Annex 9 **Analysis of the TB control system in Armenia in both the civilian and penitentiary sectors and recommendations for improvement**

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CENTER FOR HEALTH SERVICES RESEARCH AND DEVELOPMENT

ANALYSIS OF THE TB CONTROL SYSTEM IN ARMENIA IN BOTH THE CIVILIAN AND PENITENTIARY SECTORS AND RECOMMENDATIONS FOR IMPROVEMENT

Consultancy on reviewing the Health System Strengthening component of the TB Control in Prisons Program in Armenia

as part of the

"Hand Over Take Over (HOTO) Process Review"

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LIST OF ACRONYMS

AIDS	Acquired Immunodeficiency Syndrome
AMD	Armenian Drums
ARCS	Armenian Red Cross Society
AUA	American University of Armenia
BBP	Basic Benefit Package
BCG	Bacille Calmette-Guérin (vaccine for tuberculosis)
BK	Bacilli of Koch
CED	Criminal Executive Department
CEI	Criminal Executive Institutions
CHSR	Center for Health Services Research and Development
CMU	Central Medical Unit
DHS	Demographic Health Survey
DOT	Directly Observed Therapy
DOTS	Directly Observed Therapy Short-course
DOTS+	Directly Observed Therapy Short-course Plus (for drug resistant tuberculosis)
DR- TB	Drug Resistant Tuberculosis
DRS	Drug Resistance Survey
DST	Drug Susceptibility Test
FAP	Primary health care posts in villages
FD	Family Doctor
FG	Focus Group
FGD	Focus Group Discussion
GF	Global Fund
GFATM	Global Fund to Fight AIDS, Tuberculosis and Malaria
GTZ	Gesellschaft für Technische Zusammenarbeit
HIV	Human Immunodeficiency Virus
ICRC	International Committee of the Red Cross
IEC	Information, Education, Communication
IRB	Institutional Review Board
KfW	Kreditanstalt für Wiederaufbau
MDR-TB	Multi Drug Resistant Tuberculosis
MMR	Mass Miniature Radiography
MOD	Ministry of Defense
MOH	Ministry of Health
MOJ	Ministry of Justice
MSF	Médecins Sans Frontières France
NGO	Non Governmental Organization
NIH	National Institute of Health, RoA
NRL	National Reference Laboratory
NTP	National TB Program
PHC	Primary Health Care
PHCR	Primary Health Care Reform Project
RoA	Republic of Armenia
RTBD	Republican TB Dispensary

SHAI	State Hygienic and Anti-epidemic Inspectorate
SRL	Supranational TB Reference Laboratory
SS-	Smear Sputum Negative
SS+	Smear Sputum Positive
TB	Tuberculosis
USAID	United States Agency for International Development
USD	US Dollar
UV	Ultra Violate
WB	World Bank
WHO	World Health Organization
WVIA	World Vision International in Armenia
XDR-TB	Extensive Drug-Resistant Tuberculosis
YSMU	Yerevan State Medical University

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EXECUTIVE SUMMARY

Today, Armenia is facing a serious reemerging threat from tuberculosis (TB). New registered TB cases have almost tripled from 1995 to 2005. Armenia is ranked the 10th highest for TB incidence rate among the 53 WHO European Region countries. This threat has increased significantly as the rates of new drug resistant strains of TB have grown. To respond to these increasing threats, the government of Armenia has recently decentralized TB services to better control this disease.

This study provides an assessment of stakeholders' capacities in different TB control activities and an evaluation of potential capacities for future support and cooperation with the Ministry of Health and the Ministry of Justice. To achieve these objectives, qualitative semi-structured in-depth interview and focus group discussion methodologies were conducted by a professional research team from the Center for Health Services Research and Development at the American University of Armenia with 63 participants from different roles and capacities, from levels and sectors of TB control and including patients.

Study participants provided a number of strengths in the TB control system in Armenia. The establishment of the National TB Program (NTP) provided a national infrastructure for TB control. The decentralization process brings services closer to where patients live. Free TB services and TB medication are provided to the entire population. Successful collaborations in TB control have been seen in the penitentiary system and Directly Observed Therapy Short-course plus (DOTS+) pilot sites.

Some of the leading challenges identified by the study participants included the lack of awareness of specific roles and responsibilities in TB control in the civilian sector and the problems in recruiting and retaining qualified professionals in TB control in both the penitentiary and the civilian sectors due to lower compensation and fewer benefits. They also indicated that there was a lack of modern standards for infection control in TB, inadequate physical infrastructure and substandard equipment and supplies.

In addition, the participants widely indicated that there was a lack of capacity to conduct rigorous Directly Observed Therapy Short-course (DOTS) in the civilian sector and to expand DOTS+ to both the civilian and the penitentiary sectors. Moreover, the inappropriate management of TB drugs by health providers [in pharmacies and dispensaries] was mentioned by participants as an important problem in TB control in Armenia. Recommendations to meet these challenges include improving supervision, developing quality control systems, increasing resources in TB control and further developing protocols, procedures and regulations.

One of the important findings was the stigma and fear of TB that exist among both the general population and health care workers. This stigma has contributed to late utilization of TB services, negative social consequences and spread of disease. Apart from improvement in health care system itself, the participants also recommended campaigns as part of TB control to change the negative attitudes and stigma among the general public.

The findings suggest that a transitional collaboration between the NTP with its national expertise and the International Committee of the Red Cross (ICRC) and the Médecins Sans Frontières France (MSF) with their international experience may most effectively improve TB control and resolve the deficiencies in the newly decentralized TB control system. Continuous and adequate technical capacity strengthening at local level and transfer of adequate resources (with appropriate supervision) are necessary to have proper DOTS implementation in the decentralized TB control system.

INTRODUCTION

Tuberculosis

Tuberculosis (TB) is an infectious bacterial disease caused by Mycobacterium Tuberculosis (BK, bacilli of Koch) that spreads through the air by coughing, sneezing, or simply talking (1, 2, 3). Persons can be infected with the TB bacteria but not develop the disease. In most populations, approximately 95% of persons infected with TB enter a latent asymptomatic phase; these persons may develop the disease later when the bacteria overcomes the immune system of the individual (2, 4). Only about 5% of infected persons may develop the disease immediately after infection (4). The disease may be expressed as pulmonary TB and extra pulmonary TB. The extra pulmonary is much less common than pulmonary (4).

Symptoms

The most commonly affected site is the lungs, but it can affect other organs too, especially in immuno-suppressed persons where one third of the cases include other affected organs (2, 4, 5). The symptoms include cough with thick, cloudy mucus or sputum, sometimes with blood for more than 2 weeks, fever, chills, night sweats, fatigue, muscle weakness, weight loss and in some cases shortness of breath and chest pain (2).

Risk groups

This is a disease that especially targets those persons living in poverty and mostly young adults aged 15-44 who are in their reproductive years (1, 3). Men and women have equal chances to become infected with TB but men are more likely to develop the TB disease (3). The highest risk groups include migrant populations (particularly refugees), the homeless, the Human Immunodeficiency Virus (HIV) positive population, prisoners, former prisoners, orphans, people in hospices, and psychiatry hospitals, people with medical problems such as occupational pulmonary diseases, diabetes mellitus, gastric and duodenal ulcer, people who had treatment experience with corticosteroids, cytostatics, radiotherapy, people having contact with persons or animals suffering from pulmonary TB and people working at schools, municipal services, public transport, catering and grocery stores (6, 7).

Transmission

The spread of TB bacteria depends on several factors such as duration and intensity of exposure (time of exposure and the number and concentration of infectious people) and the presence of people who are more susceptible to TB (2, 3). About 30% of people who have close contact with a patient become infected (3). Each person with active TB infects 10-15 people on average, if not treated (1). Furthermore, 10% of TB-infected people develop TB disease throughout their lifetime and the risk is the greatest in the first two years after infection (1, 3).

Burden

One third of world's population, around 2 billion people, is infected with TB compared to 30 million people who are infected with HIV (3). Around 9 million new active cases of TB are estimated to occur worldwide annually (8). Each day 5,000 people die because of TB, the equivalent of two million dying each year (3). Among infectious diseases, TB is the leading cause of death among populations older than 5 (with higher mortality rates than respiratory

infections, diarrhea, Acquired Immunodeficiency Syndrome (AIDS) and malaria) (3). It also kills more women than any other infectious disease and is the leading reason for women's death even before maternal mortality (3).

Contributing factors

Socio-economic factors and migration are main contributors to TB rates (6). The shortage of competent and motivated human resources for TB control and lack of new diagnostics and pharmaceuticals are problems for many countries. Only a few countries address HIV/TB co-infection appropriately (6). Poor compliance to accepted TB control practices is a contributor to increases in drug-resistant TB disease rates (6).

Multi Drug-Resistant and Extensively Drug Resistant Tuberculosis

TB can be treated with four standard or first-line anti-TB drugs[1] (2). Misuse or mismanagement[2] of these drugs may lead to drug resistant forms of TB (2, 8). A multidrug-resistant TB (MDR-TB) case is a patient with DST resistance to at least two of the most powerful first-line anti-TB drugs: isoniazid and rifampicin (2, 8). Each year, an estimated 450,000 new cases of MDR-TB develop worldwide (1). MDR-TB is estimated to be 4.8% of all TB cases (9). MDR-TB is much more difficult to treat and more expensive second-line drugs with more side affects are required (2).

After the failure of first line drugs, if second-line drugs are misused or mismanaged extensive drug-resistant TB (XDR-TB) may develop (2). XDR-TB includes resistance of the bacteria to any fluoroquinolone in addition to isoniazid and rifampicin and at least one of three injectable second-line drugs: capreomycin, kanamycin and/or amikacin (2). The treatment of such patients is very difficult (1). Recent studies suggest that XDR-TB consists of 15% of all MDR TB cases in some areas of Europe (2). Worldwide it is estimated that XDR-TB makes up 0.2% of all MDR TB cases (9).

Patients with MDR-TB or XDR-TB can transmit the disease to others. Symptoms of any drug-resistant and non drug-resistant TB are the same (2).

Prevention, Diagnosis and Treatment

There are some preventive measures to control TB (2). Among them is the "bacilli Calmette-Guėrin" (BCG) vaccination against TB; it can prevent severe forms of TB in children (even if they are exposed to XDR-TB) but it is less effective in adults (2). The World Health Organization (WHO) and the Stop TB Partnership among others are actively working on development of new vaccines for TB (2).

TB diagnosis may be confirmed by bacteriological diagnostics (sputum smear microscopy and sputum culture), X-Ray, blood testing and tuberculin diagnostics mainly among children and teen-agers (9). Sputum smear microscopy is performed in one to two days if the bacteria are present in the sputum (2). However, this testing does not provide any information about drug-susceptibility and drug-resistance (2). The detection of Mycobacterium Tuberculosis through

[1]First-line anti-TB drugs are rifampicin (R), isoniazid (H), pyrazinamide (Z) and ethambutol (E) (10).
[2]Misuse or mismanagement – drugs taken in a wrong combination, or drugs taken fewer than those prescribed, or drugs taken in insufficient doses, or drugs taken insufficient times (2).

culture and drug sensitivity test requires 6-16 weeks (2). The BACTEC radiometric detection method requires considerably less time (only a few days) but it is more expensive[3].
The WHO recommends Directly Observed Therapy Short-course (DOTS) strategy for effective TB control (7, 8). The strategy is based on the following five principles (11):

1. "political commitment with increased and sustained financing,
2. case detection through quality assured bacteriology,
3. standardized treatment with patient supervision and support,
4. an effective drug supply and management system,
5. monitoring and evaluation system and impact measurement".

Due to the scale of the global TB epidemic a Stop TB Partnership was established in 2000 as a global movement to accelerate social and political action to stop the spread of TB around the world (1). The Partnership's goal is to eliminate TB as a public health problem and, ultimately, to secure a world free of TB. The Partnership consists of a network of over 400 committed international organizations, countries, donors from the public and private sectors, governmental and nongovernmental organizations, and individuals working together to achieve that goal.

A STOP TB strategy and a second global Plan to Stop TB, 2006-2015 has been developed and includes the following components (1):
PURSUE HIGH-QUALITY DOTS EXPANSION AND ENHANCEMENT

- Political commitment with increased and sustained financing
- Case detection through quality-assured bacteriology
- Standardized treatment with supervision and patient support
- An effective drug supply and management system
- Monitoring and evaluation system, and impact measurement

ADDRESS TB/HIV, MDR-TB AND OTHER CHALLENGES

- Implement collaborative TB/HIV activities
- Prevent and control multidrug-resistant TB
- Address prisoners, refugees and other high-risk groups and special situations

CONTRIBUTE TO HEALTH SYSTEM STRENGTHENING

- Actively participate in efforts to improve system-wide policy, human resources, financing, management, service delivery, and information systems
- Share innovations that strengthen systems, including the Practical Approach to Lung Health (PAL)
- Adapt innovations from other fields

ENGAGE ALL CARE PROVIDERS

- Public-Public, and Public-Private Mix (PPM) approaches
- International Standards for TB Care (ISTC)

[3]Palomino J.C. Non conventional and new methods in the diagnosis of tuberculosis: feasibility and applicability in the field. *European Respiratory Journal* 2005; 26: 339–350. available at http://www.emro.who.int/stb/pdf/Palomino.ERJ.2005.pdf

EMPOWER PEOPLE WITH TB, AND COMMUNITIES

- Advocacy, communication and social mobilization
- Community participation in TB care
- Patients' Charter for Tuberculosis Care

ENABLE AND PROMOTE RESEARCH

- Programme-based operational research
- Research to develop new diagnostics, drugs and vaccines

SITUATIONAL ANALYSIS OF TB SERVICES IN THE CIVILIAN SECTOR IN ARMENIA

Burden

Armenia is ranked the 10th highest for TB incidence rate among the 53 WHO European Region countries (12). According to the official country statistics, the number of active TB cases has doubled through 1988-2005: 3,205 cases in 1988 compared to 6,455 cases in 2005 (5). The number of registered new cases increased from 21.6 in 1995 to 62.4 in 2005 per 100,000 population (a 2.8-fold increase) (8). The number of active (infectious) cases among new cases has also increased: 13.5/100,000 in 1995 compared to 19.0/100,000 in 2005 (8). The total number of DOTS treated patients (both new treated and retreated cases) has increased from 1,538 in 2003 to 2,170 cases in 2006 (8). In 2006, the total number of notified cases was 2,155, out of which 1,598 (74%) were new cases and 557 (26%) retreated cases (8). In 2007, the total number of notified cases was 2,129 with 1,533 (72%) new and 596 (28%) retreated cases[4]. The death rate has also increased from 3.7/100,000 in 1995 to 5.2/100,000 in 2005 (8).

The increase in DR-TB rates in the country is of particular concern. The recent nationwide Drug Resistance Survey (DRS) conducted during March 2006 – March 2007 found that 9.4% of newly diagnosed smear positive cases and 43.0% of previously treated smear positives had MDR-TB [for comparison - 6.8% of newly diagnosed smear positive cases in Georgia are MDR-TB] (13, 14). DRS also showed that 21.4% of all tested cases (new and previously treated combined) were MDR-TB in Armenia; this is significantly higher from the worldwide estimate of 4.8% (9, 15). It is estimated that in the coming five years Armenia will have about 1,160 MDR-TB cases (8). According to the same DRS, 8 cases of XDR-TB were revealed in Armenia (8).

Knowledge and Attitude

According to the Demographic Health Survey (DHS) 2005, the majority of adults have heard of TB (91.7%) and half of the respondents could correctly identify the mode of transmission (5). Only half of female respondents and three-fifth of male respondents, who have ever heard about tuberculosis, knew that TB can be completely cured. A little less than 20.0% of respondents mentioned that they would like to keep their family member's TB status in secret (5). This figure suggests existing stigma related to TB status in Armenia.

According to the TB Communication qualitative study (2006), the public is poorly aware of TB as a serious public health issue in Armenia (16). Most people do not believe that they or their loved ones are at risk of TB disease and the majority does not recognize the symptoms of TB. As a result, they are often late in seeking health care for TB or do not complete the treatment course, especially when they see the first signs of recovery (16). TB patients are not well informed about the necessary duration of the treatment for a complete cure and about the threats of interrupted treatment or non-compliance. Some of them do not believe that TB can be cured and many of them do not believe that the services are free of charge (although officially they are) (16).

[4]National Tuberculosis Program, www.ntp.am

National TB Control Program

In December 4, 2003 decree N° 1680 of the Armenian Government established the National TB Control Program (NTP) to address the issue of TB nationwide (7, 8). NTP is under the authority of the Ministry of Health (MOH) and aims to protect the population of Armenia from TB by permanent and coordinated prevention, detection and treatment based on the WHO recommended DOTS strategy (7). Currently, the program is operating based on the new international Stop TB Strategy and Global Plan to Stop TB 2006-2015 (8). The current goal of the NTP is to reduce TB morbidity, mortality and DR-TB during 2007-2015. The financial resources of NTP come from the state budget of the Republic of Armenia (RoA) and international organizations, with primary funding coming from the Global Fund (GF)(8).

The NTP Central Office was established in the RoA MOH Perinatology and Obstetrics Scientific Centre under the MOH supervision by the order N° 908 in September 2003 (7, 17). According to the Decision No 703 from July 3, 2008 of the Government of RA, "National Office of TB control" was defined as a state non-commercial organization. The objectives of this organization are: 1) under its jurisdiction coordination, organization and monitoring of the implementation of TB control activities proceeding from the national TB program in the territory of the Republic of Armenia; 2) implementation and coordination of TB prevention activities; 3) rendering methodological assistance to TB and anti-TB services in the territory of the Republic of Armenia; and 4) advocating knowledge about healthy behavior with the purpose of TB prevention[5]. It is also responsible for ongoing training of staff, data collection and maintenance of the national database, supervision and organization of information, and provision of laboratory supplies (8). The National Office of TB Control also manages record keeping and distribution of TB drugs which are provided by the Global Drug Facility (funded by Kreditanstalt für Wiederaufbau (KfW) since 2004) (7). Drugs are distributed to health facilities based on need (7). Moreover, NTP conducts quality control on a quarterly basis of all TB facilities (7, 8).

Eleven regional NTP coordinators were assigned by the MOH to ten marzes and Yerevan on September 2003 by the order N° 913 as heads or deputy heads of the Health and Social Protection Department in the Governor's Office of the marz (Marzpetaran). They are responsible for NTP implementation in their assigned marzes (7, 18).

State Funding

TB diagnosis and treatment at both primary and specialized health care level in the civilian sector are included in the Basic Benefit Package (BBP) according to the order of N° 1927-A and are covered by the state budget (19).

According to the Ministry of Finance of RA Decree No 127-A of 18 February 2008 and Ministry of Health of RA Decree No 130-A of 04 February 2008, the mean duration of TB treatment in specialized TB facilities is 60 days for newly identified active SS+ TB cases, with the cost for the 60-day treatment per patient of 450,000 AMD. The mean duration for treatment of active SS+ drug resistant TB cases is also 60 days with the cost per patient of 450,000 AMD. The

[5]Decision No 703 from the July 3, 2008. *About Establishing "National Office of TB Control" State Non-commercial Organization.* The Government of Republic of Armenia.

mean duration for "chronic" SS+ TB case treatment is again 60 days, with the cost per patient of 460,800 AMD.

For newly identified active SS- TB cases, for active SS- drug resistant TB cases and for chronic SS- TB cases the mean treatment duration in specialized TB facilities is 50 days. The cost per patient is 375,000 AMD for newly identified active SS- TB cases and active SS- drug resistant TB cases, and 384,000 AMD per chronic SS- TB case. The treatment mean duration for TB patients with psychiatric disorders is 55 days with a cost of 478,500 AMD per patient. The mean duration for TB surgical treatment is 4 days with a cost of 48,000 AMD per patient. The mean duration for diagnostic investigations is 10 days with a cost of 60,000 AMD per patient. The mean duration for rehabilitation in TB sanatoriums is 50 days with a cost of 300,000 AMD per patient[6].

The TB control in the military system is financed and organized by the Ministry of Defence (MOD) (7).

International Financial and Technical Support

Since 2002, the German Government through Deutsche Gesellschaft für Technische Zusammenarbeit (GTZ) and Kreditanstalt für Wiederaufbau (KfW) international organizations are providing funding and technical support for TB control in the Armenian civilian sector. These organizations have covered the expenses on first-line drugs, laboratory and X-Ray equipment, supplies and vehicles for supervision, technical assistance and training in DOTS as well as supporting the national DRS and renovation of the NTP Central Office (7).

The International Committee of the Red Cross (ICRC) has also built, equipped, and trained the staff of the National Reference Laboratory and donated it to the MOH in 2001 (8).

The Médecins Sans Frontières France (MSF) in collaboration with the MOH and the Mayor's Office of Yerevan began implementing a Directly Observed Therapy Short-course Plus (DOTS+) pilot project in September 2005 to respond to DR-TB in two districts of Yerevan - Malatia/Sebastia and Shengavit (8, 18). The program has enrolled 115 patients with DR-TB; however, according to MSF estimates, there are 200 more DR-TB patients in Yerevan (outside the two DOTS+ pilot districts) who need treatment (13). In response to this urgent need, MSF is planning to extend this program to three more districts in fall 2008 and to also start providing DR-TB treatment in the penitentiary sector (13).

The World Bank (WB) and the US Agency for International Development (USAID) contribute to TB control through Family Medicine training courses for the Primary Health Care (PHC) providers (7). The Armenian Red Cross Society (ARCS) provided social support and Information, Education, Communication (IEC) program for TB patients and their families. The WHO provides opportunities for international trainings of TB specialists, monitoring and technical assistance to NTP through the TB Office for South Caucasus in Tbilisi, as well as technical assistance in developing/adapting policy documents and guidelines for TB control and health system strengthening initiatives (7, 8).

[6]Decree No 127-A of 18 February 2008 of Ministry of Finance of RA and Decree No 130-A of 04 February 2008 of Ministry of Health of RA. *The standards and mean costs for hospital care and services*.

In January 2007, Round 5 application to the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM) was approved for Armenia to support TB control for five years (8).

TB Facilities

The health care facilities that deliver TB inpatient services in the civilian sector include two specialized TB dispensaries (the Republican TB Dispensary in Abovyan (RTBD) and the City TB Dispensary in Yerevan) and 10 TB in-patient departments in general hospitals (with a total 593 TB hospital beds), and 70 TB cabinets/offices in polyclinics provide out-patient services (20).

The network of TB laboratories include 52 level I microscopy laboratories, one level II (culture) laboratory in Yerevan and the National Reference Laboratory (NRL) at the RTBD which performs microscopy, culture, microbe identification and Drug Sensitivity Testing (DST) for both penitentiary and civilian systems and carries out quality assurance of all laboratories in the country (7, 20). NRL is affiliated with the Supranational TB Reference Laboratory (SRL) in Borstel (Germany) (7).

Table 1 presents structural indicators for Armenia, Georgia, and Central Asia. The Armenian and Georgian indicators are comparable as they are developed using the same methodology and similar sources; however, this report cannot comment on comparability of data from Central Asia.

Table 1: Structure of TB services in selected countries in the region (20, 21, 22, 23**).**

	Armenia	Georgia	Kazakhstan	Kyrgyzstan	Tajikistan	Uzbekistan
Population (millions)	3.0	4.4	15.0	5.0	6.3	25.3
TB Beds	593.0	1245.0	12512.0	3611.0	2270.0	11230.0
TB Beds per 100,000	19.8	28.3	83.4	72.2	36.0	44.4
TB Beds per 1,000 patients	335.0	337.0	552.0	585.0	569.0	563.0
TB Doctors	106.0	168.0	1346.0	360.0	168.0	1449.0
TB Doctors per 100,000	3.5	3.8	9.0	7.2	2.7	5.7
TB Doctors per 1,000 patients	60.0	45.5	55.0	58.0	42.0	73.0
Patients per TB Doctor	16.7	22.0	18.0	17.0	24.0	14.0
Dispensaries	12.0[7]	14.0	334.0	17.0	63.0	111.0
Dispensaries per 100,000	0.4	0.3	2.2	0.3	1.0	0.4
Dispensaries per	6.8	3.8	2.5	0.5	2.8	1.0

[7]It includes two TB Dispensaries and 10 TB in-patient departments.

1,000 patients						
TB Laboratories	54.0	76.0	510.0	158.0	70.0	289.0
TB Labs per 100,000	1.8	1.7	3.4	3.2	1.1	1.1
TB Labs per 1,000 patients	30.5	20.1				
NRL	Yes	Yes	Yes	Yes	No	Yes

Prevention and TB Services at the Primary Health Care Level

TB prevention practices in Armenia include BCG vaccination of 1-2 days old newborns (19). Those newborns who do not receive the BCG vaccine in maternities are vaccinated in the immunization cabinets of a local health care facility. Six to seven years old children are revaccinated with BCG based on the national immunization calendar (19).

The district therapists, district pediatricians, family doctors and nurses at the Primary Health Care (PHC) level are responsible for passive case finding in the general population referring suspected cases to the TB cabinets in polyclinics (19).

Specialized TB Services

Each TB cabinet is designed to include one TB specialist and two nurses: one nurse is responsible for the functioning of the cabinet, the other nurse for patient outreach for those cases when patients miss their regular visits to the TB cabinet (19). The designed functions of the cabinet include activities directed towards TB prevention among the healthy population, early detection of TB, record keeping of new and relapsed TB cases, diagnostic procedures and treatments of new and relapsed TB cases based on the DOTS strategy, appropriate referral of the patients to specialized TB facilities as needed, dynamic dispensary surveillance of TB patients both new and relapsed, organizing treatment for children and adults in sanatoriums, medication distribution based on the DOTS strategy, organizing laboratory/instrumental diagnostic procedures by referrals to TB departments in marz facilities or RTBD as needed, performing medical examinations for pre-military and military age group males in collaboration with the adolescent cabinets, and maintaining TB control among former prisoners (19).

DOTS has been implemented in Armenia since 1995, first as a pilot program and then it reached 100% coverage by the end of 2002 (5, 7, 8). According to the National TB treatment protocol, the treatment for new pulmonary and extra-pulmonary cases is 6 months, including two months of the intensive phase of the treatment, usually at an in-patient TB care facility, and four months of the continuation/ambulatory phase of the treatment. The treatment for relapsed cases is 8 months, which includes 3 months of intensive and 5 months of continuation phase (19). For drug-resistant TB, treatment consists of 6 months intensive and 18 months continuation phases of treatment (16).

With the exception of DR-TB patients living in Malatia/Sebastia and Shengavit districts of Yerevan (the pilot sites of the DR-TB treatment project conducted by MSF), all other DR-TB patients in Armenia receive only treatment for related TB symptoms and not DR-TB disease itself (8). NTP has applied to GFATM for (Round 8) to initiate DOTS+.

Diagnosing TB

The diagnosis of TB is performed by triple direct sputum smear microscopy supported by X-ray as necessary. There is no systematic routine drug resistance surveillance in the country (20).

As soon as TB case is identified it is reported to the State Hygienic and Anti-epidemic Inspectorate (SHAI) team which visits the patient at home for contact tracing, health education, vaccination, preventive treatment and environmental disinfection. The patient is also strongly advised to bring his family members for TB check-up (7, 8). The NTP is responsible for active case detection among the contacts of an identified TB case (7).

In the military sector active case finding by mass miniature radiography (MMR) is performed among the army recruits before starting the service in the army (8).

HIV/AIDS-TB Co-infection

People living with HIV/AIDS are estimated to be less than 0.1% of the population of Armenia and thus HIV/AIDS-TB co-infectivity rates are currently low, though on the increase (8). This could become a much more serious problem in the future. From 2002 to 2007, 1,099 HIV tests were performed among TB patients; 1.8% of TB patients were co-infected with HIV in 2002 and this number increased to 3.1% in 2007 (8).

According to the National AIDS Center, currently there are 117 known HIV-TB co-infected patients in Armenia. A total of 19.7% of known HIV infected people are also infected with TB (24).

Human Resource Development

Pre-service trainings: the Yerevan State Medical University (YSMU) and the National Institute of Health (NIH) run the residency programs for preparation of TB doctors. The residency program in TB is mainly covered by the state. Between 2005 and 2008, YSMU offered one and NIH offered about six residency positions on average per year (25, 26).

In service trainings: NTP conducted two training courses: one for managers and one for laboratory staff (7). During 2003-2004, with support from GTZ 47 TB doctors and 21 laboratory staff (11 doctors and 10 technicians) were trained. Nine TB providers from both the civilian and penitentiary sectors already attended different training courses abroad on management of drug resistant TB (with support from ICRC and the Global Fund supported project) (8).

World Bank supports the re-training of general practitioners in family medicine; the Unified Family Medicine Curriculum includes a 5-day module on TB diagnosis and treatment (7).

The Unified Family Nursing Curriculum [6.5 months training, includes 33 modules] includes a 1-day TB module covering TB prevention, case detection and management. In 2007, 129 nurses from Lori and Shirak marzes, and in 2008, approximately 100 nurses from Kotayk, Gegharkunik, and Tavush went through this training. The training will cover other marzes by 2010 (totaling to approximately 470 nurses throughout Armenia) (27).

SITUATIONAL ANALYSIS OF TB SERVICES IN THE PENITENTIARY SECTOR IN ARMENIA

Worldwide the detainee population is 50 times more likely to develop active TB than the general civilian population in any given year (9). The contributing factors for TB in prisons are complex. The physical conditions of prisons (overcrowding, poor hygiene, lack of sunlight and ventilation, and others) and limited resources promote TB burden in prisons (3, 28). Prisoners are at even higher risk for developing TB because they share other high risk factors such as alcohol and drug use, poverty, having a mental health problem, belonging to ethnic minority groups or being illegal immigrants (3). In addition, two major independent risk factors for tuberculosis in prison population are co-infection with HIV and malnutrition. The infrastructures in prisons and social structures among prisoners can also negatively impact health care seeking behaviors of the prisoners (28).

Prison TB Control Program in Armenia

The main national authority responsible for TB control in prisons is the Ministry of Justice (MOJ) in Armenia, through the Medical Service of the Department of Penitentiary Institutions (8, 29). It is responsible for financing and implementation of TB control in the penitentiary system. It has been closely collaborating with the International Committee of the Red Cross (ICRC) since 1999. The ICRC has a history of promoting and implementing TB control and prevention in prisons throughout the South Caucasus from the mid-nineties (9). Based on the previous experiences in Azerbaijan and Georgia, the ICRC supported the RoA MOJ to develop a policy for tuberculosis control in the prisons of Armenia (9). The ICRC also provided technical assistance, infrastructure, equipment, medication and other supplies, training opportunities and initiated the IEC program for TB (7).

The ICRC Regional Strategic Plan to Control Tuberculosis in Prisons of the Southern Caucasus 2003-2008 calls for the transfer of all responsibilities for TB services in the prisons to national authorities. Its goal is to "strengthen the capacity of national services to achieve the objectives of the NTP." The three strategic elements to achieve this goal are to: "1) pursue quality DOTS expansion and enhancement; 2) address TB/HIV, MDR-TB and other challenges; and 3) contribute to the health system strengthening" (9).

The ICRC cooperates closely with the Prison TB Control Program. This program has been implemented by the Central Medical Unit (CMU) of the Criminal Executive Department of the MOJ (4) and has three components: 1) case finding and laboratory diagnosis; 2) treatment of TB patients; and 3) health education (8). The NTP has limited involvement with the prison TB control program, including some laboratory testing and follow-up control for former prisoners (28).

DOTS was implemented in the penitentiary system since 2002 with the support of the ICRC. In 2005, DOTS coverage in the penitentiary sector of Armenia was 100% [according to the standard WHO TB indicators] (9). DOTS treatment success rates of new pulmonary infectious cases for 2004 and 2006 were 56% and 71%, respectively. DOTS+ program started in the prisons in September 2008 in collaboration with MSF (4).

The notification rate of all TB cases were 2,853/100,000 and 1,624/100,000 in 2004 and 2006, respectively (9) (see Table 2). The number of notifications for new pulmonary infectious TB cases (NCSS+) was 703 in 2004 and 471 in 2006. In 2006, the percent of MDR-TB cases among new TB cases was 3.1%, while in previously treated cases it was 25.0% (9) (Table 2).

According to a prison survey (through saliva testing) conducted in a sample of 542 inmates by the ICRC in the penitentiary system in 2004, the prevalence rates for HIV, hepatitis B, and hepatitis C were 1.3%, 2.6%, and 22.7%, respectively (30). The Tuberculosis Assessment Mission to Armenia (Vink et al, 2005) suggested that among 42 prisoners participating in the 2004 prison survey diagnosed with pulmonary TB, 45% were positive for hepatitis C, 5% for hepatitis B and 7% for HIV (7). They also suggested that according to the same prison survey data, out of all HIV infected prisoners in the sample, 43% also had active pulmonary TB (7).

Organizational Structure of the Prison TB Control Program (4):

1. The Central Medical Unit (CMU) under the Criminal Executive Department is responsible for the overall management and supervision of the Prison Tuberculosis Control Program and coordination with the National Tuberculosis Program in Armenia.
2. The prison TB Treatment Units (where DOTS is administered to detainees and convicts diagnosed with TB) include the TB Department of the Central Hospital for Detainees in Yerevan and the Medical Departments of "Noubarashen" and "Abovian" Criminal Executive Institutions (CEI). These units are responsible for TB detection and treatment. The TB Department of the Central Hospital for Detainees is equipped for 200 patients. Patients are separated according to their infection status including MDR-TB. The three additional sites "Goris" CEI, "Artik" CEI and "Vanadzor" CEI Treatment Units, are responsible for second phase treatments or are designed to serve as back-ups for the TB Department of the Central Hospital for Detainees as needed.
3. Peripheral health units of the penitentiary system perform case-finding and referral for TB patients. All criminal executive institutions have such a unit.

Case-finding

The three main strategies for TB case-finding in Armenian prisons are entry screening, mass (active) screening and passive screening. Entry screening for TB is designed to be performed for prisoners at entry. Mass screening is active case detection in a CEI: the entire prison population should be screened twice annually using a clinical survey and Mass Miniature Radiography (MMR) (8). Passive screening includes self referral.

The main diagnostic method used is sputum microscopy which is done in the TB laboratories at the Central Hospital for Detainees and the Nubarashen CEI in Yerevan. Three civilian laboratories perform sputum examinations for the prisons located in their marz (Artik, Vanadzor and Goris CEIs). The NRL (civilian sector) performs Culture and Drug Susceptibility Test (DST) for the penitentiary sector (8).

Civilian vs. Penitentiary Sector

Although DOTS coverage in 2006 was 100% for both the civilian and penitentiary sectors, the percentage of MDR-TB among new TB cases in the civilian sector was about four times higher the percentage reported for the penitentiary sector, and the percentage of MDR-TB among

retreated cases was 1.7 times higher in the civilian sector than in the penitentiary sector (see Table 2). These differences were more striking in 2007.

Table 2: Comparison of TB Characteristics between Civilian and Penitentiary Population (5, 9, 14, 15, 23)

	Civilian sector				**Penitentiary sector**			
	2004	**2005**	**2006**	**2007**	**2004**	**2005**	**2006**	**2007**
DOTS coverage (%)	100.0	100.0	100.0		86.0		100.0	
Key indicators								
Case notification rate all*/100000	55.0	73.0	65.0	65.0	2853.0	2203.0	1624.0	1363.0
Case notification rate all new SS+/100000	20.0	19.0	19.0	15.4	703.0	680.0	471.0	206.0
TB case fatality (%)	3.7	2.5	3.0	4.5	3.9	2.8	0.0	5.2
Treatment outcome New SS+								
Success rate (%)	70.0	72.0	69.3		56.0	42.0	71.0	100.0
Died (%)		3.4	4.7		11.0	0.0	0.0	0.0
Defaulted (%)		14.5	13.6		0.0	42.0	21.0	0.0
Failed (%)		5.2	10.0		17.0	16.0	7.0	0.0
Treatment outcome Re-treatment SS+								
Success rate (%)		51.0	41.0		50.0	54.0	38.0	57.0
Died (%)		4.0	9.0		3.0	4.0	0.0	0.0
Defaulted (%)		25.0	32.0		30.0	36.0	38.0	0.0
Failed (%)		15.0	18.0		18.0	7.0	25.0	43.0
MDR Rates								
Among new cases (%)	17.0	14.9	12.4	11.7	0.0	6.1	3.1	0.0
Among previously treated (%)	46.4	41.8	43.4	35.2	7.5	10.7	25.0	4.2
XDR TB among MDR (%)				4.0				

*All TB cases – new, relapsed, failure, interruption, extra-pulmonary, other.

TB LEGISLATION AND REGULATION IN ARMENIA

Appendix 1 presents a detailed analysis of the existing legal basis of TB control in the civilian and penitentiary sectors highlights the shortcomings of the current framework, and makes cross-national comparative analysis of legislative approaches for TB control employed in some European countries and assesses suitable approaches for Armenia that can strike a balance between the individual rights coded in the "European Convention for the Protection of Human Rights and Fundamental Freedoms" and the effective protection of the public health.

The legal review concludes that the TB legislative and regulatory framework is very fragmented and lacks enforcement mechanisms.

QUALITATIVE STAKEHOLDERS ANALYSIS

Purpose and Objectives of the Study

The main objective of the qualitative stakeholder analysis was to evaluate 1) different stakeholders' capacity in different TB control activities and 2) potential capacity for the future support and cooperation with the TB Program under the MOJ.

The stakeholder analysis included understanding the roles, responsibilities and rights of major stakeholders on paper and in real life (a qualitative assessment). The qualitative study covered the major stakeholder groups: representatives from MOJ, MOH, National Institute of Health (NIH), Yerevan State Medical University (YSMU), and non governmental organizations (NGO); providers of family medicine and specialized care (including those working in the penitentiary system); and patients from the penitentiary and civilian sector, including those who have been in both systems.

METHODS

Study Design

The research team of the Center for Health Services Research and Development, American University of Armenia (CHSR/AUA), developed a qualitative study design to understand the functioning of TB control systems in the country in both the civilian and penitentiary sectors using focus groups and systematic semi-structured in-depth interviews.

Study Participants and Sample Size

Focus Groups

The CHSR/AUA research team recruited 36 participants for four focus group discussions (FGD) (with the average number of 9 participants per FGD) in June-July 2008. The participants included primary health care physicians (district therapists and family doctors), TB specialists[8] and auxiliary medical personnel (nurses, radiologists, pharmacists, social workers, laboratory doctors and psychologists). One of the FGDs was conducted with female district therapists and family doctors with the average age of 53 years and 28 years of professional experience on average working in primary health care in Yerevan. The second focus group included female TB specialists from existing and newly opened TB cabinets of Yerevan polyclinics. The average age and professional experience of this group were 47 and 19 years, respectively. The third group consisted of a multidisciplinary group of near equal numbers of male and female TB specialists, nurses, and auxiliary medical personnel working on the DOTS+ program. The fourth focus group included TB specialists, radiologists and laboratory doctors. This focus group consisted of near equal mix of male and female participants from the civilian, penitentiary and military sectors. The average age of this group was 36 years and the participants' mean work experience was 9 years.

Semi-structured In-depth Interviews

[8] A *TB specialist* is used here as a physician, who is specialized in TB treatment

Experts and health providers from the Ministry of Health, the Ministry of Justice, the National TB Program Central Office, TB dispensaries, the National Reference Laboratory, the SHAI, Yerevan State Medical University, National Institute of Health, and local and international organizations (the AIDS Prevention Centre, the Armenian Red Cross Society, GOPA Consulting, the Médecins Sans Frontières France and the World Health Organization) were invited to participate in in-depth interviews in June-September 2008. Out of seventeen invitations there was only one refusal.

Moreover, 12 TB patients (average age: 37 years) were interviewed; only 11 of them were considered for the data analysis[9]. Six of them were MDR-TB patients and five were regular TB patients. Three MDR-TB patients were SS+ and three MDR-TB patients SS- at the time of interviews. All five regular TB patients were current prisoners: one was SS+ and four were SS-. From all interviewed patients four were former prisoners: three were SS+ and one was SS-. All patient participants completed at least secondary school. Eight of the patients were from Yerevan and three from marzes of Armenia; only one of the patients was a female.

Out of the 63 participants of in-depth interviews and FGDs, 59 (93.7%) were Armenian citizens.

Selection of Participants

The ICRC and the CHSR/AUA worked together to identify participants that were key-informants or could provide important for the study information, based on their TB experience and expertise. Participants at all levels of TB control as well as TB patients were included in the study to provide a comprehensive broad profile of TB and TB control in Armenia.

The ICRC provided a list of TB experts and facilitated getting access to current prisoners with TB for systematic semi-structured in-depth interviews. The CHSR/AUA research team contacted additional TB experts identified during the study (sometimes with help from participants). The MSF supported with getting access to MDR-TB patients for in-depth interviews. Along with regular TB patients, these MDR-TB patients were also selected as participants because each individual patient experienced TB-treatment at different health care levels and often in different sectors. These particular patients provided a unique opportunity for a cross-comparison of services and an analysis of transitions between services.

Research Instruments

Focus Groups

The CHSR/AUA research team developed focus group discussion guides based on standardized qualitative research methods. The guides were developed to optimize and maximize the value of the data collected to meet the objectives of this study. Each guide was adapted to the specific make up of each focus group. A demographic form was also developed for completion by participants.

In-depth Interviews

The semi-structured in-depth interview guides were also developed based on standardized qualitative research methods. The in-depth interview guides were also developed to optimize and maximize the value of the data collected to meet the objectives of this study. Some of the

[9]During one of the interviews with a prisoner other people were present in the interview room.

questions in each interview guide were adapted to the specific participant's roles/responsibilities and experience in TB control.

English/Armenian translations were performed by the CHSR/AUA research team. The focus group discussion guides and in-depth interview guides are attached as Appendix 2.

Data Collection and Analysis

Overall, the AUA qualitative research team conducted 26 in-depth interviews and 4 FGDs. The average duration for in-depth interviews was about 60 minutes and for FGDs 120 minutes. All in-depth interviews and focus groups were conducted by the professional CHSR/AUA qualitative research team. Each focus group had a moderator and a note-taker. The roles of focus group moderator and note-taker were rotated among the research team. For each in-depth interview there was both an interviewer and a note-taker or an interviewer only. These roles were also rotated among the CHSR/AUA research team members. All focus groups and in-depth interviews were conducted in Armenian except for one in-depth interview which was conducted in English and one focus group which was conducted in both Armenian and English. All the in-depth interviews and FGDs were transcribed. Following data collection, interview and focus group transcripts were analyzed according to a pre-developed coding system.

Ethical Considerations

The study was approved by the Institutional Review Board of the American University of Armenia for compliance with locally and internationally accepted ethical standards. As "a research studying public benefit or service programs" this study received an exemption status.

All participants were informed about their rights (their participation was voluntary, they could stop at any time and refuse to answer any question they chose, and their anonymity and confidentiality would be fully respected). After being informed of their rights, all those who chose to participate provided verbal informed consent. Permission was asked to tape-record in-depth interviews and focus groups; if any one participant chose not to be tape recorded then only written notes were taken. All personal information (including names) about participants of focus groups and in-depth interviews were destroyed after completion of data collection. Transcripts and report do not contain names and employers of the respondents or any other details that could make the participants identifiable.

Strengths and Weakness

This study applied comprehensive rigorous research methodologies to meet the study objectives to 1) evaluate stakeholders' capacities in different TB control activities and 2) evaluate stakeholders' potential capacities for future support and cooperation with the TB program under the MOJ and MOH.

Though the research was diversified in both methods and sources, there were broad convergences in agreement among findings. The diversity in methods included the systematic application of two different approaches, focus groups and semi-structured in-depth interviews, using three different trained professional interviewers and facilitators who rotated responsibilities to conduct these activities.

Study participants were also very diverse in their roles in TB control and prevention. These participants included TB administrative and treatment professionals, health care providers, various auxiliary TB professionals and patients spanning all health services levels, all sectors and all stakeholders.

Along with regular TB patients, MDR-TB patients were also included as participants in the study because these particular patients individually had a much broader range of TB-treatment experiences on the different health care levels and sectors. These experiences provided individual MDR-TB patients with the unique position to compare experiences in different TB health care treatment levels and sectors as well as to provide insights into transitions between services.

The following reported findings primarily include those results where there were convergences of consistent and common agreement across participants and methods, providing valid and useful information to understand capacities and to plan for further cooperative efforts in TB control and prevention in Armenia. In a few exceptions, where certain discourses in focus groups and in-depth interviews did not always converge in agreement but illuminated other findings, then these discourses were also included in the findings.

A limitation in the study design was the lack of the participation of primary health care physicians from the marzes and TB specialists from the TB cabinets in the marzes. Thus, data collected in the study regarding primary health care and the TB cabinets in the marzes was not as detailed as information regarding all other TB services. However, some of the study participants, TB experts and specialists as well as patients, had experience and knowledge of TB control and services in the marzes, thus were able to provide information on these services. Therefore, biases associated with this limitation were probably minimal and had little or no impact on the study findings.

RESULTS AND DISCUSSION

The analysis section of this study was based on the results from the in-depth interviews and focus group discussions. The direct quotes (translated as needed) provided in the boxes in this section are abstracted from both in-depth interviews and focus group discussions. Study participants were categorized into six groups: TB experts, TB specialists, primary health care (PHC) physicians, auxiliary TB professionals, MDR-TB patients and prisoners with TB. A *TB expert* was a professional whose responsibilities include TB program administration, TB program regulation and/or oversight of TB control. A *TB specialist* was a physician, who was specialized in TB treatment. A *PHC physician* was either a district therapist or a family doctor. An a*uxiliary TB professional* was a professional who provides support services for TB treatment. An *MDR-TB patient* was a patient with multi-drug resistant TB (resistant to at least isoniazid and rifampicilin) that was either SS+ or SS- and currently using civilian sector TB services at the time the in-depth interview was conducted; MDR-TB patient participants included former inmates in the penitentiary system as well as those who had never been incarcerated. A *prisoner with TB* was an inmate or detainee in the penitentiary system as a regular TB (TB that is not resistant to isoniazid and rifampicilin) patient with either SS+ or SS- status who was using TB services in the penitentiary sector at the time of the interview. An informant identifier (eg., TB

expert 1.A.1.) that is provided in a box is for the purpose of identifying a participant who provided more than one quote within a single box. A single informant who provided quotes in more than one box would have different identifiers for each box.

Civilian Sector

1. Primary Health Care Providers

1.A. Knowledge and Surveillance of TB in the PHC after Decentralization

The PHC providers send suspected cases for X-Ray and then refer them to the TB cabinets.
TB expert 1.A.1.
In-depth interview

It is very difficult to give a definitive answer [to the question "how would you assess the role of PHC providers in TB control?"]. *In different marzes of Armenia the level of PHC involvement in TB control is different. Most of primary health care providers were not very well informed, I would say even uninformed about TB before the trainings in 2006.*
TB expert 1.A.2.
In-depth interview

The PHC has very limited involvement in TB control. I would say that practically they have almost no involvement [in TB control]. *The PHC practitioners are not alerted to the possibility of TB. They consider a TB diagnosis very late. There are many cases that had been diagnosed for cancer or Echinacoccus and only after surgery it turned out that the patient had TB. So, in reality TB problem is underestimated. This limited knowledge* [of TB] *and late consideration of the possibility of TB comes from the Soviet health care system when general specialists were not seeing TB. TB was controlled on the level of specialized care in the dispensaries.*
TB expert 1.A.3.
In-depth interview

They [patients] *wander all the rooms of the polyclinics, different hospitals and diagnostic centers before they get a TB diagnosis.*
TB expert 1.A.3.
In-depth interview

PHC providers indicated that when they identified TB cases they referred them to TB specialists. At the time of this study however, other study participants reported that PHC providers were not sufficiently involved in TB early detection and referral, as was planned by the National TB Program. TB diagnostic testing was often late and patients often expended time and resources before obtaining specialized TB care.

There was a consensus among study participants (including primary health care physicians themselves) that one reason for these delays was that primary health care providers were not

sufficiently informed about TB; this was due in part to the historical and current lack of involvement by primary health care providers in TB treatment. As a result, primary health care givers were not on alert for TB disease; often they considered the possibility of TB as a diagnosis only after all other possibilities had been eliminated. Expert informants reported that TB was under-diagnosed and that many TB cases were first identified posthumously during autopsy. One TB expert believed that this problem derived from the centralized health care system of the Soviet Union when general practitioners had limited roles in TB control and TB control was the responsibility of secondary care (the dispensaries).

Primary health care physician participants identified one of the current problems as a lack of clear definition of the distribution of roles and responsibilities between them and the TB cabinet doctors. In addition, their experiences were based on the centralized system and the decentralization had produced many of these difficulties. Before decentralization PHC providers were accustomed to referring their suspected TB patients to the TB specialist from the dispensaries with whom they had familiarity. Currently, the system is set up for TB referrals to the TB cabinets.

According to some TB experts there was a gap in knowledge and experience of TB among PHC providers. In order to resolve this existing gap, NTP was currently providing 3-day TB training sessions for PHC practitioners with the goal of training all PHC providers countrywide within the next few years. Moreover, some TB experts reported that currently there are plans to enlarge the scope of responsibilities for PHC providers in rural communities. Currently PHC providers have responsibilities for TB case findings and referrals; starting in January 2009, PHC providers in FAPs (primary health care posts in villages), village ambulatories and health units will have expanded responsibilities for distribution of TB drugs and for conducting DOT during the continuation phase of treatment. This might provide more DOTS access to patients, where TB cabinets are located long distances from their rural communities.

1.B. Willingness of PHC Physicians to Provide TB Services

… PHC providers are not willing to be more engaged in TB control. Whatever they do, they are obligated to do it unwillingly and we don't have any mechanisms to encourage them.

TB expert 1.B.1.
In-depth interview

I think that our involvement in follow-up activities for better control of TB cases should be more extensive. Current policies do not allow therapists to actively work with the TB patients, though FDs and therapists are the specialists who stay pretty close to the population and know all their health problems and needs. We could become more active and better linked in the chain of TB control than the TB cabinets. Primary health care policies have to give us more responsibilities.
PHC physician 1.B.1.
Focus group

How can family doctors have a patient-load of 500 patients and perform TB patients' follow-up too? It is not realistic.

PHC physician 1.B.2.
Focus group

It [TB follow-up] *is too much of a responsibility for us.*

PHC physician 1.B.3.
Focus group

If Family Doctors were paid appropriately for those [TB] *services, it* [expanding PHC providers' responsibilities in TB control] *would work.*
PHC physician 1.B.1.
Focus group

At the time of the study, almost all PHC providers participating in this study were opposed to expanding their TB responsibilities. This reluctance was in part due to concerns about the increase in workload as well as the possible stigma and fear of TB among physicians.

Only one PHC physician participant thought that since PHC practitioners worked more closely with the general population, they might contribute to better TB outcomes if given more responsibilities for TB control. This same participant also believed that if additional remuneration was provided for TB control to the PHC providers, that they would be willing to accept more responsibilities for TB control.

2. TB Cabinets

2.A. Decentralization

TB cabinets [the decentralization of TB services] *are not something new in the country. TB cabinets were the main institutions for TB control in marzes except Yerevan, Gyumri and Vanadzor since these big cities had TB Dispensaries. Now we have opened TB cabinets in all of Armenia including the three big cities. … The best marz in TB control is Shirak; they've had many achievements since NTP started because the TB coordinator is a very conscientious and responsible person. So they work hard, which leads to huge and sustainable results. TB cabinets are mainly the key institutions for TB control in the marzes but not in Yerevan.*
TB expert 2.A.1.
In-depth interview

One of the problems of TB cabinets in marzes is that they are located in big cities which sometimes are far from the villages. Now imagine how a TB patient from a village can visit TB cabinet everyday. Moreover, for some remote villages buses run to the cities only twice a week. So the TB patient can not physically visit TB cabinet everyday even if she/he wants to.
TB expert 2.A.2.
In-depth interview

TB cabinet implementation is a positive achievement in TB control. The idea is that instead of

going to one TB dispensary, patients will save time and money visiting to their polyclinic for TB care.
TB expert 2.A.3.
In-depth interview

The idea of TB cabinets is to improve the access to TB services. Before the opening of TB cabinets, all patients were getting their drugs from TB dispensaries. Let's assume that there is a patient from Shengavit district and he has to pick up drugs each day from Zeytun where the dispensary is located. It is practically impossible to travel that distance to pick up drugs everyday, so usually the patients pick up drugs from the hospital once in a week. Even if the patients went to the hospital everyday they would infect many people, including the driver of the marshutka [mini van] *and the passengers.*
TB expert 2.A.1.
In-depth interview

It is a good idea to move the services to the patients, but they [authorities] *don't know how to do it.*
TB specialist 2.A.1.
Focus group

I feel that TB specialists don't want to move to TB cabinets since they feel more comfortable in the hospital where they've spent many years. They have all needed diagnostic equipments and laboratory in the dispensary and can easily perform any differential diagnostics.
TB expert 2.A.4.
In-depth interview

Many organizations have tried to do something in this area but were not effective because the main obstacle is that the health infrastructure is not yet ready. We are improving services, equipments etc., but we have to improve the whole system.
TB expert 2.A.5.
In-depth interview

The decentralization of TB services to more effectively reach TB patients is a proven concept in many countries, but the transition is yet complicated and incomplete. In addition, there is resistance to the changes.

One expert indicated that in the beginning of the decentralization process the heads of the polyclinics were against the idea because they would be adopting new responsibilities for TB control. The TB specialists were also resistant to changing their working environment. Moreover, personally they believed that it would be more helpful to work only two days in the polyclinics and to spend the rest of their time in the dispensary, as they did before the decentralization.

2.B. Definition of TB Specialists' Roles in TB Cabinets

> *Patients in the continuation phase of treatment acquire sufficient TB medications from the dispensary for a one month period to take them daily at home. So the patients do not need TB cabinets in the continuation phase of treatment. They* [the TB patients] *do not need us. I do not know why we are in the polyclinic.*
> TB specialist 2.B.1.
> Focus group
>
> *We do not know our functions; we are just running between the dispensary and the polyclinics.*
> TB specialist 2.B.2.
> Focus group

The newly opened TB cabinets need further definition of their role. The study showed that the TB cabinets were not involved in early detection and referral, directly observed treatment in the ambulatory phase of treatment, nor follow-up of the patients.

Even though the medical staff of the cabinets was already appointed, TB specialists did not have a clear perception of their responsibilities and rights, and the coordination between TB cabinet and other TB control institutions such as the dispensaries, the NRL and other TB services was still developing.

2.C. Infrastructure and Equipment of the Cabinets

TB cabinets of N#19 (Malatia/Sebastia) and Arshakunyats (Surb Astvatsamayr Medical Center in Shengavit) Polyclinics [pilot polyclinics implementing DOTS+]

We have too little space for patient care. Very often we have to wait for other doctors to finish with the patients, and then we can meet ours.
TB specialist 2.C.1.
Focus group

TB cabinets excluding the pilot polyclinics

They [meaning specialists from TB cabinets of N# 19 (Malatia/Sebastia) and Arshakunyats (Surb Astvatsamayr Medical Center in Shengavit) Polyclinics] *are lucky. We do not have anything for infection control. We use regular masks, nothing else. We put two masks together, but, you know, it is not effective. What can we do? It is our job. TB cabinet is nonsense in its current format.*
TB specialist 2.C.2.
Focus group

Very often we have to take all the infected stuff to our homes with us at the end of the working day, because in the next morning we have to be in the laboratory or registration room which is out of our cabinet. In my bag, right now, I have a bunch of patient cards. I do not know why it is not regulated, it is impossible to continue working in the same way.
TB specialist 2.C.3.
Focus group
[Question: Do you have a laboratory in polyclinic?]
Yes we do, but it is a laboratory of the whole polyclinic that is located on the same floor as the department of pediatric services and does not have separate place for the sputum intake. I can not ask TB patients to cough for sputum on the backyard of the polyclinic or on the street.
TB specialist 2.C.1.
Focus group

You know TB cabinets cannot work appropriately now because they do not have special infection control mechanisms, separate laboratory, isolated corridor- isolated way of TB patients entrance. If these measurements are not provided then TB cabinet become useless.
TB specialist 2.C.4.
Focus group

TB cabinet doctors complain that cabinets are not fully ready for work. They are not completely prepared to provide TB control service, very often they are allocated in the most unpleasant room of the polyclinic or do not have a place yet.
TB expert 2.C.1.
In-depth interview

This study suggested that rooms of the TB cabinets were established, but the rest of the infrastructure for TB services was deficient. Infection control was inadequate. The space

available in the rooms was limited, averaging 12 m^2. The rooms were not provided with UV lamps. The physicians were not provided TB masks though they already saw patients. TB doctors were using surgical masks. One TB cabinet was located in the children's polyclinic while other services used by this TB cabinet, including registration, GP services and the laboratory, were located in the adults' polyclinic.

The TB cabinets [at the time of the study] did not have storage for drugs and they were not currently supplied with TB drugs. All first line DOTS drugs were maintained in the dispensary. Patients were acquiring medication from the dispensary nurse without any registration in the ambulatory services. TB cabinet doctors were unaware of their patient drug intake and any interruptions in drug use.

Though it was planned that each cabinet should have a TB laboratory, not all the polyclinics had one. Multi-stratified X-ray, an important method for TB diagnosis, was available only in a few polyclinics. As a result the TB cabinet doctors had to send their patients to the dispensary for further testing. Afterwards, the patients were expected to return to the TB cabinet for final diagnosis; if the diagnosis was confirmed as TB, the patient was expected again to return to the dispensary for in-patient treatment. This system was not functioning well and informants, both physicians and patients, hoped that improvements could be made.

2.D. Compliance of TB Cabinets to TB Treatment

TB cabinets of the pilot polyclinics

During the last two years in the MSF project I took all my drugs under strict direct control of the medical staff. Nothing matters, including holidays and even hours of medication; intake can not be changed. If on any occasion, I could not go to the polyclinic on a particular day, a nurse alone or a nurse and a physician visited me at home, bringing the pills and supervising the drug intake.
MDR-TB patient 2.D.1.
In-depth interview

All patients [covered by the DOTS+ pilot program] *go to the polyclinic daily and take drugs from the nurse, drinking them under the direct observation of a medical professional.*
TB specialist 2.D.1.
Focus group

During the intensive phase as well as the continuation phase of treatment in MSF, everything was under the strict control and supervision of the medical staff. During the last two years [of treatment in the pilot project] *I have been taking the drugs everyday except Sunday. It does not matter even with holidays; the days and even the hours of taking medication could not be changed. If somebody or me for any reason could not come to the polyclinic at that day, a nurse alone or with the doctor would come to the patient's home to provide him with pills and supervise intake.*
MDR-TB patient 2.D.2.
In-depth interview

Even before treatment commences, some patients refuse to start DR-TB treatment. In some cases patients interrupt treatment because of the side effects of the second line drugs. A nurse, a social worker and a psychologist work with each patient individually and try to encourage continuing treatment.
Auxiliary TB professional 2.D.1.
Focus group

Sometimes the reason for rejecting treatment is that the patient is the wage earner of the family and doesn't want to loose his/her job. MSF provide social support for DR-TB patients with food and money for transportation for each visit to the TB cabinet. We have social support not only for patients but also for family members.
Auxiliary TB professional 2.D.1.
Focus group

TB cabinets excluding the pilot polyclinics

I was provided 3-months of treatment in the Abovian dispensary and then 1-month of treatment at home, out of an anticipated 6 months [of treatment]*; so I skipped 5 months of treatment at home since I already felt good.*
MDR-TB patient 2.D.1.
In-depth interview

Let's assume that the TB patient is from Shengavit [a district in Yerevan] *and he has to take drugs from the city dispensary in Zeytun* [a district in Yerevan]. *It is basically impossible to travel that distance everyday to take drugs; so, usually patients take drugs once a week. Even by going to the hospital that often, patients infect many people-- including the drivers and the passengers of the marshutkas. For example, the last stop of marshutka number XX is the city dispensary and I know couple of cases when the drivers of that marshutka were infected with TB.*
TB expert 2.D.1.
In-depth interview

I took pills every 10 days from the polyclinic, but after a while I felt better and stopped intake of that medication on my own. After that I remained well for a year, following which I had a recurrence [of TB] *again. I then went to the Hoktemberyan hospital, then the dispensary, starting the whole process again--repeated again for another two months.* [After this reoccurrence this patient had three additional reoccurrences of TB]
MDR-TB patient 2.D.2.
In-depth interview

[This patient had experienced four failed treatments during the continuation phase of treatment in TB services not associated with the DOTS+ treatment].
I think that I am personally guilty for my DR-TB situation since I didn't take my drugs appropriately and always abused alcohol and everything else. I should be more cautious and take care of myself. Though, I think that if they applied DOTS in the continuation phase of treatment like the MSF project does, I wouldn't have developed DR-TB. Patients do not realize the consequences of non-compliance, so they [the health care providers] *have to observe them*

[the patients] *taking the drugs not only in the dispensary but also in the polyclinics. Observation of drug intake during the polyclinic phase of treatment is the main reason why MSF treatment was effective for me. My suggestion to improve TB control is to introduce strong regimen of directly observed therapy for TB as well as to adequately explain to patients about the future consequences of non-compliance and to make them fear TB.*

MDR-TB patient 2.D.3.
In-depth interview

For the last two years in the MSF pilot districts of Shengavit and Malatia, the project provided rigorous DOTS+ treatment for DR-TB patients. Currently no place else in the country has these services nor the capacity to conduct DOTS+. This program is based in the DR-TB department in the Abovian TB dispensary, providing approximately 6 month in-patient treatment, and in the two TB cabinets at the polyclinics in Shengavit and Malatia which provide the ambulatory phase of treatment of around 18 months duration. The primary complaint by DR-TB patient informants was related to the strong side effects of 2nd line drugs; because of these side effects, sometimes these patients resisted taking the doses even under heavy persuasion by the DOTS+ medical staff and the support of the auxiliary professionals. Another concern noted by a study participant was the inadequate space in the TB cabinets for the patient-load carried by the project.

During this time of transition, in the rest of the civilian sector DOTS was not completely implemented, though the intent was to improve the situation by the decentralizing of TB services. By Ministerial decree, to improve access to TB services and DOTS during the ambulatory phase of treatment, TB control system was decentralized by opening TB cabinets countrywide as of June 1 of 2008 and shifting some TB specialists from dispensaries to TB cabinets. Such a network of cabinets was intended to perform early detection and referral, directly observed treatment in ambulatory phase of treatment and follow-up of the patients, thus controlling treatment interruption and the spread of the disease.

2.E. Recruitment and Retention of TB Specialists in TB Cabinets

Very often I face the problem of the flow of TB specialists to other fields, especially to family medicine. Frequently we train a TB doctor for a certain TB cabinet and during our next visit we see that the doctor left his/her position and changed the specialty. The problem is that the TB doctor's salary is lower than that of the FD.
TB expert 2.E.1.
In-depth interview

We have a shortage of TB specialists in Armenia. Doctors are not willing to become TB specialists. Our government has to think about improvements of the payment system for the TB specialists.
TB specialist 2.E.1.
Focus group

We [TB specialists] *receive only a 50% bonus, while infectious disease physicians receive a 100% bonus. I think this discrimination is unfair because TB is also a dangerous infectious*

disease. Also, we only have 30 days of vacation time, while they [infectious disease physicians] *have 48 days.*
TB specialist 2.E.2.
Focus group

Very often it is said that TB doctors are "starving doctors of starving patients". For this reason, sometimes TB doctors agree to treat the patient at the patient's home for financial reasons.
TB specialist 2.E.3.
Focus group

Now we do not have such specialist [highly qualified TB specialists] *because they are not paid enough. Moreover, you know the work with TB patients is not attractive, thus we do not have new qualified professionals.*
PHC physician 2.E.1.
Focus group

Medical staffs at the TB cabinet level in the marzes reportedly were paid lower salaries which lead to staff leaving TB services to better-paid medical fields.

Experts also mentioned that the head of the marzpetaran health department in each marz were assigned as the TB coordinators. According to the study, the rationale for appointing TB coordinators by the NTP was to provide them with adequate authority; these coordinators could introduce TB control in their marzes. According to one TB expert, the marz with the best TB control was Shirak. The success of the marz was attributed to the conscientious responsible commitment of the TB coordinator; no incentive mechanisms were introduced to motivate this TB coordinator.

However, the retention and recruitment of TB specialists to maintain sufficient numbers of qualified personnel to run adequate TB services nationwide was identified as a problem by many study participants. Salaries, vacation time and the lack of other incentives were identified as central problems for attracting and maintaining health professionals into the field. The stigma of TB and fear of contracting this disease among health care providers might also be a contributing factor to the difficulties in recruitment for this field.

3. TB Dispensaries

3.A. Conditions of the TB Dispensaries

Sanitary Conditions
It is better for them to take more care of their dispensary [than to sanitize the patient's apartment – this patient was very angry when speaking]. *The sanitary conditions of that institution are awful. I wouldn't be surprised if besides tuberculosis I also got cholera and HIV/AIDS from there* [the dispensary]. *I could not sleep for 2.5 months because of cockroaches in the dispensary and nobody cares about that. I asked my family to bring poison to get rid of cockroaches.*
MDR-TB patient 3.A.1.In-depth interview

Each weekend I had to go home [from the dispensary] *to take a shower: could we stay there for months without taking a bath?*
MDR-TB patient 3.A.2.
In-depth interview

Infectivity Risk
When I was in the Abovian dispensary for the first time there were four patients in our ward. Three of us were smear negative but one patient was smear positive. My sister was living with us in the same room since I was seventeen and I was feeling uncomfortable staying there alone. She did not have TB but she was sleeping with me in the same bed. My doctor knew about that [the sister staying with the patient] *and allowed her to stay with me. But during the doctors' morning visits she left the room in order not to be noticed by other doctors.*
MDR-TB patient 3.A.3.
In-depth interview

Doctors are not protected…I do not have enough masks; the NTP gave me a few [masks]. *How can I protect myself against TB? It is necessary that the higher authorities find a solution to this problem.*
TB specialist 3.A.1.
Focus group

One of the major problems in TB care in dispensaries according to the majority of TB experts and patients is inadequate infection control. The SS+ patients and DR-TB patients were often not isolated from others in the dispensaries. There were SS+ patients staying in the same ward with SS- patients. According to the study participants, there were no bathrooms in the dispensary and the shared toilets were in very bad conditions. Overall, the dispensaries were reportedly in very poor sanitary hygienic conditions. Patients, including SS+ patients, reportedly left the hospital in the weekends to go home for their basic needs. Very often family members visited the patients without using any infection control methods, including masks. The visitors were not informed by the dispensary about TB protection. Doctors were reportedly also not sufficiently supplied with masks and other means of infection prevention.

A TB professional noted there were many "chronic cases" of TB who periodically were "cured" in the RTBD and returned to the dispensary again for more treatments. Repeat treatments for these cases had reportedly sometimes lasted for ten years or more.

3.B. Quality of DOTS in the Dispensaries

DR-TB department within Republican TB Dispensary [supported by MSF]
Doctors [TB specialists of DR-TB department] *always watch how I take medication and if for some reason I can not take pills on a particular day, they always make marks in the journal. Before this treatment I had a temperature for 8 months and constantly perspired, but now I feel much better and even gained 4 kilos.*
MDR-TB patient 3.B.1.
In-depth interview

TB dispensaries in Armenia excluding the DR-TB department [supported by MSF]
When I was in Abovian Dispensary medication intake was not under the doctor's direct supervision at all. Nobody cares whether you take drugs or not. ... With the new recurrence I was admitted to the Zeytun dispensary and received treatment for 2 months. Whether I took my pills totally depended on me; they didn't observe it.
MDR-TB patient 3.B.2.
In-depth interview

I judge it [the quality of care in dispensaries] *very poor. It would be better not to have any dispensaries at all in Armenia than to have the services that they provide.*
TB expert 3.B.1.
In-depth interview

They [the TB specialists from the TB dispensary] *treated me with streptomycin injections and red-colored pills. Medication intake was not under the doctor's supervision and sometimes I could bring it with me to the ward to take later. They also allow us to go home for about one week each month and gave us the medication for that period. I took all medication accurately.*
MDR-TB patient 3.B.1.
In-depth interview

I was taking my drugs from med personnel everyday and was drinking the drugs in my ward by myself without any observation.
MDR-TB patient 3.B.3.
In-depth interview

A common problem identified by the majority of the TB experts was the provision of inadequate DOTS in the intensive phase of treatment at the dispensary. According to the participants the majority of medical specialists distribute drugs to the patients which later they take at the wards without direct observation. No systematic system is in place to control drug intake of the patients; some TB specialists reportedly supervised and observed drug intake, while the majority reportedly did not. However, most patients were believed to take the drugs as prescribed while at the dispensary since they present symptoms during much of the intensive phase of treatment and willingly abide by directions to recover.

3.C. Inappropriate use of Second Line Drugs in Dispensaries

I asked one pharmacist whom I have known for a long time, to pay attention to the consumers who buy 2nd line drugs and we've discovered a couple of cases when a patient with a regular TB diagnosis presented a prescription for 2nd line drugs.
TB expert 3.C.1.
In-depth interview
I purchased some drugs from the pharmacy during my first treatment at the Abovian dispensary. The doctor told me that the dispensary is short on good drugs because the drugs are expensive and recommended that I buy them [2nd line TB drugs] *from a certain pharmacy.*
MDR-TB patient 3.C.1. In-depth interview

There were some TB specialists who reportedly used their own individual schemes for treatment. These TB specialists begin treatment of regular TB with second line drugs, especially if the patient was able to pay for these more expensive drugs; reportedly, the patient sometimes provided an additional payment to the physician for this special attention [TB treatment is officially provided at no cost to the patient]. Second line TB drugs often reportedly showed rapid recovery. This practice could promote DR-TB making patients feel improvements more rapidly and therefore discontinue drug intake too early, especially because patients would feel improvements.

4. Laboratories

4.A. Decentralization of Laboratory Services

The NTP has decided to open a peripheral laboratory in each of the polyclinics with a TB cabinet. But I don't agree with this decision. First to keep so many laboratories and finance them is an ineffective distribution of resources. It is also hard to supervise and conduct external quality assessments for each peripheral laboratory. Second, the quality may be affected. Lab network decentralization is not the right approach. The right approach is to have a centralized system of TB laboratories in order to keep the quality high. Maybe decentralization of TB specialists is optimal but not for labs. If a lab technician looks at only 1 to 2 samples a week instead of 25 to 26, the ability of the eye to recognize the bacterium is diminished. I suggest collecting samples from different TB cabinets in the polyclinics, keeping the samples in special refrigerators and sending them to one integrated microscopic laboratory. If it is difficult to take a sample in a cabinet, there is also another option: sending the patient who needs the SS test to the microscopic laboratory. Finally having a TB lab in each polyclinic may be an extra source of TB infection. It is difficult to control san-epidemic regimens [infection control] *in those labs to assure the safety of the working staff and the patients.*
TB expert 4.A.1.
In-depth interview

Our TB cabinet does not function appropriately because there is no isolated space to collect smear sputum.
TB specialist 4.A.1.
Focus group

We refer our patients to the TB dispensary with their records to have a SS test and then call them [TB patients] *back to the polyclinic for the analysis.*
TB specialist 4.A.2.
Focus group

Sputum analysis is performed only in the MSF [N# 19 (Malatia/Sebastia) and Arshakunyats (Surb Astvatsamayr Medical Center)] *Polyclinics. The rest of the polyclinics do not have the equipment to perform such services.*
TB specialist 4.A.3.
Focus group

The primary problem reported by study informants was the absence of any general systematic mechanisms for the transportation of samples from the general lab network to the NRL and for reporting results back. There was a direct link between the NRL and the City TB dispensary in Yerevan and the TB cabinets of the N# 19 (Malatia/Sebastia) and Arshakunyats (Surb Astvatsamayr Medical Center Shengavit) Polyclinics. According to the study participants, the coordination between the NRL and other laboratories was performed either by telephone or by personal contact.

A TB expert mentioned that the NRL was responsible for supervision and quality assessment of all laboratories in Armenia three times a year; however a new MOH decision had assigned the supervision and quality assessment of peripheral laboratories located in Yerevan to the laboratory of City TB dispensary in Yerevan which in turn would be supervised and assessed by the NRL.

4.B. Management of the National Reference Laboratory

I think that NRL should be independent, not under the supervision of a manager who works by the "more patients is better for us" principle. It should be national as its name indicates and under the supervision of the NTP or the MOH.
TB expert 4.B.1.
In-depth interview

The quality of the NRL [lab testing] *is very good. The only problem is that it is overloaded. It should be independent and work with clear standards. The regional laboratories need to improve managerial and organizational aspects of their work there.*
TB expert 4.B.2.
In-depth interview

Some TB experts believed that the NRL should be administratively independent from the National TB dispensary, which they believed would lead to more coordination with all TB services and improve timeliness to these services.

The plan for decentralization of TB control was designed to provide each TB cabinet with laboratory services. The laboratory exports discouraged this idea; they believed that it would be an inefficient use of resources, it would increase the risk of infection for the polyclinics and the quality of microscopy may also suffer. They suggested collecting the samples in the TB cabinets, then sending them to one integrated microscopic laboratory to perform the SS test there.

4.C. Retention of laboratory personnel

The salary of [TB] *lab personnel is very low. We train people and prepare them for work, then they move to another job, for example, in the clinic-diagnostic laboratories which are much safer and are not free of charge like the TB lab services. Usually we loose our professionals and get those who were not very brilliant and were fired from their previous jobs. The quality of work is*

very much affected by these factors.
TB expert 4.C.1.
In-depth interview

As indicated by many study participants for other TB professionals and lab personnel, salaries and benefits were less for TB laboratory professionals, impacting recruitment and retention.

4.D. Coordination and Communications between Laboratory and other TB Services

The samples from the MSF [N# 19 (Malatia/Sebastia) and Arshakunyats (Surb Astvatsamayr Medical Center)] *polyclinics and the City dispensary reach the National Reference Laboratory on time. There are some problems related to the sample transportation from the marz TB laboratories to the National Reference Laboratory. There is no linkage between the marzes and the NRL.*
TB expert 4.D.1.
In-depth interview

The linkage between the NRL and other labs for communicating test results is mainly by telephone. ... There is also another "Armenian way" to do it: results are given to an intermediate person who knows both sides [the NRL and the TB lab].
TB expert 4.D.1.
In-depth interview

The problem was reported to be especially significant in the marzes. Though each marz was reportedly given a special car primarily for transportation of the samples and transferring the results, the cars were reportedly not used for this purpose.

5. State Hygienic and Anti-epidemic Inspectorate (SHAI)

5.A. SHAI Activities, Including Household Sanitation for the Control of TB and its Social Consequences

A draft on new anti-epidemic rules including TB control, TB case management and isolation is in the process of development. As soon as it is revised and approved it will be used as a special official document and legal act that should be used in practice.

TB expert 5.A.1.
In-depth interview

They [SHAI] *use very ancient methods for infection prevention in the households. And after their disinfection, the home is totally a mess.*
TB specialist 5.A.1.
Focus group

Sometimes the family pays them [the SHAI house disinfection staff] *an informal fee not to*

disinfect their house.
TB expert 5.A.2.
In-depth interview

When I was in the dispensary for treatment, people from the san-epidemic station came by car and disinfected my home using their equipment: it was the same as advertising to my neighborhood that I had TB. They made a mess in my home and it was terrible.
MDR-TB patient 5.A.1.
In-depth interview

Many experts from different levels of TB control stressed that the main problem of SHAI was the lack of modern approaches for TB control; some of the SHAI practices were coming from the Soviet times (e.g., household disinfection). It was reported that under the guidance of the NTP, SHAI was working on new TB guidelines based on the WHO recommended standards.
The study discovered broad concerns from health care providers, TB experts and especially TB patients about the disinfection of TB patient's homes conducted by SHAI.[10]

The patients stressed that conducting disinfection in their apartments and homes was a violation of patient's rights and confidentiality: after such disinfection activity the neighbors of a TB patient would learn about the diagnosis. The stigma of TB reportedly had serious social consequences on some TB patients and their families.

6. National Management of TB

6.A. Strengthening the National Management of TB Control and Prevention

I want to emphasize that there is a need for strict and continues control of the TB control process; we need state assistance in this process and very strict control of the President [of Armenia]*, like in Georgia. The first lady of Georgia is a nurse and she is supervising the TB control process in their country; that is why they have achieved success in TB control.*
TB expert 6.A.1.
In-depth interview

I am definitely for obligatory treatment in the country, which could be called necessary instead of obligatory. It sounds good for patients because some patients don't understand that the TB treatment is necessary. I think that the benefit to the population is higher than freedom of just one infected person freely walking in the city, being in the same marshutka [mini van] *with you, me and our children and infecting us. In Riga they have an obligatory hospital with high fences for TB treatment in the forest. It would be nice to use their experience and have something like that in Armenia.*
TB expert 6.A.2.
In-depth interview

[10] This method is inherited from Soviet times and includes chemical disinfection of buildings, homes and apartments of TB patients. The method is not recommended by the WHO because it is considered ineffective.

Mandatory treatment is effective but very difficult to implement. We have to have certain mechanisms in place for it to work.
TB specialist 6.A.1.
Focus group

Population awareness about TB is very poor in Armenia; public education campaigns are not appropriately organized. There was only a very short one minute videotape on TV on March 24 (the International Day of TB Control) and that's it.
TB expert 6.A.3.
In-depth interview

It was a good idea for patients to receive incentives such as social and food parcels to enforce utilization of TB services during the continuation phase of treatment.
TB specialist 6.A.2.
Focus group

TB patients are people with low socioeconomic status, so even transportation costs may be critical for them.
PHC physician 6.A.1.
Focus group

For the national management of TB, many recommendations were made by the study participants. Most of the TB experts agreed that there was a lack of attention to the management of TB by the government of Armenia. They saw a need to increase the advocacy for the TB control and involvement of government authorities to find solutions to this problem. Some study participants advocated for more compulsory treatment, others suggested using incentives for completing the treatment, and some recommended educating the population through public campaigns (addressing TB risk, control, treatment, reducing stigma, and drug-resistant TB).

The majority of the experts indicated that there should be closer collaboration between stakeholders in TB control including both national and international organizations. Some indicated that the system lacked integration and transparency. Some indicated that it was sometimes difficult to get epidemiological data on TB in Armenia. The experts also highlighted the need to improve human resources in all levels of TB control. Another recommendation by participants was to develop an integrated curriculum based on the DOTS strategy for the National Institute of Health and the Yerevan State Medical University.

6.B. The Stigma and Fear of Tuberculosis in Armenia

Health Professional

Everybody is afraid of it [TB], *even doctors. When we invite other specialists for consultation of possible diseases in our TB patients, they open the door of the TB cabinet using their foot. Sometimes doctors express their disappointment when it turns out that the patient has TB instead of cancer, though TB is curable while cancer is more difficult to treat if not impossible.*
TB expert 6.B.1.
In-depth interview

General Population

Once we had a family with TB. They were using polyclinic TB services. Very soon community got aware of it and changed their attitude. So this family had to change the place of their residence in order to avoid stigma.
Auxiliary TB professional 6.B.1.
Focus group

When I was back from the dispensary none of my neighbors wanted to talk with me because of my diagnosis. Everyone avoided me.
MDR-TB patient 6.B.1.
In-depth interview

The stigma of TB was identified as a problem by the majority of the study informants. Many TB patients faced social problems because of their diagnosis; sometime they even had to sell their homes and move because of the neighbors' negative attitudes towards the patients and their families. This stigma even reportedly deterred persons with TB to seek care, especially in TB cabinets. There was a reported fear of being fired from job or not being hired because of current or former diagnosis of TB. This stigma and fear of TB was reported to be a significant issue not only among the general population, but medical professionals as well.

7. Human Resource Development

TB specialists are always considered [for residency] *under the State order* [provided free of charge] *and on average we have two vacancies in TB clinical residency annually… I can say that TB clinical residency traditionally has State ordered vacancies.*
TB expert 7.1
In-depth interview

TB specialists are very needed in Armenian health care; however it is a pity that young and enthusiastic resources are not wanted in the dispensary. Those who want to do something new and creative in their work are rejected.
TB specialist 7.1 In-depth interview

The curriculum of Yerevan State Medical University TB residency is based on the DOTS strategy and international requirements. It is not unified; National Institute of Health has its own curriculum. However it is also based on DOTS requirements, and it is legally accepted

strategy which should be spread countrywide for all residents… I can say that it would be very effective to enlarge the TB module in the curriculum of Family Medicine and have more topics in TB in order to understand the differential diagnosis of this disease very well and thus increase the early detection of TB.
TB expert 7.1
In-depth interview

I can say the clinical preparation was suffering. During my TB residency I had theoretical training myself [self taught from books]*; we did not have structured classes for theory. I did not have my personal patients. I was doing the paper work and following the patients' treatment, but I did not prescribe treatment myself…*
TB specialist 7.1
In-depth interview

According to one of the participants medical students were afraid of getting infected with TB, other students were not very much interested in the field and many of them disliked working with patients who did not show rapid resolution of the disease as a result of treatment. There were also students who applied to TB residency because it was covered by the state [free of charge]. Another participant claimed that TB specialists working in the field for many years were not very open to hiring new, young, enthusiastic specialists.

A participant mentioned that the curriculum of the TB clinical residency at YSMU and NIH was not unified; however both of them were based on the DOTS strategy. This participant thought that the YSMU curriculum was well developed and based on the international standards and requirements. Another participant believed that the theoretical part of the training could be improved and suggested that there was a shortage of practical training in clinical skills.

8. TB Drug Regulation in Armenia and DR-TB

You know in Armenia people can get medication [for TB] *on the advice of their neighbors, relatives and family members. When a person has tuberculosis they may advise him/her to purchase drugs from the pharmacies where they are available. There were many attempts by the government of Armenia to establish a law prohibiting sale of 1st line TB drugs in pharmacies but unfortunately they didn't succeed.*
TB expert 8.1.
In-depth interview
T*he sale of first line drugs should be prohibited by law; likewise there should be strict control on* [writing] *prescriptions for second line drugs.*
TB expert 8.2.
In-depth interview

Reportedly, Armenia was supplied with 1st line TB drugs to meet TB treatment needs until 2011 through funding by GTZ's KfW and annually 30 000 to 40 000 drug doses were used in the country. The NTP provided/distributed the first line anti-TB drugs to TB control institutions.

According to the study participants, the retail sector, particularly pharmacies, did not import 1st line drug combination capsules to be used for TB treatment only; however, the 1st line drugs in individual capsules were widely available in pharmacies.

Reportedly, 2nd line drugs were also prescribed for conditions and diseases other than TB and were available in pharmacies. The experts recommended that the utilization of 2nd line drugs by other specialists must be strictly regulated.

According to the majority of experts in the study, DR-TB was an emerging problem in Armenia and urgent steps should be taken to control the situation. The spread of DR-TB was increasing through the misuse and mismanagement of treatment and person-to-person transmission of these TB strains. The experts mentioned about contributing factors for the current DR-TB situation: a) after the collapse of the Soviet Union in 1990s, 1st line drugs were not available in the country and practitioners had to prescribe individualized treatment schemes; b) laws controlling drug management were inadequate; and c) 1st line drugs were available in pharmacies and the patients could get them without prescription of a specialist.

Several TB experts suggested that inadequate or incomplete implementation of DOTS during both the intensive and continuation phases of treatment at dispensary or TB cabinet levels could be a major contributor to the increase in DR-TB rates. Moreover, inadequate infection control in the dispensaries could increases the likelihood of transmission of DR-TB to non DR-TB patients, staff and visitors in the hospitals.

The TB health providers also reported that only smear positive cases were further investigated using DST and culture; however not all smear positive samples were sent to the NRL. Therefore, they suggested that DR-TB was under-diagnosed in Armenia. Even if the patient was diagnosed with DR-TB, there were no official treatment protocols provided by the NTP. Thus, these patients were potential sources for spread of drug resistant TB. To deal with this problem, NTP was planning to initiate DOTS+ on a national level with support from the Global Fund. However, many experts indicated concerns that DOTS+ might not be rigorously conducted resulting in more serious drug resistance.

Some experts indicated that some physicians in the dispensary tried to treat DR-TB patients by individualized schemes, though the effectiveness of those treatments was questionable.

9. HIV/AIDS-TB Co-infection

Blood testing for HIV detection [for TB patients] *could not be mandatory, because it is a right of the patient* [to refuse or comply].
TB expert 9.1.
In-depth interview

In the TB Republican hospital, HIV testing of TB patients is performed under the title of "general biochemical analysis" because some TB patients [if they were informed about the HIV test] *may refuse to have HIV testing*.
TB expert 9.2. In-depth interview

On one hand, we have to maintain confidentiality for HIV-TB co-infected patients, but on the other hand we must think about the spouse who may get infected.
TB expert 9.3.
In-depth interview

According to some experts, HIV/TB co-infection was currently not a large problem in Armenia. A few experts raised the problem of confidentiality and voluntary testing for HIV among TB patients. Reportedly, HIV testing in the dispensary was performed without the patients' consent. There was no consensus regarding this issue among the participants, attempting to balance the patient's right against the right of the general population to be protected. Some participants suggested providing counseling and information to the TB patients about the importance of the HIV testing, with further education and support for HIV/TB co-infected persons to prevent the spread of these diseases.

An expert mentioned that the management of co-infection was performed by the NTP and the National AIDS Prevention Center. The strategy to detect co-infection was reportedly as follows: all TB patients in dispensaries would be tested for HIV/AIDS and all people with HIV/AIDS would be tested for TB (tuberculin test twice a year, X-Ray and triple sputum microscopy once a year). The co-infected patients would get their TB treatment at the TB dispensaries and as soon as they were SS- they would start HIV/AIDS treatment at the AIDS Prevention Center.

Penitentiary Sector

1. DOTS in the Penitentiary Sector

DOTS in Prisons
I take it [the medication] *in this procedure room under the direct supervision of the doctor every day without any interruptions. I can not leave the room without taking all the medication. I even turn the cap down, so the doctor can see that no drug is left. I understand that taking medication is important; I am not the enemy of myself.*
TB Patient 1.A.1. In-depth interview
Every morning I come to the procedure room with a cup of water and take my daily drugs in front of the nurse.
TB Patient 1.A.2.
In-depth interview

DOTS in transition between civilian and penitentiary systems
In my continues phase of treatment in the civil sector the court decision was made and I was imprisoned and taken to the isolator (Nubarashen Criminal Executive Institute)…doctor could not contact the city dispensary [to learn patient's TB treatment history] *… doctor listened my lungs and breathing, took smear testing (which was negative). I was in the isolator for ten days where I was taking both pills and intravenous injections for TB treatment then was referred to the Central Hospital of Detainees, where I was diagnosed again with smear negative TB and received ambulatory phase of treatment.*
TB Patient 1.A.3. In-depth interview

I don't think that the coordination between civilian sector and prison is very critical since we have only 3 to 4 cases of TB prisoners who are released annually. As soon as TB cabinets start to function as planned, the coordination will be performed properly. However, we still may have problems with the addresses of former prisoners, since usually they give wrong addresses and it is impossible to find them after release.
TB expert 1.A.1.
In-depth interview

When a detainee is released with TB, a special TB 09 referral form is used to refer him/her to the TB cabinet in the civilian sector. It consists of three parts- the first part is filled out by his doctor in the prison dispensary, where it is noted about the patient's treatment he received in penitentiary system; the second and the third sections remain unfilled, and this form is mailed to the prisoner's regional TB cabinet. When the doctor of the TB cabinet receives this form, she/he cuts off the third part and sends it back [to the penitentiary system]. *The physician of the TB cabinet must write all the information about the patient's treatment in the civilian sector in the second part of the TB 09, and if that patient suddenly is put in the prison again, this second part of the form should be sent back to the penitentiary sector to inform the prison physician about the treatment process of the patient in the civilian sector. The penitentiary sector has not received any second or third parts of the TB 09 from the civilian sector so far.*

Now let's discuss the problem with the mail delivery process. We have to send this form by mail; however, very often we use our private contacts to see whether the letter is received by the recipient or not. There was only one case that I gave this form to my patient who was released; I had confidence in him and he delivered this form appropriately to his regional doctor.

TB specialist 1.A.1.
Focus group

According to the majority of TB experts (both from the civilian as well as penitentiary sectors), regular TB was not a problem in the prisons since ICRC had implemented an effective strategy for TB early detection, referral and DOTS treatment in the penitentiary system. A concern was expressed that the situation might worsen as ICRC stopped its involvement in TB control in prisons.

All TB experts working in the penitentiary sector agreed that immediately after entering a criminal processing unit all prisoners were screened for TB (fluorography, triple smear sputum analysis and a special TB detecting questionnaire). In the marzes, only a questionnaire was used as a screening tool. They also confirmed about active case finding among all prisoners countrywide twice a year using portable digital fluorography machines. If a person entered a prison with a TB diagnosis, the civilian sector physician of that patient was contacted to decide how to manage that patient.

As soon as the TB diagnosis was made, the treatment of TB prisoners was organized in the Numbarashen CEI before the final court verdict and in the Central Hospital for Detainees after the verdict of being guilty. According to the TB experts, unlike the civilian sector, DOTS was strictly performed in the prisons. Both the intensive and the continuation phases of the treatment

were performed within the health care facility (the Nubarashen CEI and/or the Central Hospital for Detainees).

A few experts noted that when a person on TB medication was arrested and sent to a cell for preliminary imprisonment, it was practically impossible to continue treatment until he/she was transferred to a CEI.

The primary problem in collaboration between penitentiary and civilian sectors in TB control, stressed by almost all the experts (from civilian and penitentiary sectors), was the lack of systematic coordination between the two sectors. Informants felt that civilian-penitentiary and penitentiary-civilian sector transfers of TB-patients could be strengthened and streamlined. One of the experts indicated that it would not be difficult to improve this coordination since only a few TB patients move from one system to the other annually.

2. TB Infection Control the Penitentiary Sector

There are infection control mechanisms in the prison, including separated departments for smear negative, smear positive and MDR cases, the smear positive and MDR department's entrance is different and the patients' walking areas are also separated. There are even separate phones in each department. Doctors have masks; there are bactericide lamps and a good ventilation system in the rooms. Visitors also wear masks during short visits.
TB expert 2.1.
In-depth interview

One of the problems in TB control in prisons is infection control.
TB expert 2.2.
In-depth interview
I can see other smear negative TB prisoners in the corridors [this patient is also SS-]. *Smear positive cases are located separately and their doors are always closed, including small gates at the doors, and we can't contact each other- unlike the Abovian dispensary. There* [the Abovian dispensary] *everybody lives in the same building without any separation and smear negative patients can easily meet and talk to smear positive cases and to those with what we call "crocodile" infections* [patients with DR-TB].
TB Patient 2.1.
In-depth interview

We [patients with TB] *cannot communicate with the other patients of different departments, or with smear positive or MDR TB patients. They are in the separate departments with the different entrances.*
TB Patient 2.2.
In-depth interview

My family members visit me sometimes, we meet in the room for visitors, and they do not wear any preventive masks since I am smear negative now.
TB Patient 2.2. In-depth interview

TB patients mentioned that compared to the colder humid less-sanitary prisons, the conditions at the Central Hospital for Detainees was much better, and according to the experts, there were cases when prisoners tried to buy positive smears from TB prisoners to self-infect to develop TB and be transferred to the Central Hospital for Detainees.

3. Other Issues in the Penitentiary Sector

One of the concerns of the TB medical staff working in the penitentiary sector was low compensation and lack of benefits (shorter working day and vacation) leading to shortage in TB staff in the prisons; the civilian sector medical providers expressed the same concerns.

Another concern raised by the experts of TB control in the penitentiary system was DR-TB. Although the system had control over regular TB, DR-TB was a significant problem in the prisons. The TB experts indicated that all identified DR-TB cases were separated into a special department in the Central Hospital for Detainees and received only symptomatic treatment until their release. There was an agreement between the MSF and the MOJ to start DOTS+ in the penitentiary system. However, the experts were concerned that because of shortage of mid-level medical personnel (2 nurses) the start of the project would get delayed. Fortunately, the project started in September 2008.

CONCLUSIONS

This study performed a qualitative analysis of the TB control services in the civilian and penitentiary sectors and evaluated the cooperation between the civilian and penitentiary sectors and different stakeholders in TB control in Armenia. Summarizing the findings of the study about all the strengths and limitations of the TB control system in Armenia the following conclusions were made.

Strengths of the TB Control System in Armenia

- The National TB Program in Armenia provides a national infrastructure for TB control.
- Decentralization of TB services and integration of these services with primary health care by establishing TB cabinets in the polyclinics brings TB services closer to the TB patients' residence.
- The NTP TB training program for primary health care providers strengthens knowledge and awareness of TB for those professionals.
- Collaborative TB control efforts in some areas between the government and international organizations (especially ICRC and MSF) integrated national with international experiences for successful TB control programs.
- Successful implementation of the DOTS+ pilot project in two districts of Yerevan and the in-patient MDR department in the Republican TB Dispensary with the lead partnership of MSF.
- Successful implementation of DOTS and infectious control systems for TB control in the penitentiary system with the partnership of ICRC.
- Inclusion of TB services and medication in the Basic Benefit Package (no cost to the patient).
- Assurance of a TB first line drug supply to meet the needs for TB treatment nationwide.

Limitations of the TB Control System in Armenia

- Inadequate TB knowledge and awareness of PHC providers leading to late detection of TB and stigma towards TB among general practitioners and family doctors.
- Lack of remuneration or incentives for PHC providers to participate in TB control, reducing the effectiveness of early detection, referrals and participation in DOTS.
- Unclear perception of the division of roles and responsibilities between PHC providers and TB specialists in TB cabinets, leading to incomplete TB control activities.

- A shortage of space, supplies, and utilities in the TB cabinets, hindering the effectiveness of TB cabinets.

- Lower salaries and lack of incentives for TB specialists and TB laboratory workers reduce recruitment and retention, producing shortage of qualified staff and lower qualifications of existing staff.

- Poor sanitary and physical conditions in TB dispensaries and cabinets (excepting DR-TB MSF pilot sites).

- Inadequate directly observed therapy (DOT) implementation during intensive and continuation phases of TB treatment.

- Interruptions in the use of incentive and social support mechanisms for TB patients for the implementation of DOTS, especially in remote areas.

- The absence of available treatment for DR-TB patients (excepting DR-TB MSF pilot sites).

- Inadequate infection controls in TB cabinets and TB dispensaries in the civilian sector (excepting DR-TB MSF pilot sites).

- Inappropriate DOTS implementation: unregulated inappropriate use of second line TB drugs for the regular TB treatment in some dispensaries, leading to increased likelihood of serious DR-TB in Armenia.

- Lack of efficient systematic mechanisms for laboratory samples transportation and reporting of results.

- Over decentralization of level I microscopy laboratories leading to inefficient use of resources and potentially questionable quality of sputum smear microscopy (because of insufficient number of samples).

- Difficulties in cooperation between the laboratory network and some TB services negatively impacting timeliness in diagnostic results for TB.

- Poor infection control mechanisms inherited from the Soviet times, including household sanitation which is both ineffective and has serious ethical consequences.

- The systematic contact investigation mechanism developed by NTP central office has not been fully implemented.

- No national mechanism has been established for regular close cooperation between different TB control stakeholders in Armenia.

- Lack of knowledge about TB among the general population, leading to late detection and spread of the disease as well as fear, stigma and discrimination towards TB patients.

- Lack of regulatory mechanisms to control the sale and the use of first and second line drugs, which increases the likelihood of serious DR-TB in Armenia.

- Ethical violation of TB patient rights by not informing them about HIV testing in the TB dispensaries.

- DOTS or treatment interruption for TB patients during the transition of patients from the civilian system to the penitentiary and from the penitentiary system to the civilian.

- Poor coordination of TB control between the civilian and the penitentiary sectors.

- Shortages of auxiliary TB professionals, especially nurses, for TB control in the prisons.

- Fragmented TB legislative and regulatory framework that lacks enforcement mechanisms.

RECOMMENDATIONS

In this difficult time of transition, the most rapid successes in TB control have occurred when the government's national TB expertise has been enhanced by the international TB control experiences of the ICRC in Armenian prisons and the MSF in two districts of Yerevan.

The overriding recommendation, based on the study findings, is that a transitional collaboration between the NTP with its national expertise and the ICRC and the MSF with their international experience may most effectively improve TB control in the newly decentralized civilian system.

The specific recommendations are to:

Civilian sector

- Implement the newly developed unified curriculum for the residency programs in TB.

- Increase awareness of PHC providers and specialists in TB cabinets about their specific roles and responsibilities in TB control.

- Introduce TB control services related indicators in the performance based payment system for the PHC providers [to be implemented in 2009] to further integrate primary health care in TB control.

- Improve physical conditions, space, and utilities of TB cabinets to ensure adequate functioning of TB cabinets.

- Consistently and rigorously implement WHO-recommended DOTS in Armenia in order to improve TB control, providing a foundation to expand DOTS+ services.

- Expand consistent rigorous DOTS+ countrywide.

- Ensure continuity of incentives and social support mechanisms for TB patients for the implementation of DOTS.

- Expand TB training sessions to improve the quality of TB care in different levels of TB control.
- Revise the benefit package for TB specialists and TB laboratory workers to make it similar to the package for Infectious Disease specialists to increase motivation, recruitment and retention.

- Introduce performance based payment approach for TB specialists and TB laboratory workers to increase motivation and improve the quality of provided services.

- Improve cooperation and timeliness between laboratory network and other TB services (could be reached through performance based payment mechanism having specific indicators).

- Improve the coordination of the National Reference Laboratory with other TB Control Services (could be reached through performance based payment mechanism having specific indicators).

- Establish a systematic and unified approach for sample transportation and result reporting.

- Replace substandard equipment of laboratory services wherever needed.

- Improve systematic infection control in all levels of TB services.

- Consistently and rigorously implement the existing systematic methodology for contact investigation.

- Develop and implement comprehensive and continuous quality improvement/assurance mechanisms for TB services in Armenia: it must include not only quality related external activities at the national level by the NTP (including monitoring activities) but also internal at the facility level. TB facilities should have a formal, explicit, documented Quality Management and Improvement (QMI) programs. TB facilities should assign specified staff to be trained and to conduct monitoring of QMI activities at the facility level. Formal processes should exist for planning and implementing projects designed to improve the quality of care.

- Improve coordination and increase regular supervision and monitoring at all levels of TB control.

- Ensure closer cooperation between all the stakeholders in TB control (organizations of local, national and international as well as TB patients) in Armenia.

- Conduct ongoing Information, Education and Communication campaigns to reduce the stigma and discrimination of TB among the general population.

- Conduct programs to reduce stigma of TB among health care providers and consultants.

- Consider establishment of compulsory TB treatment system to improve TB control in Armenia.

- Improve regulation of anti-TB drugs (first and second line) to reduce the spread and development of DR-TB in Armenia.

- Inform TB patients about HIV testing and explain the importance of this testing to protect the individual and the public health.

Penitentiary sector

- Revise the benefit package for TB specialists and TB laboratory workers to make it similar to the package for Infectious Disease specialists to increase motivation, recruitment and retention.

- Introduce performance based payment approach for TB specialists and TB laboratory workers to increase motivation and improve the quality of provided services.

- Reduce the shortage of nurses for TB control in the prisons.

- Establish a more practical systematic approach of coordination between the civilian and penitentiary systems.

Legislative framework

- Introduce a comprehensive modernized TB control related points in the draft Public Health law under consideration for Armenia.

    - Need to cover roles & responsibilities, timely notification, confidentiality & exclusion of discrimination, regular analysis of surveillance data & dissemination of results, contact investigation, medical screening & examination, exclusions for TB patients from specified activities, vaccination, diagnosis, treatment, and drug management.

    - Need to provide for clear enforcement mechanisms for these vested powers in the executive for such measures and should define the appropriate balance of compulsory and voluntary measures.

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APPENDIX 1 - LEGISLATIVE AND REGULATORY APPROACH TO TB CONTROL IN ARMENIA AND IN EUROPE

In December 4, 2003 decree N° 1680 of the Armenian Government established the National TB Control Program (NTP) to address the issue of TB nationwide (1). The Government of the Republic of Armenia (RA) approved the "National TB Control Program for 2007-2015" on 28 December 2006 (2). This strategic plan of the NTP was prepared in collaboration with international experts from the World Health Organization (WHO) and GOPA worldwide consultants. The National TB Control Program for 2007-2015 and the Timetable for its Implementation was developed taking into consideration recommendations from the WHO and other international organizations, as well as recommendations provided by the Stop TB Strategy and the Stop TB Global Plan 2006-2015 (2). The NTP has adopted the WHO recommended DOTS strategy for TB control in Armenia. However, the TB strategy plan is a policy document rather than a legal document; it does not provide strict legally binding obligations for the Government and its agencies and other institutions, nor does it provide justiciable rights (capable of being properly examined in court) for individuals.

Each year the RA Government approves by decree the order and conditions for the Basic Benefit Package (free of charge health care and health services guaranteed by the state). The TB services including TB diagnosis, treatment and medicine are covered by the state (3). TB medical services are exempted from value added tax (4).

Law is an important tool that policy-makers can draw upon to support disease control efforts and, according to the WHO, represents a tangible expression of political commitment and will (5). There exists no separate law addressing TB control alone in Armenia. Thus, the first part of this paper will endeavor to identify and describe compulsory legal measures in force in Armenia which contain inter alia rules aimed at TB control (TB control imbedded in larger general rules for infectious disease control) within the civilian population, in the army and in the penitentiary system. The second part of this paper will focus on a cross-national comparative analysis of legislative approaches for TB control employed in some European countries and assess suitable approaches for Armenia that can strike a balance between the individual rights coded in the "European Convention for the Protection of Human Rights and Fundamental Freedoms" and the effective protection of the public health.

Part I: Mandatory Legal Measures in Force in Armenia

Qualification of TB as a Disease

In the government's Decree No. 1286, approved on the 27th of December 2001, TB is included in the list of diseases posing a threat to the public (6). The Ministry of Trade and Economic Development's Decree No. 67-N alerts medical observation to the diseases on the list, promotes the assessment of the state of health of the population as well as develops methods to implement public health policy (7). In this decree, TB is classified as an epidemic and infectious disease, and it is categorized into five groupings: 1) the tuberculosis of the respiratory organs confirmed

by microscopy or tissue test, 2) the tuberculosis of the respiratory organs without confirmation by microscopy or tissue test, 3) the tuberculosis of the neural system 4) the tuberculosis of other organs, and 5) the miliary tuberculosis. Each group also includes additional sub-categories (7).

Surveillance

- The order of the Ministry of Health No1009/12N of 4 October 2004 approved the Ministry of Health's Annual Statistical Reporting Forms that requires the anti-TB clinics and policlinics to complete a reporting form on the number of TB-infected patients (8). The completed form must indicate the number of patients infected with pulmonary and extra-pulmonary TB, all their family members and contact persons, the number of patients re-infected with TB, the number of deaths of patients infected with active TB, as well as information concerning clinical and ambulatory treatment of TB-patients (8). The report is submitted to the RA Ministry of Health and National Statistical Service.
- The RA Government Decree No 1081-N of 3 August 2006 qualifies TB as a particularly dangerous disease for animals (9). Also, the decree lists TB among the diseases subject to notification to the appropriate veterinary authorities.

No legal act requiring prompt notification or contact investigation in the civilian sector was found.

Mandatory Screening and Examination and Exclusion from Respective Activities

- According to the RA Government Decree No 748-N of 10 July 2008 on approving the procedure for assessing the state of health of male citizens of pre-conscript and conscript age, the conduct of medical examinations, the organization of medical assistance and services thereof, male citizens of pre-conscript and conscript age are subject to mandatory screening, and when TB is detected the case is promptly reported to the regional military registration and enlistment office and is subject to registration and oversight by the cabinets of TB control in the RA polyclinics (10). The subsequent treatment of conscripts is carried out by the cabinets of TB control at the patient's place of residence.
- The RA Government Decree No 1089-N of 15 July 2004 requires medical screening of persons working in certain types of industries or performing certain types of work subjecting them to harmful and hazardous activities and exposures for the purpose of preventing occupational diseases including TB (11). The screening is mandatory both prior to admission to work and thereafter periodically.
- The RA Government Decree No 347-N of 27 March 2003 designates twenty work activities where individuals are subject to mandatory screening (12). These activities principally deal with health-care, teaching and the food industry. Individuals are subject to screening both prior to employment and thereafter periodically. If "open forms" of TB (SS+), active SS- pulmonary TB, extra-pulmonary TB with bacillus in fistula and urine, patients are temporarily excluded from work until the treatment is completed and the laboratory examination reveals negative results. The head of the local center of the RA Ministry of Health State Hygiene and Anti-Epidemic Inspectorate issues the decision on the temporary exclusion from work (12). This decision is subject to administrative review within six months of its issuance.

- All forms of active TB constitute medical indications for abortion (13).

The RA legislation does not provide for compulsory treatment of TB in the civilian population.

Disqualification from Certain Types of Eligibility

- The RA Government Decree No 517-N of 5 May 2005 states that persons with open forms of TB (SS+) are not eligible to adopt a child, to become a guardian or a foster parent (14).
- The RA Government Decree No 49-N of 28 January 2008 sets the list of diseases for which an alien with one of these diseases is prohibited entry to the RA unless that person wants to enter the RA to receive treatment for a given disease (15). Active TB of respiratory organs is included among those diseases. According to the RA Law on Aliens, no alien may be granted an entry visa (persona non grata) if he/she suffers from the above mentioned disease (16). The RA Government Decree No 115-N of 25 January 2008 designates procedures to maintain a data base on those persons (17).
- The RA legislation also provides for exclusions for certain professions or services like community or civil service, diplomatic service, police service, the prosecutor's office, civil aviation, the state enforcement service, and judge (18). Those measures are aimed at ensuring that these professionals are able to implement their powers in a due manner.

Drug management

The order of the RA Ministry of Health No78 of 24 February 2000 on approving the list of the essential medicines of the RA lists five anti-TB medicines: *Ethambutol, Isoniazid, Rifampicin, Pyrazinamide, Streptomycin* (19). The Ministry of Health order No 100 of 26 February 2002 requires that the standard prescription form approved by the RA Government decree No 759 of 14.08.2001 be completed by a physician who has a personal stamp for all medicines except for those medicines listed in the RA MOH order No 72 of 5 February 2002 (20, 21). None of the anti-TB medicines mentioned above is among the medicines which can be released without prescription (21). Accordingly, anti-TB drugs cannot be released from pharmacies without prescription (20, 21). According to the RA Government Decree No 867 of 29 June 2002, drug stores must post the list of the drugs which, pursuant to the above-mentioned order, may be released without prescription (22).

The RA Code of Administrative Violations, however, does not specify any sanctions for violations of those rules by pharmacies (23). Nonetheless, violations of this kind can serve as a basis for the Ministry of Health to revoke the license of a given pharmacy.

Vaccination

TB is one of the nine diseases for which vaccination is carried out in the RA in accordance with the national vaccination calendar (24). The two legal acts found containing rules on BCG vaccination are the following:

- The RA Ministry of Health order No 1028 of 20 October 1994 provides that newborn children are vaccinated during the first 24-28 hours of their life by the doctor's order, and sets the time, place and conditions of BCG vaccination and the conditions for keeping the BCG vaccine (25).

Sanitary and Anti-epidemic Services

- According to the Statute of the RA State Hygiene and Anti-epidemic State Inspectorate (SHAI) approved by RA Government Decree No 1316-N of 15 August 2002, the SHAI is entrusted with general functions for the control and prevention of infectious diseases (not specific only to TB control and prevention) (26).
- The RA legislation provides for sanitary and hygiene rules with regards to meat, bread and milk products to control and prevent TB (27).
- The RA Government Decree No 595-N of 5 December 2002 sets specific requirements regarding equipment, medical instruments and professional qualification of the staff for TB facilities and services (28).

Army

- The RA Government Decree No 595-N of 22 May 2008 on approving the internal code of rules of the garrison disciplinary cells of the RA Ministry of Defense does not lay down measures specifically aimed at TB control (29). However, it provides for medical screening upon acceptance to the cell of arrested servicemen and servicemen sentenced to detention, and in the case of suspicion of any disease, a screening is carried out by a member of the medical profession, and a record is drawn up thereupon. It is also prohibited to keep a detainee suffering from an infectious disease in the disciplinary cell. These detainees are transferred to specialized medical institutions or to military hospitals (29).
- The RA Law on Approving the Code of Internal Service of the RA Armed Forces requires the head of the medical service of the regiment to notify the regiment commander about each case of hospitalization of military servicemen as a result of an infectious disease (30). In order to protect servicemen from infectious diseases, vaccinations are conducted on a regular schedule and during epidemics on the order of the chief commander.
- The law Approving the Code of Rules of Garrison and Patrol Services of the Military Forces of the RA of 3 December 1996 requires the head of the garrison medical service to organize medical examination of the servicemen kept in the garrison disciplinary cell once a month with medical care as needed (31). The head of the garrison medical service is also obliged to notify the head of garrison without delay about the cases of infectious diseases at the military unit and among the local population and the measures adopted to prevent them.

Penitentiary system

According to the Penitentiary Code of the RA:

- Convicts suffering from an infectious disease are subject to compulsory treatment based on the opinion of a medical commission (32).
- Convicts infected with certain types of TB may not leave the territory of the correctional or detention facility without guard or convoy (32).
- TB-infected convicts may be granted a short-term leave only upon an opinion of a doctor or a relevant specialist assuring that the convict does not pose a threat to the public (32).

According to the RA Government Decree No 825-N of 26 May 2006 (33):

- One of the primary tasks of the medical service department of the Penitentiary Service is to control the state of health of the detainees and convicts through periodic medical screening and examination, treatment, Information, Education and Communication for convicts and detainees, meeting the requirements of sanitary legislation in the criminal executive institutions, planning and implementing preventive measures in the penitentiary institutions.
- This decree designates the process of notification from the treating specialist to the medical service department head of the penitentiary institution.
- Medical service department head of the penitentiary institution carries out early detection of infectious diseases, contact persons and takes appropriate anti-epidemic and preventive measures.
- Specialists of the special medical department of the medical penitentiary institution isolate the detainees and convicts with infectious diseases and inform the medical service subdivision head.
- Member of the medical profession on duty isolates the detainees and convicts with infectious diseases located in the medical service department or specialized medical department.
- Detainees and convicts are screened and/or examined upon admission to or transfer from a detention or correctional facility and the findings thereafter are recorded.
- Active TB-infected persons, when released or transferred from a penitentiary institution, are transported separately.
- Medical service department makes an entry in the registry of detainees and convicts suspected of being infected with TB.
- Certain forms of TB are among the diseases hindering the execution of sentence.

Part II: Mandatory Legal Measures in Some of the European Countries

A fundamental function of government is public health protection. This requires formulation and implementation of public health policies in order to prevent diseases such as TB, underpinned by legal regulation authorizing public health interventions. As such, public health law, that is ''the legal powers and duties of the state to assure the conditions for people to be healthy and the limitations on the power of the state to constrain the autonomy, privacy, liberty, proprietary, or other legally protected interests of individuals for protection or promotion of community health'' is an important component of the state's responsibilities (34). Yet at the heart of public health law is a tension between individual rights and the protection of public health. The state must protect public health and as well safeguard the legal rights of individuals.

Authorities may address disease control by persuasion through health promotion, they may create incentives to support people and agencies to implement public health measures, or they may compel individuals and institutions to conform to a set of behavioral standards or practices (34). For the prevention and control of communicable diseases, health legislation defines the rights and duties of individuals, agencies and institutions, creates the administrative tools to facilitate the control of those diseases, and provides for the sanctions the state may impose if individuals or bodies are non-compliant.

This part of the paper describes legislative tools used to support TB control in 14 countries from the WHO European region (Czech Republic, England, Estonia, Finland, France, Germany, Hungary, Israel, Norway, Poland, Russia, Spain, Switzerland, and the Netherlands), and discusses the extent to which their application might withstand scrutiny under the European Convention of Human Rights (35, 36).

Legally binding compulsory measures to control and prevent TB as applied in this sample of European countries include screening, medical examination, treatment, detention, vaccination, quarantine and exclusion from specific activities. No two countries' legislation has the same set of compulsory measures for preventing and controlling TB. The number of identified compulsory measures varies from none in Spain to a maximum of six compulsory measures in Russia and Norway (35). Overall, each category of compulsory control measures is authorized in more than half of the countries, while compulsory TB preventative measures such as compulsory vaccination and compulsory screening are enforced in a minority of these countries.

Many countries have two or three compulsory TB control measures. Russia and Norway (six each), Czech Republic (five), Hungary (four), Estonia (four) and Switzerland (four) have more authoritarian legal frameworks for the control of TB (35). All countries, apart from the Netherlands, France and Spain, apply either compulsory treatment or compulsory detention or both. Those countries that do not provide for compulsory treatment or compulsory detention usually have more TB prevention legislation, granting routine or compulsory vaccination, compulsory or targeted screening, and sometimes compulsory medical examination.

Models are widely divergent on the power to issue a compulsory order for TB control and prevention, with some countries resorting to the courts to issue the order while others leave their appointed administrative public health or local authorities to do so. Even for more drastic

measures like compulsory detention or treatment, the order is issued by the courts in a minority of countries (England, Estonia, Poland, and Russia).

All countries possess a surveillance system that requires notification of TB through a central registry (35). An underlying principle behind compulsory examination is the suspicion of infectious TB in six of the seven countries that authorize compulsory examination. In six countries, refusal to comply with treatment may prompt compulsory treatment. Exemptions from compulsory orders are limited in all countries, with only Russia and Switzerland offering possible exemptions from compulsory measures on the basis of health or age (35).

Legislative Models

There are different 'families' of legislative models for TB control and prevention in the European region. The first model is 'authoritarian', with a high number of compulsory control measures. This model includes at least three compulsory measures, including compulsory examination, detention and treatment, but also provides for 'upstream' measures of prevention such as compulsory vaccination and screening. The second model is 'moderate' with predominantly compulsory control measures without recourse to compulsory vaccination or population screening. The third model, a 'preventive' model, is based on compulsory provisions oriented towards preventive measures, such as compulsory screening, medical examination and vaccination, and does not include compulsory treatment or detention. The fourth model is the absence of all compulsory measures for TB prevention and control.

Part III: Scrutiny under the European Court of Human Rights

While considering to which model to adhere policy choice makers should consider any possible conflicts with the European Convention of Human Rights. The Convention has significant implications for public health interventions and offers a framework to examine the legitimacy of legal sanctions. The Convention facilitates challenge of legal powers by means of judicial review and litigation for damages in countries that are signatories to the Convention, where compulsory powers are not administered in accordance with Convention rights. The Convention includes specific provisions that strengthen individual rights such as the right to life (article 2), the right not to be subjected to inhuman and degrading treatment (article 3), the right not to be deprived of one's liberty arbitrarily (article 5), and the right to a private and family life (article 8) (36). While, in common with other human rights instruments, the Convention allows compulsory measures that restrict human rights where public health is threatened, sanctions must be proportionate, nondiscriminatory, and not be applied arbitrarily. Moreover, interventions must be authorized by law and the processes of application of powers must ensure, under article 6, the right to a fair and public hearing including a right of appeal (36). Achieving a balance between the threats posed to public health and the recognition of individual rights is challenging. Interventions must be in response to a pressing public health need, be proportional to this social aim and be no more restrictive than necessary to achieve the intended purpose.

Summary Conclusion

Currently, Armenia has no law specific to the control and prevention of TB. The existing legislative and regulatory measures are highly fragmented and lack appropriate enforcement mechanisms, and some of them are outdated. With the emerging unique challenges of TB in Armenia, there is a need for a comprehensive modernized legislative approach to TB control which includes measures for defining roles and responsibilities, timely notification, confidentiality and exclusion of discrimination towards TB patients, regular analysis of surveillance data and dissemination of results, contact investigation, medical screening and examination, exclusions for TB patients from specified activities, vaccination, diagnosis, treatment and drug control. These legislative measures should become a part of the draft Public Health law for the RA under consideration and they should also clearly specify the enforcement mechanisms for these vested powers in the executive for such measures and should define the appropriate balance of compulsory and voluntary measures.

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APPENDIX 2 – QUALITATIVE STUDY INSTRUMENTS

Examples of Instruments:
Focus Group Guide
(TB Cabinet)
Place_____

Date_____

Time_____

Moderator_____

Recorder_____

Introduction
Welcome
Welcome all participants to the focus group and thank them for coming.

Introduction of workers
Introduce moderator, recorder and observer.

Review of the program
The Center of Health Services Research and Development of American University of Armenia by the order of ICRC is conducting a study which aims to analyze TB situation and TB control system in Armenia in order to come up with policy recommendation to strengthen TB services in the country.

Participation
Your full participation in our discussion is important. There is no "right" or "wrong" answers. We are interested in your opinions and feelings. We hope to learn from you.

Ground rules
All of you should feel free to discuss all questions among yourselves; don't wait for the moderator to ask for your opinion. But please do not interrupt others when they are speaking. Everyone will have a chance to speak. All of you should feel free to disagree with anyone's opinions.

Confidentiality
This discussion will be confidential. Only first names will be used; we will not tell anyone your names or that you participated in this discussion. All your comments will be used for research purpose only. We have a recorder who will take notes throughout the session. We also will tape record the discussion to make sure that no idea remains out of our attention.

Icebreaker
We would like to learn your names in order to give you a nametag and call you by your name.

1. **What is your name?**

What type of activities you are involved in?

Transitional question

2. **What do you think is TB a problem in Armenia and why?**

Introduction of topic

3. **What are your actions if you meet a patient suspected with TB? How often do you have such patients? How do you perform their admission and referrals?**

4. **In your facility what are the procedures of TB cases registration and reporting? What, how often and whom do you report? What kind of special TB reporting forms do you have and use? Who is your direct supervisor? And how often your supervisor assesses the services provided by TB cabinet?**

5. **In your facility what are TB diagnostic steps? How often do you use diagnostic services? What diagnostic services for TB cases detection are there in and out of your facility? Do you use them? (When do you send sputum for culture and drug susceptibility test)? What problems occur in diagnostic procedures, how are they solved?**

6. **What treatment procedures do you perform for TB new cases, relapsed and "chronic" cases? What are the differences between relapsed and "chronic" cases treatment? Do you perform DOTS? How? What proportion of TB patients is treated based on DOTS strategy and how do you perform it? What barriers do you face in DOTS administration?**

7. **How do you perform TB free of charge medication distribution? From where and how often do you get drugs? Bases on what criteria is drug supply in your facility performed? Does it cover the needs of your patients? How are the drugs stored in your facility? How often do you have adverse affects of drugs and whom do you report about it? Are there any interrupted periods of drug supply and how do you solve that problem?**
   Probe: **What proportion of your drugs is utilized?**

8. **How TB cases surveillance and follow-up is performed by your cabinet? What do you do with "lost cases"?**

9. **What and how do you deal with MDR-TB prevention?**

10. **How do you deal with HIV-TB co-infection?**

11. **How does the former prisoner with TB reach your facility and how do you perform his registration and follow-up? What are difficulties that you have during collaborating with prison? What would you suggest to solve the problems? What are difficulties regarding TB management in former prisoners, particularly what**

actions does your cabinet undertake with "lost cases"? What are the differences between TB control among civilians and former prisoners?

12. **Please, tell what specific actions do you perform for TB prevention in your community?**

13. **How would you assess the collaboration between different TB control knobs, please emphasize the problems, particularly between TB cabinet and**
    - **Family physicians/nurses in rural/urban facilities,**
    - **specialized TB care,**
    - **NTP/NTP Central Office,**
    - **TB laboratories,**
    - **MOH,**
    - **MOJ,**

14. **Do you have any quality assurance strategy? If yes, specify.**

15. **Are there any infection control mechanisms in your facility? If yes, what are there?**

16. **Do you have any protocols or guidelines for TB patients' management available in your facility? What are they? Do you use them, if yes how often and if no why?**

17. **How would you assess your level of preparedness (knowledge and skills) in TB control? In other words do you consider that the level of your preparedness matches the level of your responsibilities in TB control in RoA? Is the workforce of your cabinet sufficient to serve your community? Tell us about TB trainings experiences in last five years. What additional trainings do you need, if any?**

18. **Are you aware about TB reforms in PHC?**

Thank you for participating in our study – your answers have been very interesting and helpful!

In-Depth Interview Guide
(MDR-TB Patient)
Place_____

Date_____

Time_____

Interviewer _____

Introduction

Welcome

Welcome the participant of in-depth interview and thank him/her agreeing to participate.

Introduction of participants (interviewers)

Introduce yourself.

Review of the program

The Center of Health Services Research and Development of American University of Armenia by the order of ICRC is conducting a study which aims to analyze TB situation and TB control system in Armenia in order to come up with policy recommendation to strengthen TB services in the country.

Participation

Your full participation in our interview is important. There is no "right" or "wrong" answers. We are interested in your opinions and feelings. We hope to learn from you.

Ground rules

Please, feel free to express your opinion regarding our questions.

Confidentiality

This interview will be confidential. We will not tell anyone your name or that you participated in this in-depth interview. All your comments will be used for research purpose only. We will take notes throughout the session. Also upon your permission we will tape record the discussion to make sure that no idea remains out of our attention. Can we proceed with tape recording?

Icebreaker

1. **What is your name?**

Transitional question

2. **We will now talk about TB problem in Armenia particularly on your example. Please, tell us in your opinion what is the difference between TB and MDR-TB?**

Introduction of topic

3. **When have you been diagnosed with TB at first and where (*in PHC or TB dispensary*)? Do you know from who have you got infected? When have you been diagnosed with MDR-TB at first and where?**

4. **How did you learn about this Dispensary and how did you come here?**

5. **Have you ever been informed about TB infection, TB treatment and consequences of non-compliance? If yes, where, when, and by whom?**

6. **Have your family members been informed about TB? When, where and by whom? Did they pass any diagnostic or preventive procedures? If yes, specify what?**

7. **Were you explained why TB became MDR-TB in your case? If yes, why? Who did explain it to you? Now please tell us, why it happened in your opinion? What could have been done differently to avoid it?**

8. **How many times did you get TB treatment?**

Now, let us talk about difficulties that you experienced during your previous treatments. Please, answer the following questions for each treatment experience.

9. **Where did you treated? How long were you treated in dispensary and ambulatory? How many patients were in the same ward with you in dispensary? Could you have contacts with other patients from other wards or from other departments?**

10. **Did you take your medication regularly in accurate dosage, as was prescribed by doctor, and was it under the direct observation of the health care provider? Do you ever miss your drug intake? Why?**

11. **Who and how often give you TB drugs in dispensary and ambulatory? Did you ever experience any interrupted periods of drug supply? Why? Did you ever acquire drugs from pharmacies or other private sources? Why?**

12. **How often did you have visitors? Where did you see them? What kind of preventive methods were used during those meetings, for example: ventilation, sunlight, UV exposure, respiratory masks, etc?**

13. **Did you pay for any TB services or any TB drugs? Where, whom and how much?**

Thank you for participating in our study – your answers have been very interesting and helpful!