
- Install a BSC or a simple extraction hood with mechanical ventilation to improve biosafety for the laboratory technician while preparing smears.
- Provide boxes for storing microscope slides.
- Organize SOPs for the laboratory.

National TB Reference Laboratory (visited on 29–30 April 2011)

Dr Alla Mirzoyan, head of the laboratory, supervises the following staff members: three doctors, six laboratory technicians, two administrators, two laboratory support staff and one engineer. The staff of NRL are motivated and knowledgeable.

RTBD hosts the official National TB Reference Laboratory of Armenia and is a well-functioning, well-equipped laboratory, where a safe and correct workflow is realized. The laboratory receives primary specimens for culture and DST from all regional laboratories in the country and performs smear microscopy for all marzes, except Yerevan City. The equipment is in good condition, mainly new, except the centrifuges. The current mycobacteria growth indicator tube (MGIT) machine was overloaded; a second one is on order and definitely needed. The BSC is regularly maintained by trained local staff.

Primary samples are decontaminated using the commercially available Beckton, Dickinson & Co Mycoprep kit. Microscopy is performed with standard Ziehl-Neelsen staining. Culture is done on both MGIT and Löwenstein-Jensen (LJ) medium. Drug susceptibility for first-line drugs is done in the MGIT system and susceptibility to second-line drugs is tested on home-made LJ slants. Recently, a PCR line probe assay was successfully implemented for rapid detection of MDR-TB and identification of *M. tuberculosis* complex. In addition, identification is carried out using four biochemical tests. IQC is performed in a fully satisfactory manner. NRL performs EQA for YCTBD, and vice versa, and for all the laboratories in the marzes.

A database registering all samples is functioning well, and reports can easily be prepared from it. In 2010, for 2428 patients 3390 liquid cultures were performed and for 2874 patients 5635 solid cultures were performed. On liquid medium, the positivity rate was 95.1% (468/494) for smear-positive samples and 7.0% (189/2787) for smear-negative samples. On solid medium, the positivity rate was 91.8% (469/537) for smear-positive samples and 5.6% (164/3101) for smear-negative samples. Overall contamination rate was 2.9% on liquid medium and 4.4% on solid medium. Of 691 cases tested for first-line drugs, 177 (25.6%) were MDR, 77 (11.1%) were polydrug-resistant, and 99 (14.3%) were monodrug-resistant. This amounts to 56.0% (387/691) cases with any resistance.

The Supranational Reference Laboratory (SRL) in Borstel, Germany, performs EQA for NRL, which sends 20 proficiency study strains to NRL on a yearly basis, in accordance with WHO guidelines. NRL obtained excellent results in the last proficiency study in 2009; 100% concordance for rifampicin, isoniazid,

streptomycin and pyrazinamide, and 94.4% for ethambutol. There is good long-term collaboration between SRL and NRL.

Recommendations

- Buy a new centrifuge that can achieve the proper speed for primary isolation, cooling and aerosol-tight lids (3000-3200 x g).
- To control the proper speed of the centrifuge before running, a sign on the centrifuge may be useful.
- Implement the identification of nontuberculous mycobacteria by purchasing and introducing the HAIN CM PCR line probe assay.
- Inoculate saliva when no better specimen is available.
- Implement PCR line probe assays for rapid second-line drug testing of samples from MDR-TB patients.
- Implement second-line DST on MGIT with the support of SRL Borstel.
- In view of the introduction of the molecular identification assays and the low prevalence of *M. bovis*, biochemical identification tests are no longer needed.
- Remove electricity cables from high-traffic areas of the floor.
- Hire one additional specialized laboratory technician, so that NRL can deal with its increasing workload.
- In future, upgrade the biosafety level 2a laboratory according to the WHO guidelines to a biosafety level 3 facility and add more space.
- Allocate a small budget to improve flexibility and basic hygiene.

Laboratory at Gavar polyclinic, Gegarkunik region (visited on 2 May 2011)

The laboratory at Gavar Polyclinic is part of the general clinic laboratory and provides services for the polyclinics. One doctor and one nurse work in the laboratory (Ruzan Tadevosyan and Christine Hovhanisyan). The laboratory is equipped with one microscope (Boeco) in good condition. External quality control and staining materials are organized by NRL. Last staff training took place in 2010. In 2009 and 2010, sputum smear microscopy was performed for 55 patients and 73 patients (2-3 each), respectively. Of these, only one was positive in 2010. In contrast to this, five patients were recorded in the patient registry (four smear-positive and one culture-positive and smear-negative result came from NRL). Of the 24 TB patients, 19 were without laboratory confirmation.

Recommendations

- Improve collaboration between laboratory and diagnostic services at the facility.
- Perform IQC (as discussed with the staff) with a positive and a negative slide.
- Waste disposal should be connected to the hospital disposal system, which should not be a problem since the clinic laboratory is already connected.

Laboratory in the Martuni polyclinic, Gegarkunik region (visited on 2 May 2011)

The laboratory in the Martuni polyclinic comprises one recently renovated room for staining and one for microscopy. One doctor and two technicians have worked in the laboratory for a long time (Sona Papoyan and Emma Lazaryan). The laboratory is equipped with a microscope in good condition (Boeco). A safe workflow is realized, and SOPs are available. To date in 2011, smear microscopy had been performed for 35 patients, in 2010 for 177 patients, and in 2009 for 125 patients. Of these, only three patients in 2009 and three in 2010 were smear-positive. In the patient registry of 2010, slightly more patients were registered, namely 38 patients. Over 50% of the samples were classified as saliva. External quality control and training are organized by NRL.

Recommendations

- Perform IQC (as discussed with the staff) with a positive and a negative slide on a weekly basis.
- Provide new boxes for storage of microscope slides.
- Provide a new burner (the old one is leaking).

Aparan Medical Centre, Aparan, Lory region (visited on 2 May 2011 – unannounced visit)
In 2010, 12 TB suspects reported to the polyclinic, of whom nine were diagnosed with TB (two died; of cancer and suicide, respectively). The laboratory sent samples from all patients to NRL in Abovian, but received feedback on only three of them (one culture-positive, two culture-negative). In 2009, 19 patients were diagnosed out of 60 TB suspects. In 2008, there were 58 suspects. To date in 2011, they have received six suspects, of whom five were diagnosed with TB; four were admitted to the clinic, and one MDR-TB patient was sent to RTBD.

The building in which the laboratory was situated was in very bad condition, with holes in the walls and the floors, no central heating, no running water and unprotected electricity cables. It is planned for the clinic and the laboratory to move to a new facility, but it is unclear when this will happen. Preparation of the sputum slides is done on a table near the open window, with the door to the central hallway closed, with staff wearing masks. Staining is done on the same table, with manual washing. Microscopy (Boeco) is done in a separate room. Samples are sent to NRL twice a week.

The laboratory technician takes pride in her work, knows the smear-microscopy-related procedures and was last trained at NRL in 2007. When she is on holiday, another worker on temporary contract takes over her duties. EQA of microscopy is in place according to protocol, and waste management is in order. Staining reagents are obtained from NRL and are replaced once a year. In 2010, 180 samples from 104 patients were investigated and 10 were found to be positive (one patient had already been diagnosed in 2009). To date in 2011, 48 samples from 25 patients were investigated and two were found to be positive.

Recommendations
- Install a BSC or simple extraction hood with mechanical ventilation to improve biosafety for the laboratory technician while preparing smears.
- Take a more proactive attitude to obtaining feedback from NRL on culture and drug susceptibility results.
- Change UV lamps after the number of burning hours recommended by manufacturer.

Vanadzor TB Dispensary, Lory region (visited on 2 May 2011)
This laboratory is the central microscopy laboratory for the marz; it receives samples from six sputum collection points and also from Stepanavan polyclinic (which receives samples from Tashir). Sputum is transported only once per week because they have only a few samples and transport is expensive.

The laboratory, which looks nice and clean, consists of two rooms; one room contains a home-made mechanical biosafety cabinet with airflow to outside and refrigerator. The other room is for staining and microscopy (Boeco). EQA of randomly chosen slides is in place. Waste is disinfected with chlorine. Various SOPs are displayed in laboratory and the staff are well-trained.

For 22 out of 25 patients samples were sent to NRL. Culture and/or DST results are received from NRL after about one month – or longer, 56 days for DST.

In the TB dispensary, a relatively new digital X-ray machine is in use, which has been placed inside an old X-ray machine to protect the environment from radiation. X-ray pictures are viewed on a computer screen.

In 2010, sputum smear microscopy was performed on 300 samples; 48 samples originated from sputum collection points in the region, 30 from the hospital and 222 from the TB dispensary itself. In total, 58 cases were SS+; 36 of these were new cases and 22 were known cases that were already on treatment. Thirty cases were referred to this TB dispensary. It is anticipated that the number of samples for smear microscopy will increase significantly in 2011, as collection from sputum collection points started only in October 2010.

Recommendation

- Send sputum twice a week when there are samples to be tested.

Stepanavan polyclinic; Vanadzor polyclinic #1, Lory region (visited on 2 May 2011)

TB diagnostics is performed in the general microbiology laboratory of the clinic. There are four rooms. The first room is used for blood analysis, one for filling out the forms and microscopy, one for preparation and staining of the slides, and one for X-rays (this room was locked, as we were there after regular working hours). The laboratory has a good refrigerator and microscope (Boeco) in the microscopy room. There is a BSC in place with an old UV lamp, but it is not clear where the air goes. Some of the laboratory equipment, especially in the blood analysis room, is very old. Staining reagents are obtained from NRL and replaced once a year (they have to apply for new reagents) and EQA of slides is in order. No IQC is performed. Waste is autoclaved. In 2010, 59 suspected cases were investigated and three of these were smear-positive. A car comes only when they have samples to send to Vanadzor.

Recommendations

- Send sputum smear-positive samples to Vanadzor for culture at NRL; do not send the patient in person.
- Implement IQC.
- Buy a new closed-system centrifuge for centrifuging blood samples safely.
- Buy a refrigerator for storage of sputum samples, until then use the refrigerator for “clean” materials.
- Buy new distillation unit for preparation of distilled water for recycling of glass and preparation of reagents.
- Buy a new microscope for blood analysis.
- Change the UV lamps in BSC as soon as possible and subsequently after the number of burning hours recommended by manufacturer.

Annex 9: Laboratory network and sputum collection points in marzes

- Aragatsotn Marz: one regional SM laboratory, three SCPs, one peripheral SM lab.
- Ararat Marz: one regional SM laboratory, four SCPs.
- Armavir Marz: one regional SM laboratory, two SCPs, one peripheral SM laboratory (with one SCP).
- Gegharkunik Marz: one regional SM laboratory, three SCPs, one peripheral SM laboratory (with one SCP).
- Kotayk Marz: one regional SM laboratory, two SCPs, one peripheral SM laboratory (with one SCP).
- Lory Marz: one regional SM laboratory, six SCPs, two peripheral SM laboratories (of which one has one SCP).
- Shirak Marz: one regional SM laboratory, nine SCPs, one peripheral SM laboratory (with three SCPs, of which one is in a prison).
- Syunik Marz: one regional SM laboratory, two SCPs, one peripheral SM laboratory (with three SCPs).
- Tavush Marz: one regional SM laboratory, two SCPs, two peripheral SM laboratories.
- Vayots Dzor Marz: one regional SM laboratory, two SCPs.
- Yerevan: one regional SM laboratory (YCTBD), five SM laboratories (with in total 19 SCPs); and, in addition, two SM laboratories in prisons, which sent samples directly to NRL.

Annex 10: Treatment outcomes for MDR-TB and PDR-TB patients

Table 4: Treatment outcomes for MDR-TB patients, 2008-2011 (as at April 20, 2011)

Year	Registr. Group	Cured	Comp-leted	Failu-re	De-fault	Died	Transfer-red out	Still on treatment	Total
2008	New case	1	1	0	0	0	0	0	**2**
	Previously treated with first-line dugs	24	9	5	5	1	1	1	**56**
	Previously treated with second-line drugs	7	0	3	17	1	0	1	**19**
Total 2008		**32**	**10**	**8**	**22**	**2**	**1**	**2**	**77**
2009	New case	6	3	1	3	1	0	7	**21**
	Previously treated with first-line dugs	12	2	11	12	3	3	15	**58**
	Previously treated with second-line drugs	9	2	2	9	6	1	7	**36**
Total 2009		**27**	**7**	**14**	**24**	**10**	**4**	**29**	**115**
2010	New case	2	1	1	4	1	1	24	**34**
	Previously treated with first-line dugs	2	0	0	6	4	5	57	**74**
	Previously treated with second-line drugs	0	0	1	3	4	1	30	**39**
Total 2010		**4**	**1**	**2**	**13**	**9**	**7**	**111**	**147**
2011	New case							15	**15**
	Previously treated with first-line dugs							12	**12**
	Previously treated with second-line drugs							0	
TOTAL		**63**	**18**	**24**	**59**	**21**	**12**	**169**	**366**

Table 5: Treatment outcomes for PDR-TB patients, 2008-2011 (as at April 20, 2011)

Year	Registr. Group	Cured	Comp-leted	Failu-re	De-fault	Died	Transfer-red out	Still on treatment	Total
2008	New case	1	1	0	1	0	0	0	**3**
	Previously treated with first-line dugs	5	0	2	0	0	0	1	**8**
	Previously treated with second-line drugs	1	0	0	0	0	0	0	**1**
Total 2008		**7**	**1**	**2**	**1**	**0**	**0**	**1**	**12**
2009	New case	6	3	1	2	0	0	0	**12**
	Previously treated with first-line dugs	1	3	0	3	0	0	0	**7**
Total 2009		**7**	**6**	**1**	**5**	**0**	**0**	**0**	**19**
2010	New case	1	1	0	2	0	1	17	**22**
	Previously treated with first-line dugs	6	2	0	1	0	0	13	**22**
	Previously treated with second-line drugs	0	0	0	0	0	0	1	**1**
Total 2010		**7**	**3**	**0**	**3**	**0**	**1**	**31**	**45**
2011	New case	0	0	0	0	0	0	14	**14**
	Previously treated with first-line dugs	0	0	0	0	0	0	2	**2**
	Previously treated with second-line drugs	0	0	0	0	0	0	1	**1**
Total 2010		**0**	**0**	**0**	**0**	**0**	**0**	**0**	**17**
TOTAL		**21**	**10**	**3**	**9**	**0**	**1**	**49**	**93**

Annex 11: Observations in TB facilities of the penitentiary system

Nubarashen

Nubarashen has capacity for 800 detainees, but currently accommodates over 1300. All detainees serving life sentences have been transferred to Nubarashen and occupy around 100 places, while the rest of the capacity is reserved for persons awaiting court decisions. The building is outdated and the lack of capacity presents a major challenge for prison (health) staff working in this institution. Prisoners are accommodated in cells of around 20 persons, although there are not enough beds available for that number. This means that prisoners have to sleep in shifts. Except for the opportunity to go outside for one hour a day, prisoners spend all their time in their cells.

A new institution to replace Nubarashen is under construction, but construction work has been interrupted by the financial crisis.

At Nubarashen, all detainees undergo medical screening within 72 hours of entry to the institution, which includes basic analysis (including blood and urine tests), MMR and voluntary HIV-testing. The results of MMR are analysed by the prison TB doctor and radiologist. In all other institutions, medical screening upon entry includes a basic questionnaire on TB and counselling for HIV, but no MMR or laboratory tests.

All medical records are kept in hard copy (handwritten).

At Nubarashen, there are currently nine TB patients, five smear-positive and four smear-negative. Two patients have been sentenced and diagnosed with DR-TB, but refuse treatment and are therefore held in isolation at Nubarashen. Smear-positive and smear-negative patients are accommodated separately in rooms for 4-5 patients and never come into contact with one another.

One doctor and one medical assistant work on the TB ward. DOT is performed in a special room on the TB ward on weekdays. At weekends, patients do not receive TB medicines, and their treatment is prolonged accordingly. A UV lamp is installed on the corridor of the TB ward as an infection control measure. There is no ventilation system in place in the ward. The DOT room also includes an X-ray machine, which is very outdated and needs replacement.

Interviews were held with two smear-negative TB patients, who were satisfied with the treatment they received and did not experience any treatment interruptions. However, they were afraid of being transferred to the regular wards again because of the bad living conditions in these wards (“I am sure that I will be sick again immediately if I have to go there”).

Nubarashen has a laboratory facility which is poorly equipped. A surgical room for minor surgery has been renovated, but has no equipment because of a lack of funds. For all types of surgery, prisoners are referred to the Central Hospital for Detainees. In some cases, prisoners receive specialized health care in civilian facilities if required.

Central Hospital for Detainees

The Central Hospital for Detainees has capacity for 420 patients and 20 health-care staff members work there. The average population is 400, with 720 patients going through the Hospital annually. The Hospital has eight wards: therapeutic, surgical, infectious diseases, TB, psychiatric, narcological, physiotherapy and dental.

The X-ray equipment, housed on the TB ward but serving the entire hospital, is very outdated. The equipment may be replaced if NTP’s GFATM Round 10 proposal is successful.

In the hospital both active and passive TB case detection takes place, as is the case at Nubarashen.

Currently there are 31 TB patients on treatment at the Central Hospital for Detainees, among whom there are 17 DR-TB patients (eight with MDR-TB). Of the 14 patients with regular TB, five are smear-negative and nine are smear-positive. Smear-negative and smear-positive patients are accommodated separately on different wards. However, patients from different wards can come into contact with one another, so infection control is not fully guaranteed.

MSF-F specialists support treatment and psychological support for DR-TB patients in the hospital, a task that is gradually being taken over by NTP (for new cases). MSF-F also provides side-effect drugs for DR-TB patients. Side-effect drugs for patients with regular TB are provided by the Ministry of Justice.

There are 18 HIV-positive patients on ARV treatment in the hospital, including three TB/HIV coinfected patients. Three HIV-positive patients are accommodated in other penitentiary institutions because they are not in need of ARV.

Annex 12: National Health Information Analytical Centre at the National Institute of Health

Terms of Reference of the National Health Information-Analytical Centre at the National Institute of Health

- Development and implementation of the National Programme on Enhancing the Health Information System.
- Development, implementation, assessment and enhancing of the programme of Health Information System Enhancing and its main elements and components.
- Development of regional information system models and infrastructure.
- Harmonization of the Health Information Statistical System with international regulations, classifications, norms and rules.
- Collection and analysis of State medical statistics and medical and sanitary information from health facilities; ensuring preparation and control of recording/reporting medical documentation.
- Collection and analysis of important health indicators; providing the health system and other institutions with complete information.
- Implementation activities aimed at the assessment and forecasting of the population's health status.
- Participation in postgraduate education of specialists.
- Evaluation and monitoring of the population's health status, monitoring of services and conducting special research in major health and health-care problems.
- Participation in the process of health system reform, development of policies and strategies; participation in organization of preventive measures and development of modern public health models.
- Publishing activity: publishing of information reports (monthly, annual), special issues, bulletins, methodical and other materials.
- Providing consultation and methodical assistance for health facilities.
- Organization of conferences, seminars and other meetings on health information system enhancement, health and public health issues.
- Cooperation in the above areas with other organizations, institutions and structures, international and nongovernmental organizations and foundations.
- Assistance with scientific research and development.
- Providing methodological and practical assistance for the Health Information Statistical Centre of Nagorno-Karabakh; other activities consistent with the Centre's functions and the legislation of the Republic of Armenia.

The Centre has been subcontracted by GFATM PIU to develop the list of core indicators for the TB section of the electronic joint health statistics information system, as well as establishing the electronic management and trend analysis integrated into the electronic information system for TB, HIV and malaria, and revising the set of reporting and recording forms for TB data management.

Structure of the Centre

- Department of Medical and Sanitary Statistics
- Department of Monitoring Systems
- Department of Special Investigations and Applied Research
- Department of Health System Performance Assessment
- Department of Information Technology
- Department of Regional Services
- Department of Information and Publications
- Department of Specialist Training

TB related operational research

- Special features of clinical management of retreated TB patients in Yerevan city.
- Analysis of delays in seeking TB care in Armenia (this study showed that there is an urgent need to raise awareness of the signs and symptoms of TB, both among the public and in the clinical community).
- In 2006, a countrywide TB prevalence survey protocol was developed and planned for use in 2007, but owing to a lack of political support the survey did not take place.
- Role of surveillance in raising treatment efficiency and prevention of drug-resistance among TB patients.

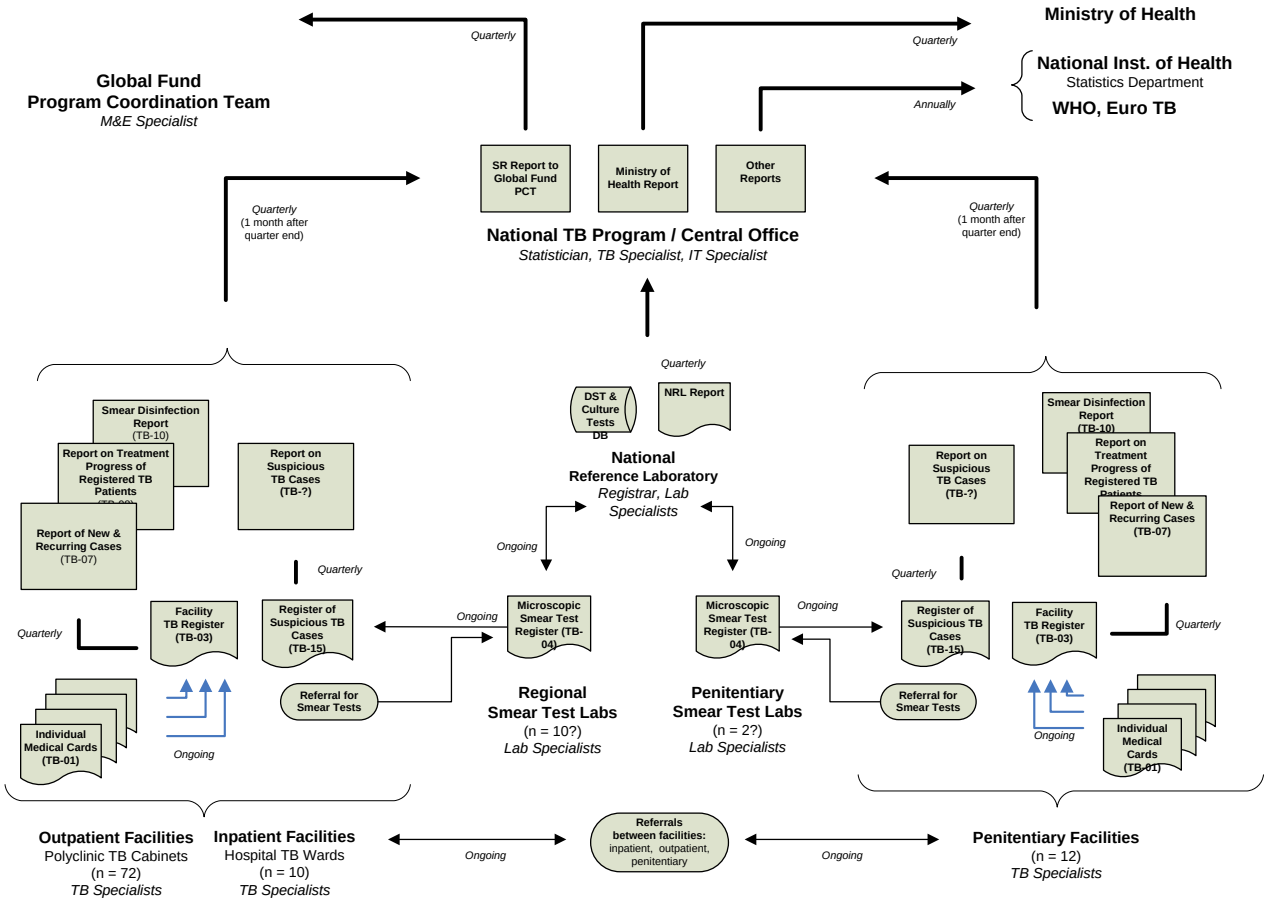
Annex 13: Specific recommendations for revision of the TB performance framework

Indicator	Comment
Case-detection rate for new SS+ TB cases (number and percentage of new SS+ TB cases detected under DOTS as a proportion of the estimated (by WHO) number of new SS+ TB cases in a given year)	- Discontinue monitoring for this indicator - Continue with CDR for all incidence cases - Consider target at the same level - Use data taken from the latest Global TB report
Nondocumented treatment result rate (default, transfer-out, not evaluated) among new SS+ TB cases (number and % of new SS+ TB cases who interrupted treatment or were transferred out without being re-registered in another treatment unit or not evaluated for treatment outcome as a proportion of the total number of new SS+ TB cases registered in a given year)	- Reduce target to 5% (since transfer-out was previously misclassified in Armenia) - At present the default rate is around 9-10%, it should come down to 5%. This is the only way to increase the treatment success rate, by supporting treatment adherence (wide implementation of incentives and enablers), as we can do almost nothing with failures because of MDR and death because of HIV. Not-evaluated figure should be close to 0%
Treatment success rate of MDR-TB patients: number of patients who were cured or completed Category IV treatment (% of the total number of patients in the same registration cohort)	- Increase the target to 75%
Number and percentage of laboratory-confirmed MDR-TB patients still receiving treatment, of those enrolled in second-line anti-TB treatment 12 months before	- The target should be close to 100%, but not less then 75%
Number of patients who default from treatment	- This indicator should be reported in percentage with a target of no more then 5% - It is also recommended that monitoring of this indicator be discontinued because of duplication
Number of suspected TB cases referred by PHC workers and diagnosed with TB	- Targets are underestimated (should be 5000 – 7000)
Number of patients who received food parcels in ambulatory phase of treatment	- Targets are overestimated; in 2009, the country reported about 2000 TB cases (all TB), while targets indicate that more parcels should be distributed (incentives cannot be distributed to more patients then registered; considering that the notification rate should be reversed by 2015, the targets should go down)
Number of culture investigations (manual proportion method) performed for confirmation of TB diagnosis	- Culture cannot be used for detecting TB (this is not in compliance with national protocol). Practice of performing culture for suspects should be immediately discontinued, because of overloading of NRL, which should concentrate on EQA and EQC of smears and introduction of new laboratory techniques, e.g. Gene-Xpert MTB/Rif
Number of TB patients covered by DST to first-line drugs for DR-TB diagnosis	- This should be at least 50% of smear-positive cases and ideally 100% of all TB - Consider removing ePulm

Indicator	Comment
Number of patients tested for rapid identification of R/H resistance using PCR technique	- It is recommended that this indicator should be replaced in the second phase by coverage with Gene-Xpert MTB/Rif of all suspects (with target of 100%)
Treatment success rate of MDR-TB patients: number of patients who were cured or completed Category IV treatment (% of the total number of patients in the same registration cohort)	- Consider target of 75% recalculated in absolute numbers
Number and percentage of laboratory-confirmed MDR-TB patients still receiving treatment of those enrolled in second-line anti-TB treatment 12 months before	- Target should be not less than 75%
Number of DST investigations for second-line drugs performed in MDR-TB patients on treatment	- The target should be in accordance with estimated number of MDR-TB cases (refer to MDR-TB global report)
Number of TB patients who receive HIV counselling and testing	- Reconsider the target (voluntary counselling and testing cannot be provided for more TB cases than notified (about 2000), or at least new + relapses (about 1500)
Ratio of TB suspects tested to outpatients aged 15 years and older	- Redefine the indicator (clarify what testing should be done)
Smear conversion rate at two (or three) months (depending on treatment category) for new SS+ cases	- Discontinue monitoring for this indicator, recommendation issued three years ago
Proportion of TB suspects tested who were SS+ (positivity rate)	- For PHC should be 5-10%, for TB service about 30%
Number of TB case-finding and treatment outcome reports that were recorded completely and accurately	- To be done via capture-recapture, compare TB04 and TB03, target 100%

Annex 14: Routine recording and reporting

TB Case Notification and Treatment Outcome Monitoring



The WHO Regional Office for Europe

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ISBN
WHOLIS number
Original:

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Regional Office for Europe

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