Center for Health Services Research and Development School of Public Health American University of Armenia

Household TB Infection Control Pilot Project:

Counseling for TB Patients and Their Family Members

Prepared for

Armenian Medical Fund

STUDY TEAM

Nune Truzyan, DVM, MPH Tsovinar Harutyunyan, MPH, PhD Marianna Koshkakaryan, MD, MPH Ruzanna Grigoryan, MD, MPH Meri Tadevosyan, MPH Hripsime Martirosyan, MD, MPH Byron Crape, MSPH, PhD Varduhi Petrosyan, MS, PhD

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EXECUTIVE SUMMARY

Armenia is facing a serious reemerging threat from tuberculosis (TB). In 2010, the number of newly diagnosed TB cases was 41.3 per 100,000 population; it was estimated that approximately 9.4% of these new cases were multi-drug resistant TB (MDR-TB). Moreover, approximately 43.0% of previously treated TB cases became MDR-TB in 2011. According to the World Health Organization (WHO) statistics for 2011, 21 cases of extremely-drug resistant TB (XDR-TB) were found in Armenia. WHO has classified Armenia as having a high rate of DR-TB.

The Center for Health Services Research and Development (CHSR) of the American University of Armenia (AUA) implemented the Household TB Infection Control Pilot Project in 2012, in collaboration with the National TB Control Program (NTP) of the Ministry of Health of the Republic of Armenia and with support from the Armenian Medical Fund. The project included 1) document and literature review; 2) qualitative study among the TB patients, their family members, TB health care providers, and TB experts; 3) a Training of Trainers (TOT) course for the teams that conducted the counseling sessions with TB patients and their family members; 4) TB household counseling sessions with TB patients and their family members in Aragatsotn, Kotayk, and Shirak marzes of Armenia, 5) baseline – follow - up evaluation surveys of the participants of counseling sessions; 6) a TOT course for 52 TB nurses serving in the TB outpatient centers; and 7) comparison of treatment outcomes between the TB patients who participated in the household pilot counseling sessions and the national statistical data provided by NTP.

The findings from document / literature review, including previous CHSR TB research, and the qualitative assessment informed and provided directions for the planning and implementation of the household counseling by two teams of professional trainers, each of them consisting of a psychologist and a TB nurse. In total, 136 TB patients and their family members participated in 90 minutes interactive counseling sessions conducted for each family using a training manual designed for the training and counseling, a flipchart, supplemental materials, and TB brochures. During the counseling sessions TB patients and their family members learned about the importance of 1) taking TB drugs regularly, 2) monitoring and reporting side-effects and symptoms, 3) monitoring and reporting potential TB symptoms among other family members and contacts for follow-up check-ups, 4) taking appropriate safety and prevention measures as needed, and 5) providing psychological support to TB patients. These household TB counseling sessions were designed to curtail the spread of TB epidemics, reduce the rates of failed treatments and development of drug resistant TB, and reduce the stigma related to TB in the community.

Baseline – follow -up panel evaluation of the household counseling intervention showed that patients and their family members were interested in learning more about TB. The intervention helped to correct misconceptions about TB, alleviate fear and anxiety related to the disease, change behaviors to increase the likelihood of successful TB treatment outcomes, and reduce the stigma of TB disease among patients and their family members. There was a noticeable improvement in the support and interpersonal relationships between patients and their family members as a result of the counseling sessions emphasizing the importance of family-based TB control. Household TB trainings substantially and positively impacted treatment outcomes of TB leading to increased rates of treatment success and decreased rates of treatment failure and default.

This project demonstrated that conducting a single household TB counseling session for households with TB patients is a cost-effective intervention.

Considering the effectiveness and viability of the Household TB Infection Control Pilot Project, the overriding recommendation of the research team is to institutionalize and integrate this approach in the National TB Control Program to expand it to the entire country. Other recommendations include enhancing the psychological support of TB patients and their family members through engagement of psychologists into counseling at outpatient TB centers in Armenia.

In addition to the TOT session for the teams of the Household TB Pilot Project trainers, CHSR organized TOT sessions titled "Educational and socio/psychological support for regular TB patients and their family members" for 52 TB nurses working in TB outpatient centers in Armenia. This session was organized to improve TB nurses' evidence-based knowledge and the skill-sets for effectively working with TB patients and their family members, which were highlighted during the household counseling sessions.

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} Persons can be infected with the TB bacteria but not develop the disease. The disease may be expressed as pulmonary TB and extra pulmonary TB. The extra pulmonary is much less common than pulmonary.^{1,2} More than 80% of active tuberculosis in the world is concentrated in 22 low and middle income countries.³

Symptoms

The most commonly affected site is the lungs but it can also affect other organs, especially in immune-suppressed persons. The symptoms include cough with thick, cloudy mucus or sputum, sometimes with blood for more than three weeks, fever, chills, night sweats, fatigue, muscle weakness, weight loss and in some cases shortness of breath and chest pain.^{2,4}

Risk groups

Men and women have equal chances to become infected with TB but men are more likely to develop TB disease.⁴ High risk groups include migrant populations, the homeless, persons living with the Human Immunodeficiency Virus (HIV), prisoners, former prisoners, orphans, people in hospices or 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.^{2,5} After infection the risk of developing TB disease is the highest among children younger than 4 years old- then it decreases. Starting from the age 15-19 the risk substantially increases again, peaking between the ages of 20-30 years.⁶

Transmission and disease development

The spread of TB bacteria depends on several factors such as duration and intensity of exposure, related to the time of exposure of those without TB to infectious person with TB and the number and concentration of infectious persons, and the proportion of exposed persons who are more susceptible to TB. About 30% of people who have close contact with an infectious person with TB become infected. 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 Only about 5% of persons infected with TB develop the disease immediately after infection.⁷ In most populations, approximately 95% of persons infected with TB enter a latent asymptomatic phase; these persons may develop TB disease later if the bacteria overcome the immune system of the individual. It is estimated that each person with active TB infects 10-15 people on average if not treated.⁷

Drug-resistant TB

TB can be treated with five standard first-line anti-TB drugsⁱ. Misuse or mismanagementⁱⁱ of these drugs may lead to drug resistant (DR) TB. DR-TB includes mono-resistant TB, poly-resistant TB, multi-drug resistant TB (MDR-TB) and extensively drug resistant TB (XDR-TB). A mono-resistant TB case is a TB patient with a Drug Susceptibility Test (DST) result showing resistance to one first-line anti-TB drug. A poly-drug resistant TB case is a TB patient with DST results indicating resistance to several anti-TB drugs but not to both rifampicin and isoniazid. 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. XDR-TB is resistance of the bacteria to any fluoroquinolone drug in addition to isoniazid and rifampicin and at least one of three following injectable second-line drugs: capreomycin, kanamycin and/or amikacin. Patients with DR-TB can transmit DR-TB to others. Symptoms of drug-resistant and non drug-resistant TB are the same.² Treatment with second-line drugs is more expensive, less effective and more toxic.⁸ Those infected with DR-TB are more likely to die due to their disease than those patients with regular TB.

According to the World Health Organization (WHO) 2011 progress report, each year an estimated 450,000 cases of MDR-TB develop worldwide and 150,000 will die.⁹ According to WHO in 2009 out of all new TB cases, 3.3% had MDR-TB.^{9,10} The estimated number of multidrug-resistant TB cases is highest in India, followed by China and Russia.¹¹ By the end of 2010, in the world at least one case of XDR-TB was reported in 69 countries. The current annual estimated number of XDR-TB cases in the world is 25,000.⁹

i First-line anti-TB drugs are isoniazid, rifampin, pyrazinamide, ethambutol and streptomycin (S).

ii Misuse or mismanagement – drugs taken in a wrong combination, or fewer drugs taken than prescribed, or drugs taken in insufficient doses, or drugs taken for insufficient time.

Treatment adherence

Adherence to treatment for an individual patient is usually reported as the prescribed doses or the prescribed number of pills each day of the medication actually taken by the patient within the prescribed period. Adherence rates are typically lower among patients with longer-term disease conditions such as tuberculosis, as compared with those with shorter-term acute conditions.¹² Up to half of people with tuberculosis do not complete their treatment worldwide, therefore strategies to improve adherence to treatment are important.¹³

Major predictors of poor adherence to treatment are:

- Presence of psychological problems, particularly depression
- Treatment of asymptomatic disease
- Side effects of medication
- Patient's lack of believe in benefit of treatment
- Patient's lack of insight into the illness
- Poor understanding of the seriousness of the problem
- Poor provider-patient relationships
- Presence of barriers to care or medications
- Missed appointments
- Complexity of treatment
- Stigma related to taking medication

Many barriers to adherence are under the patient's control, thus attention to the patient is a necessary and important step in improving adherence. The main reasons mentioned by patients for not taking medications included forgetfulness, other priorities, decision to omit doses, lack of information, and emotional factors. Physicians contribute to patients' poor adherence by failing to explain the benefits and side effects of a medication adequately and having poor therapeutic relationships with patients.¹⁴

Involving family members in TB treatment adherence intervention has been shown to be effective in a number of studies. ^{15-18 15}

TUBERCULOSIS IN ARMENIA

Burden

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 2005.¹⁹ The official Armenian statistics reported a consistent decline in the overall number of active cases of TB, from 6,455 cases in 2005 to 3,446 cases in 2009.^{20,21}

According to the National TB Control Program, the number of newly diagnosed TB cases was reported to be 1,582 in 2011. According to WHO Global Tuberculosis Control report 2011 estimations, 9.4% of these new cases were MDR-TB and approximately 43.0% of previously treated TB cases became MDR-TB (Table 1).²² Armenia was one of the 27 countries identified by the WHO XDR-TB task force in 2008 to have a high burden of MDR/XDR TB, which lead to Armenia's participation in the Ministerial Beijing Declaration of 2009 for High MDR/XDR TB burdened countries.²³ According to WHO statistics for 2011, 21 cases of XDR-TB were reported in Armenia.²⁴

<u>HIV/AIDS-TB Co-infection</u>: Exposure to mycobacterium tuberculosis puts HIV patients at increased risk for mortality and greater severity of morbidity, because their immune system is depressed and they have a 20-30 times higher probability of developing active TB.²⁵ Currently, 2,500 people are estimated to be living with HIV/AIDS in Armenia. Although this number has been slowly increasing each year since the early 1990s, it still comprised 0.1% or less of the population of Armenia in 2010. The population rate for HIV/AIDS-TB co-infectivity is only 0.001% but appears to be slowly and steadily increasing.^{22,26}

Out of 1,099 TB patients that were tested for HIV from 2002 to 2007, 1.8% of TB patients were reported to be co-infected with HIV in 2002, climbing to 3.1% in 2007.¹⁹ However, based on the 1,242 TB patients tested for HIV in 2010, the percent of co-infected persons with HIV dropped to 1.4%.²⁷

Indicators	Rates
Mortality (excluding HIV) in 2011	8.8 (7–15) per 100,000 [*]
Prevalence rate (incl HIV) in 2011	78 (48–189) per $100,000^*$
Incidence rate (incl HIV) in 2011	55 (60–87) per 100,000 [*]
Incidence rate (HIV-positive) in 2011	$1.8 (0.55 - 1.6) \text{ per } 100,000^*$
Case detection, all forms in 2011	74 (52–76) %*
New MDR-TB cases	9.4 (7.0–12) %*
Previously treated TB cases with MDR-TB	43 (38–49) % *
Treatment success rate among new smear-positive in 2010	72 %
Treatment success rate among new smear-negative/	85 %
extrapulmonary in 2010	
Treatment success rate among retreated cases in 2010	67 %
*Uncertainty intervals	

 Table 1.²²
 TB indicators for Armenia for 2010 and 2011

National TB Control Program

The Government of Armenia's National TB Control Program (NTP) was established on December 4th, 2003 by the decree N° 1680. The NTP adheres to the International STOP TB strategy and the Global Plan to STOP TB 2006-2015 to apply best practices for organizing prevention, detection and treatment efforts, based on the WHO recommended Directly Observed Treatment Short-course (DOTS) strategy.^{28,29}

The current ongoing goal of the NTP is to reduce TB morbidity, mortality and DR-TB during the period of 2007-2015. All TB facilities undergo quality control checks by the NTP on a quarterly basis. Record keeping and distribution of drugs also falls under NTP management. TB medications are distributed to health facilities based on reported need every month.^{29,30} In September 2003, by order N° 913 of the Government of Armenia, one TB coordinator was assigned to each of the Health and Social Protection Departments in the 10 Marz Governors' offices (marzpetaran) and Yerevan Municipality. These TB coordinators carry out NTP responsibilities in their assigned marzes and Yerevan.¹⁹

Service delivery

In Armenia, TB services in the civilian sector are organized through health care facilities which are located in 10 marzes and Yerevan. These include two specialized TB dispensaries (the Republican TB Dispensary in Abovian and the City TB dispensary in Yerevan), 10 TB in-patient departments in general hospitals (with a total 518 TB hospital beds), and 72 TB outpatient centers/offices in polyclinics providing out-patient services.^{27,29} The functions of

the outpatient centers include 1) activities directed towards TB prevention among the healthy population, 2) early detection of TB, 3) record keeping of new and relapsed TB cases, 4) diagnostic procedures and treatments of new and relapsed TB cases based on the DOTS strategy, 5) appropriate referral of the patients to specialized TB facilities as needed, 6) dynamic dispensary surveillance of both new and relapsed TB patients, 7) organizing treatment for children and adults in sanatoriums, 8) medication distribution based on the DOTS strategy, 9) organizing laboratory/instrumental diagnostic procedures with referrals to TB departments in marz facilities or Republican TB Dispensary in (RTBD) as needed, 10) performing medical examinations for pre-military and military-age males in collaboration with the adolescent outpatient centers, and 11) maintaining TB control among former prisoners.¹⁹

The National Reference Laboratory (NRL), which is located in the RTBD building, is an independent legal entity and performs microscopy, Drug Sensitivity Testing (DST) and culture growth. The NRL, together with one level II (culture) laboratory (situated in Yerevan) and 30 level I microscopy laboratories, comprises the network of TB laboratories in Armenia. In addition, the National Reference Laboratory is also responsible for quality assurance monitoring of all laboratories in the country.³⁰

Prevention

TB prevention practices in Armenia begin with BCG vaccination of newborns at the maternity wards during the first 24-48 hours of life. The BCG vaccination was introduced in 1998 and is currently officially scheduled by the National BCG Calendar. The Sofia, Bulgaria/ InterVac Ltd Toronto, Canada BCG vaccine is used in Armenia, with approximately 94% coverage. Vaccines are only administered after an infant gains 1,700 grams or more. Those newborns who do not receive the BCG vaccine in maternity hospitals are vaccinated in the immunization outpatient centers of the local primary health care facilities. Those children who do not develop a scar after the initial vaccination are revaccinated with a second dose of BCG vaccine at six to seven years of age.³¹

People who have been in contact with TB patients are examined during the first seven days after the diagnosis of the patient has been confirmed. TB disease screening for investigation of adults who have been in contact with an infectious TB patient is conducted using fluorography or triple sputum test (when sputum is available).²⁷ Children under the age of 18

can additionally undergo Tuberculin Skin Test (TST). Those individuals with a positive skin reaction of more than 5 mm diameter are further subjected to chest X-rays. Three months of Izoniazide prophylactic treatment is prescribed for exposed children from the patient's household under the age of 15. After this period, TST is conducted and if the results are positive the treatment is continued for an additional 3 months.²⁷

For HIV/AIDS patients, people with suppressed immune systems and all children under the age of 4 who have been in contact with a TB patient, prophylactic treatment is prescribed regardless of TST results. Three months-long Izoniazide prophylactic treatments are also performed for newborn babies of mothers having pulmonary TB, after which follow-up TST is conducted. If the TST results are positive, the treatment is continued for three months. If the result is negative result the child is vaccinated with BCG, while those with positive results continue for an additional three months of treatment.²⁷

Diagnosis

The main method of TB detection is passive case finding by primary health care level specialists such as therapists, pediatricians, family doctors and nurses, who then refer all patients with suspected TB to the local polyclinic TB outpatient centers for diagnoses.²⁷ Two nurses assist the TB specialist. One of the nurses is responsible for the functioning of the TB outpatient center and the other nurse is responsible for patient outreach to reach those patients who miss their regular appointments with the TB outpatient center. All TB outpatient center specialists who had direct contact with patients undergo certification training for WHO DOTS strategy.²⁷

Although BCG vaccination can produce high numbers of false-positives in TST testing, this testing is used for screening of males of military age and for children up to 18 years-of-age who have been in contact with newly diagnosed TB patients. Those individuals with a positive skin reaction of more than 5 mm diameter are further subjected to chest X-rays.²⁷ Triple direct sputum smear microscopy serves as the main TB diagnostic method in Armenia. The results are negative, chest X-rays are also conducted. For all new cases of TB, to identify drug resistant strains Drug Susceptibility Testing (DST) for bacterial growth is conducted.³²

The diagnosis of MDR-TB patients is based on drug susceptibility tests.²⁷ As soon as an MDR-TB case is identified, they are registered on their personal MDR-TB medical records by the tuberculosis specialist at their local MDR-TB outpatient center. In those situations when there are no MDR-TB services in their TB outpatient center, the patients are referred to the closest MDR-TB outpatient center.²⁷

All cases of TB and drug-resistant TB are reported to the State Hygiene and Anti-epidemic Inspectorate (SHAI) team.²⁷ The SHAI team visits patients at home and conducts environmental inspections and informs the households on TB infection. Reports are also sent to the *Disease Control and Prevention Centre LLC*. Moreover, the NTP regularly provides the SHAI with brief summaries of all quarterly reports and an annual report.²⁷

Treatment

The DOTS program was implemented in Armenia in 1995 as a pilot program and reportedly achieved full national coverage by the end of 2002 ³³, though a follow-up assessment conducted by the Center for Health Services Research and Development of the American University of Armenia during Operational Research on Investigation of TB Risk Factors in Armenia in 2012 indicated that directly observed therapy was not universally conducted.

According to the National TB treatment protocol, treatment for new regular pulmonary and extra-pulmonary TB cases is six months. The first phase of treatment is two months of intensive treatment with HRZEⁱⁱⁱ, usually at an in-patient TB care facility.²⁷ The second phase is four months of treatment with HR (Isoniazid(H), Rifampicin(R)). The treatment for relapsed regular TB cases is eight months – two months of intensive treatment with HRZES followed by HRZE (Streptomycin removed) for one month, followed by five months of treatment with HRE. If after this treatment the patient is still smear positive, the intensive phase treatment is extended for an additional month.²⁷ The patients receive the continuous phase of treatment at their local TB outpatient centers. For those patients who live far from the local TB outpatient center, the rural health facilities (Medical Ambulatories and FAPs) provide TB care during this phase of treatment, as well as visiting any patient that has missed their regular appointment with the health facility. During both intensive and

ⁱⁱⁱ Isoniazid(H), Rifampicin(R), Pyrazinamide(Z), Ethambutol(E), Streptomycin(S)

continuous phases of treatment, directly observed treatment (DOT) is required on paper.²⁷ However, recent assessments conducted by the Center of Health Services Research and Development within the Operational Research on Investigation of TB Risk Factors in Armenia showed that patients taking the TB drugs in the presence of a healthcare provider (DOT) in 83% of cases during inpatient TB care and only in 22% of cases during out-patient (ambulatory) treatment. The responsibility for direct supervision of patients taking TB medication primarily falls on in-patient and out-patient health facilities.²⁴ When necessary, nurses receive extra pay to stay on duty on Saturdays to conduct directly observed treatment for TB patients.²⁷

In 2009 the World Health Assembly resolution 62.15 urged member states "to achieve universal access to diagnosis and treatment of multidrug-resistant and extensively drug-resistant tuberculosis".³⁴ From the 27 high MDR-TB burden countries, 20 (including Armenia) began adapting their national TB control plans to adhere to the resolution to include MDR-TB treatment. In 2010, Armenia was one of the first countries to present their adapted national TB control plan to WHO.³⁴

Médecins Sans Frontières France (MSF France) initiated MDR-TB DOTS+ treatment in two districts of Yerevan (Malatia/Sebastia and Shengavit) as a pilot program in 2005 in collaboration with the Armenian Government. By the end of 2011 this program was expanded to cover the entire country, with an ongoing handover of this treatment program to the National TB Program. A multidisciplinary team, which included doctors, nurses, social workers and psychologists, was formed to assist and encourage patients and to decide on treatment approaches as well as systematically conducts training sessions on TB infection and TB treatment related difficulties.²⁷

MDR TB patients are directly treated by TB physicians who have undergone specialized training for DR-TB management. In Yerevan, the treatment of these DR patients is located at specific polyclinics. Patients from other polyclinics who have been diagnosed with MDR-TB are referred to those polyclinics with DR-TB treatment programs.²⁷

The treatment for drug-resistant TB is complicated and varies widely depending on the response of the bacteria to the treatment and on side effects.²⁷ Treatment for DR-TB requires a minimum of 21-24 months or 18 months after the smear and the culture are negative.

Before starting the treatment for DR-TB, biochemical and hematological tests are conducted for side-effects due to the medication and HIV testing is recommended since TB is an opportunistic disease for HIV. For these DR-TB patients, the intensive phase of treatment is provided in specialized TB dispensaries or in-patient departments. The continuous phase of treatment for these patients is provided in TB outpatient centers that have DR-TB services. All the marzes and Yerevan have TB outpatient centers that provide DR-TB services.²⁷

Once the drug sensitivity test results are available, a specialized treatment plan is developed for each patient.²⁷ Based on their previous history of disease and treatment, 4-5 effective medications are chosen to begin the intensive treatment phase. Medications are administered twice a day, 6-7 days a week- initially, dosage is lower and is increased to full dosage within 3-14 days.²⁷

Currently the Armenian Red Cross Society NGO, with financial support from the Global Fund through the Government of Armenia, and MSF France provide social support and food and hygiene parcels to patients undergoing intensive treatment and for taking medication under supervision to improved compliance to treatment regimens.²⁹

Financing

The necessary funding for NTP is generated through various sources, including the Global Fund, the Republic of Armenia state health budget, funds from international organizations, and other sources.^{29,35}

State Funding: The diagnosis and treatment of TB is included in the Basic Benefit Package (BBP) and is fully covered by the state budget.¹⁹ According to the Ministry of Finance of RA Decree No 127-A of 18 February 2008 and the 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 regular and DR smear positive sputum TB cases, with payment from the State set at 450,000 AMD for the 60-day treatment. The mean duration for "chronic" sputum smear positive TB case treatment is also 60 days, with budgeting per patient set at 460,800 AMD.¹⁹

For newly identified active regular, DR and "chronic" smear negative sputum TB cases, the mean treatment duration in specialized TB facilities is 50 days.¹⁹ The payment per patient is

375,000 AMD for regular and DR smear negative sputum TB cases for this group and 384,000 AMD per "chronic" smear negative sputum TB case. The treatment mean duration for TB patients with psychiatric disorders is 55 days with payment of 478,500 AMD per patient. The mean duration for TB surgical treatment is four days with payment of 48,000 AMD per patient. The mean duration for diagnostic testing is 10 days with payment of 60,000 AMD per patient. The mean duration for rehabilitation in TB sanatoriums is 50 days with payment of 300,000 AMD per patient.¹⁹ TB control in the military system is financed and organized by the Ministry of Defense.²⁸

International Financial and Technical Support: The Global Fund to Fight AIDS, Tuberculosis and Malaria has supported the Government of Armenia for TB control with the total amount of about 26,909,020 USD. This support includes the strengthening of the National TB Control Program to improve TB, MDR-TB and TB/HIV co-morbidity diagnosis, standardized treatment and quality DOTS, patient support, advocacy, communication and social mobilization, capacity of the health workforce, as well as for renovating and equipping TB facilities, procuring first and second line TB medications, lab equipment and other necessary resources.^{36,37}

Collaborating with the Government of Armenia since 2005, the Médecins Sans Frontières France (MSF France) has provided financial and technical support to strengthen DR-TB control in Armenia.²⁹ This support includes training of healthcare providers, building service infrastructure, renovation and construction, drug supplies and other activities.²⁹

The WHO and the Stop TB Partnership, through the Green Light Committee Initiative, contribute to the management of MDR-TB in Armenia by providing guidelines and second line medication.

The Government of Germany, together with its affiliate organizations Deutsche Gesellschaft für Technische Zusammenarbeit (GTZ) and Kreditanstalt für Wiederaufbau (KfW), provided financial and technical resources to strengthen TB control in Armenia during the period 2002-2009.²⁹ These resources have included laboratory and X-ray equipment, vehicles, renovation of the NTP Central Office, training of specialists in DOTS and technical assistance.²⁹

In 2001, on behalf of the Ministry of Health the International Committee of the Red Cross (ICRC) built and equipped the National Reference Laboratory and trained the staff. From 1999 to 2008 ICRC, in close collaboration with the Ministry of Justice of the Republic of Armenia, developed a policy for TB control in the prisons, financing and implementing TB control in the penitentiary system.¹⁹

Human Resource Development

<u>Pre-service training</u>: the Yerevan State Medical University (YSMU) and the National Institute of Health (NIH) run TB residency programs for physicians. The cost of these TB residency programs is heavily subsidized by the State. Between 2005 and 2008 YSMU offered one and NIH offered six TB residency positions per year.¹⁹

<u>In-service training</u>: NTP has organized training for 134 TB specialists, of which 27 received training in project management, 53 TB physicians received training in DOTS strategy and 54 laboratory technicians received specialized TB laboratory training. Twenty specialist received trainings abroad, while the rest received their training in Armenia, with assistance provided directly from the Government of Germany, from GTZ and from KFW/GOPA. MSF France has also provided training for TB specialists in the treatment of DR-TB.^{19,30}

In 2003 and 2006 the Government of Armenia approved the Unified Family Medicine and Unified Nursing Curriculums developed by USAID funding. Both curriculums include a single-day training module on TB prevention, case detection and management. From 2005 till May 2011, a total of 1,327 family physicians and 1,592 family nurses have undergone this retraining.^{38,39}

OBJECTIVES

The Center for Health Services Research and Development (CHSR) of the College of Health Sciences, American University of Armenia in collaboration with the National TB Control Program of the RA Ministry of Health and with financial support from the Armenian Medical Fund implemented the Household TB Infection Control Pilot Project. The project aimed to establish a model, where members from households with TB patients help to assure that 1) TB drugs are taken regularly, 2) side-effects and symptoms are monitored and reported, 3) identification for potentially-infected contacts for follow-up check-ups is supported, and 4) appropriate safety measures (e.g., open windows, restricted spaces for children, appropriate masks) are taken as needed.

The goal of the project was to design a national household-based intervention that integrates into the current TB control system to ultimately contribute to the reduction of failed treatments and therefore, rates of drug resistant TB, spread of TB, and diminishing the stigma of TB in the community.

The specific objectives of the project were:

- To review and summarize existing studies, international literature, and other published information on TB control in Armenia to reveal the gaps, evaluate the populations at highest risks of infection, and develop a pilot project
- To conduct qualitative study through using focus group discussions and in-depth interviews among TB patients and their family members and TB providers to inform and provide direction for the intervention
- To develop a TB training module for the TB nurses and psychologists
- To develop TB educational materials (leaflets) for TB patients and their family members
- To facilitate household trainings for TB patients and their family members in the pilot sites
- To monitor and evaluate the effectiveness of the pilot project
- To organize and conduct a Training of Trainers (TOT) course for TB nurses and psychologists in Armenia
- To share the experience with the National TB Control Program (Ministry of Health) for considering a nationwide implementation.

PRE-INTERVENTION QUALITATIVE RESEARCH

Methodology

<u>Study Design:</u> To provide direction for conducting effective intervention among TB patients and their family members the study team developed and implemented a qualitative study using focus group discussions and semi-structured in-depth interviews.

<u>Study Participants:</u> The CHSR identified key informants using purposive and convenient sampling methods to provide pertinent information for the assessment, based on key informants' experience and expertise in TB services. Five groups of participants took part in the qualitative study 1) TB outpatient centers' physicians, 2) TB outpatient centers' nurses, 3) family members of TB patients, 4) TB patients, and 5) experts from the National TB Control Program, MSF, and the social workers of the Armenian Red Cross Society.

Nineteen key informants (15 females and 4 males) participated in four focus group discussions (FGDs), facilitated by the CHSR research team. The focus groups were supplemented with five in-depth interviews. Considering the stigma associated with TB, the research team conducted only in-depth interviews with the TB patients. To optimize the program design for both urban and rural regions, and to account for differences in TB services and family culture in different regions, the research team invited representatives from both Yerevan and marzes to take part in the qualitative research.

<u>Research Instrument:</u> A semi-structured in-depth interview and focus group discussion guide was developed based on conventional qualitative research methods. The guide was first developed in English and then translated into Armenian (Appendix 1). A short demographic information form was developed to be completed by participants after each focus group discussion.

Data Collection and Analysis: Each focus group had a trained moderator and a note-taker. These roles were rotated among the CHSR research team members. All focus group discussions and in-depth interviews were transcribed. The CHSR team used standard research techniques of heterogeneity and triangulation⁴⁰, utilizing mixed – conventional inductive and directed deductive content analysis techniques for the analysis.^{41,42} The analysis section of this study was based on the results from professional judgments and experiences derived from the in-depth interviews and focus group discussions.

<u>Categorization of Study Participants:</u> Study participants were categorized into four groups: 1) *expert*, 2) *TB health care provider*, 3) *TB patient*, and 4) *family member*.

Experts were professionals employed in the TB control system and involved in implementation of TB health policies in Armenia. *TB health care providers* were doctors and nurses with professional experience working in TB outpatient centers in Yerevan and marzes. *TB patients* were people who had TB or DR TB treatment in the past. *Family members* were representatives of households of TB and DR TB patients.

The direct quotes provided in the boxes are abstracted from both in-depth interviews and focus group discussions. The individual informant identifier (e.g., Expert 1.A.) specifies the group of the participant providing the quote and indicates if the same participant 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. After each identifier, the quote is reported as a product of a focus group discussion or an in-depth interview.

<u>Ethical Considerations:</u> The Institutional Review Board of the American University of Armenia approved the study for compliance with locally and internationally accepted ethical standards (Appendix 2). All participants were informed that their participation was voluntary, that they could stop at any time and refuse to answer any question they chose, and that their anonymity and confidentiality were fully respected. After being informed of their rights, all those who chose to participate provided verbal informed consent. Audio-recording was possible only with permission of all participants; if a participant did not want to be audio-recorded, only written notes were taken. Transcripts and the final report do not contain respondents' names, positions, institutions, or any other details that could identify the participants.

Results and Discussion

Key informants from Yerevan city, Shirak, Ararat, and Armavir marzes participated in both FGDs and in-depth interviews. Fifteen participants were from Yerevan and four from marzes, with the mean age of 41. The average number of years of professional experience of TB specialists and TB experts was 12 years. About one-fifth of the study participants were males. The mean duration of the focus group discussions was 68 minutes and the mean duration of in-depth interviews was 50 minutes.

Findings

1. Basic Information and Possible Barriers for the Household Training

All study participants agreed that the training of TB patients and their families is an important part of successful TB treatment and infectious control. They believed that even though TB patients and their families receive some information from TB medical office and for many it was difficult to accept that they have TB, most patients and their families were interested in learning more about the disease, because health information provided by health care providers was insufficient.

The participants indicated that before starting a household TB program the study team should fully understand the structure and the function of the families of the TB patients and receive permission from the entire family before their participation in the program. Because some TB patients may hide their TB status from family members, it was important to know whether this was the situation in the family before moving forward with the program. In addition, participants indicated that the teams who would conduct household training for the program should be aware of the TB infectivity status (SS+/SS-) and the emotional status of the patient and his/her family members. All study participants indicated that the TB medical office's doctors were the best source of information related to TB patients and their families.

Almost all study participants from both focus group discussions and in-depth interviews indicated that the best place for the training was the home of the TB patients. They believed that the family would feel more comfortable and stress-free in their homes rather than in the TB medical offices. However, all groups of participants agreed that trainers should rigorously maintain the confidentiality of these sessions, avoiding bringing attention of neighbors and other people to the training session.

Most of the study participants recommended providing the families that would be involved in the Household TB Pilot Project training with some incentives such as food, clothes, or mobile phone recharge cards to facilitate their participation.

A TB household training project is a good idea, because generally we work with the patients (mainly with DR-TB patients) but not with family members.

Expert 1.1 Focus group discussion, Yerevan

TB patients and their family members would be eager to learn more about the disease. I am very supportive for implementing such a program. It would be a very useful intervention for TB patients and their families.

TB patient 1.1 In-depth interview, Yerevan

The more you know, the safer you are.

Family member 1.1 Focus group discussion, Yerevan

It is frightening, but in marzes you meet TB patients who receive TB treatment but do not know that they have TB. They think that they have pneumonia. No one, including doctors, inform the patients about their health status and their infectivity. Family members are especially unaware and do not know the consequences of the disease.

> Expert 1.2 In-depth interview, Yerevan

It is difficult for TB patients to accept the fact that they have TB.

TB health care provider 1.1 Focus group discussion, Yerevan

The information that the TB medical office provides to the patients is insufficient and too general. For example, when I was diagnosed I had to search the internet, look up TB in the encyclopedia and search other sources to find the information I needed and wanted to know. TB patient 1.2

In-depth interview, Gyumri

First, the social worker should receive permission from the patient to contact him/her... I had a patient who received 8-month of TB treatment but his wife didn't know.

TB health care provider 1.2 Focus group discussion, Yerevan

You should first meet the patient's TB doctor to have a complete profile on his health status and the dynamics in his family, including the knowledge of other family members concerning TB and their awareness of who has TB in the family. I don't maintain secrets from my relatives and friends about my health status; they all know that I had TB, but there could be people who want to hide their health status from other family members.

> TB patient 1.2 In-depth interview, Gyumri

The social worker should know everything about the TB patient, how many family members are there in the family and do they know that someone in the family has TB.

Expert 1.1 Focus group discussion, Yerevan

At first, the social worker should be familiar with the psychological state of the patient, after which a social worker would decide how to approach him/her.

TB health care provider 1.3 Focus group discussion, Yerevan

You should be more careful working with regular TB patients. Most first-time TB patients are aggressive and are difficult to work with. You should speak and work more carefully with these patients.

Expert 1.1 Focus group discussion, Yerevan

A social worker should know everything about the TB patient – the socioeconomic condition of the patient's family, relations within the family, and the educational level of family members – to know where to start. The social worker should also be informed about the TB patient's current sputum positive/negative status.

TB patient 1.3 In-depth interview, Yerevan

The best place for conducting training is in the houses of the patients. It is impossible to conduct training in TB medical offices because it is time consuming for both patients and TB medical office personnel.

TB health care provider 1.4 In-depth interview, Gyumri

I think working with the family in the polyclinic is not a good approach. Patients are infrequently coming to polyclinics for even a simple physical examination.

Expert 1.1 Focus group discussion, Yerevan

The best place to conduct the training is the home of the patient, where the family will feel comfortable because they are hosting the process. Do not conduct training in the polyclinic in the presence of a doctor. Medical institutions always make them feel like they are just patients. You can ask them to sit in their garden (if it is a house) and if they want, to invite other people (maybe relatives or friends) to participate in the training.

Expert 1.2 In-depth interview, Yerevan

Training definitely should be conducted in the homes. In our case, when we were informed that my husband and child had TB, it was very stressful for me. I would be more comfortable at home where I feel relaxed.

Family member 1.2 Focus group discussion, Yerevan

Do not talk to the patients in the presence of a stranger or others... Social workers must hide the reason of their visit to the TB patients' homes from neighbors and other strangers.

TB health care provider 1.5 Focus group discussion, Yerevan

Sometimes, especially in some marzes such as Shirak marz, people might not want their neighbors to know who and for what purpose someone might enter their home. That's why confidentiality should be assured. For example, some patients have said that it is better to arrive by taxi but not with a car with identifiable numbers or logos.

Expert 1.2 Focus group discussion, Yerevan

Incentives

For example, when you conducted your previous TB studies, you provided patients with mobile phone recharge cards. It was an incentive for them. It was a good idea.... or some food assistance would help energize participation.

TB health care provider 1.2 Focus group discussion, Yerevan

It will be better to give the families some clothes. Material aid will bring in more patients into the program.

TB health care provider 1.6 Focus group discussion, Yerevan

2. Training Topics and Format

The study participants indicated a list of topics that needed to be included in the training materials such as modes of TB prevention and transmission, common signs of TB and how it is diagnosed, the importance of completing TB treatment and the consequences if not completed, possible complications, the importance of frequent checkups for other family members, and infection control. Some study participants also suggested emphasizing the importance of latent TB infection treatment for prevention of TB disease for children under 15-years-of-age and regular HIV/AIDS screening for all TB patients.

According to the study participants' personal and/or professional experiences, they suggested having one or two training sessions in the same month. Both FGD and IDI participants agreed that training sessions should last no longer that an hour and include simple but thorough talks, flipchart presentations, brochures, and a question-answer session. They felt that using colorful pictures could attract the participation of children. For those TB patients or family members less willing to participate in the training, some educational materials such as booklets or leaflets could be left in their houses for further reading.

According to the study participants, though the training would be best conducted for the entire family with possible involvement of friends, personal preferences of each family should be considered. Experts believed that the training for regular TB patients and their families should be sustainable to be effective, thus should be an integral part of the national TB Control program.

It is necessary to explain what is TB and the ways it is transmitted, and that if you completely follow the directions and treatment provided by your doctor, you will be cured. It is also important to explain what happens when TB patient don't take drugs.

TB health care provider 2.1 Focus group discussion, Yerevan

First it should be explained what kind of disease TB is, second what could be done in order to prevent it, and third what should be done if you get TB.

Family member 2.1 Focus group discussion, Yerevan

When I was searching for TB information I was looking for historical information, modes of transmission, and how it could be cured. The patients should also be informed about the treatment schedule and what to expect after the treatment is completed – I mean what they should do to avoid relapses and how long they have to maintain vigilance for TB reoccurrence. TB patient 2.1 In-depth interview, Gyumri

It is necessary to inform the patients and their family members about the importance of regular checkups for other members of the household, especially children under 15 years of age and the necessity of isoniazid prophylaxes to prevent TB among these children. Teaching about personal hygiene is also important. Another important point is that we have to inform TB patients about the importance of HIV/AIDS screening.

TB health care provider 2.2 In-depth interview, Gyumri

Information could include modes of TB transmission and prevention, importance of treatment, possible side effects of medications, hygienic norms and infection control. You could also teach a breathing exercise technique... You should provide the general information in simple sentences, maybe in bullets to be more understandable and easy to remember.

Expert 2.1 In-depth interview, Yerevan

Everything about TB should be explained thoroughly...Children could be informed using pictures. Those people that don't want to participate in the training could be informed by providing them with special brochures and other materials. Let them know about the materials... Maybe he/she doesn't want to be in the training, but if you give him/her a booklet, he/she will read it.

Family member 2.2 Focus group discussion, Yerevan I think that the most effective technique is to provide brochures and to talk to TB patients and their family members personally. A very important issue is the appearance of the social workers, their knowledge level, as well as being friendly without an attitude of superiority... Talk to everyone in the family as a group at the same time. One hour once a month is enough. They [TB patients and their families] will avoid long frequent meetings.

TB health care provider 2.3 Focus group discussion, Yerevan

You can organize trainings individually or in groups. May be group training could work better, but again it depends on individual preferences of the patients and their family members.

TB patient 2.1 In-depth interview, Gyumri

These educational sessions should be agreed upon by the National TB Control Program. Having adequate knowledge does not always mean that they will use it in practice. Also, people have different mental capacities. Some people completely forget everything they were just told. It needs to be sustainable.

> Expert 2.2 Focus group discussion, Yerevan

3. TB Treatment Adherence

3.A. Problems related to TB treatment adherence for adults and children

The major difficulties related to TB treatment adherence for adults, noted by all study groups during focus group discussions and in-depth interviews, included the long duration of TB treatment and the side effects of medication. These factors reportedly contributed to depression and unwillingness of the TB patients to continue their drug treatment. The study participants indicated that after in-patient TB care patients started feeling better and sometimes they thought that they were cured, and thus stopped taking their medication.

Another problem of TB treatment adherence, as reported by many study participant groups, was access to polyclinics. The barriers for TB patients visiting polyclinics included lack of time because of work, fear of being recognized by other people, laziness, not realizing the importance of not interrupting treatment, lack of funds for transportation to the polyclinic, and lack of means of transportation to the polyclinics in remote areas.

However, almost all TB patients participating in this study indicated that those patients who clearly understood the seriousness of their disease and wanted to be cured were highly adherent to treatment and were able to overcome barriers.

All study participants agreed that adherence to TB treatment by children was not a problem because mothers in Armenia took full responsibility and were very protective of the children and their health. They also noted that children would have TB complications and TB drugs side effects less often than adults.

Adults

Adherence to treatment is the most difficult part of the treatment process. Because when a patient feels better (doesn't have cough or fever) but has drug side effects, regardless what you say, he/she may give up taking the TB medicine thinking that his/her discomfort is due to the medicine. What can I do when a patient is vomiting right in your TB medical office 10 minutes after taking the drugs? Moreover, the psychological factor is also crucial – can you imagine taking these medicines for 18 or 24 months. It is much easier to have a treatment plan on paper, than to put it into action!

TB health care provider 3.A.1 Focus group discussion, Yerevan

It does not matter how aware the patient is, at some point he/she wants to give up... I notice that it often happens on the fourth month of treatment when they [patients] consider themselves cured and try to quit their treatment.

Expert 3.A.1 Focus group discussion, Yerevan

The main difficulty is the long duration of treatment. Sometimes patients have nausea, liver disorder, allergies, etc., as side effects from the medication. Because of these difficulties and because TB symptoms on the most part are disappearing after in-patient care, they do not want to continue their treatment. This is the most critical time to explain to patients and their families the importance of completing treatment.

Expert 3.A.2 In-depth interview, Yerevan

TB treatment can be very depressing for patients. Many patients stop treatment midway. This is the most important time that they need support from their family members and TB doctors. TB patient 3.A.1 In-depth interview, Gyumri

Sometimes patients do have allergies from the medications. We are using four medications combined in one pill and sometimes one of the ingredients can cause allergies, depending on the individual. In that case we change the treatment regiment, trying to exclude the medication that caused allergies for the patient.

TB health care provider 3.A.2 In-depth interview, Gyumri

When my husband was told that he should be in the hospital for TB treatment for 50-days he was depressed and refused hospital treatment, although he agreed to take his TB medicines at home.

Family member 3.A.1 Focus group discussion, Yerevan The most serious barrier for patients going to the polyclinic for TB medicines is psychosocial. For example, when my husband was receiving TB treatment he attempted to visit the polyclinic without anybody noticing him. And he also refused to accept the food aid – he did not want to be noticed getting it and also told me not to accept it.

Family member 3.A.2 Focus group discussion, Yerevan

...It is difficult for men to go to the polyclinic and take the TB medicine. It's men's psychology. At first, they are lazy; the wife must give everything to them "on a plate". Also they are too busy because they work – they have to work to survive. In addition, people from marzes lack transportation to go to the polyclinics for their medications.

Family member 3.A.3 Focus group discussion, Yerevan

The government has to cover transportation costs of patients to support DOT, because sometimes a patient does not have 100 drams to come to the polyclinic for their medications. Expert 3.A.2 In-depth interview, Yerevan

The most difficult problem is visiting TB medical office daily to acquire medicines. TB health care provider 3.A.3 Focus group discussion, Yerevan

I personally did not have any difficulties during my treatment. I think generally it is the patient's responsibility to take the medicine regularly, if the patient clearly understands the seriousness of the disease and the necessity for taking the prescribed TB drugs regularly and ultimately wants to be cured, then there are no obstacles that will stop them from following the treatment plan.

TB patient 3.A.2 In-depth interview, Yerevan

Children

Adherence for children to TB treatment is not a problem, because mothers take responsibility for treatment of their children and all mothers want their children to be healthy. Usually, children also do not have side effects from medications.

Expert 3.A.2 In-depth interview, Yerevan

Adherence for children is not a problem. The mother is the central caregiver for the child and is responsible for his/her health. All mothers think first about their children before anyone else, so they will do anything to keep their children healthy.

> TB health care provider 3.A.2 In-depth interview, Gyumri

Children tolerate the side effects of TB drugs better. It's much easier to work with children than with adult patients.

TB health care provider 3.A.1 Focus group discussion, Yerevan

Working with children with TB is much easier because the mothers take full responsibility... I

have these patients – a mother and her two children of 8 and 9 years-of-age. The mother directed everything and assured that the children took all of their TB medicines on schedule because the mother was very responsible.

Expert 3.A.3 Focus group discussion, Yerevan

I don't have any problems with treating child-patients; they are very obedient. TB health care provider 3.A.4 Focus group discussion, Yerevan

3.B. Role of family in treatment adherence of TB patients

All study participants emphasized the important role of the family in treatment adherence for TB patients. It was difficult for both TB patients and their family members to deal with the stresses and pressures of this disease, causing serious emotional strains and barriers between TB patients and their families. Study participants indicated that it was important to provide family members with the necessary practical information and understanding so that they can support and encourage the TB patient to overcome the difficulties related to TB treatment adherence. Moreover, participants indicated that it was important that the patients and their families understand that full treatment adherence would also protect other family members from developing the disease.

The study participants identified the best candidates in the family for supporting the TB patient for full treatment adherence. The patient's spouse, followed by the patient's child (if the TB patient was married) and then possibly the patient's mother (if he/she was not married) were all identified as possible candidates. However, all key informants agreed that it depended on the personal relationships and power structures within a family.

Sometimes family members don't understand what is happening. When a TB patient returns home from the hospital and finds family members are very depressed, his health becomes worse. Family members should know how to support the patient – the disease forms barriers between family members and patient.

Expert 3.B.1 Focus group discussion, Yerevan

TB patients do not complete their treatment in most cases. Family members of the patient can help in treatment adherence.

TB health care provider 3.B.1 Focus group discussion, Yerevan

I have spent three months in the TB hospital and I was in ambulatory treatment for another four months. It is very long time, especially during the treatment in the TB hospital; I needed

the support of my family very much, though the doctors were very kind, helpful, and supportive... Patients should have ongoing support from family members. When patients returns home, it means that they are past the most difficult part of the treatment and family members should help the patients understand that they have already overcome 80% of the difficulties and that only 20% is left to complete, for example. They should also remind the patient that he/she has to continue to take the TB medicines to be cured. The patient might not take the medicine every day in the TB medical office because he/she forgets or misses a dose. Family members could help remind the patient to take their drugs.

> TB patient 3.B.1 In-depth interview, Gyumri

The family should support the TB patient psychologically. They should also explain to the patient the necessity of taking their medicine.

Family member 3.B.1 Focus group discussion, Yerevan

All family members usually understand the seriousness of the disease and support the patients in taking the drugs regularly to be cured effectively, since they realize that the patient's successful treatment can affect their health as well.

TB patient 3.B.2 In-depth interview, Yerevan

If a man [TB patient] *does not listen to his wife, let the mother-in-law* [mother of the TB patient] *explain to him or influence him. It should be someone whose opinion is respected by the patient.*

Family member 3.B.1 Focus group discussion, Yerevan

Of course, family members can help the TB patient in treatment adherence. Sometimes it could be the mother, sometimes wife/husband; even the grandchildren could play a role. TB health care provider 3.B.1 In-depth interview, Gyumri

If a patient is married, then the wife/husband could help, if not, then parents, depending on the individual family. Sometimes children can play a role in some situations, because wives/husbands sometimes argue with each other but they are both more tolerant with the children.

TB patient 3.B.1 In-depth interview, Gyumri

I suppose that mothers would have an influence on the patients to take their medicine. Or some person that is respected by the patients, it depends on the relationships within the family. We can't say who it would be for every family.

> TB patient 3.B.3 In-depth interview, Yerevan

3.C. Role of health care providers and government in treatment adherence of TB patients

Though all study participants agreed on the important role of family for psychological support and encouragement of TB patients in treatment adherence, they emphasized that taking TB drugs should be under control and observation of health care providers. Key informants also noted that it was possible to organize treatment in the homes of the TB patients to make it easier for them, but even in these cases the presence of health care providers was necessary when patients took the TB drugs. Many participants indicated that trust and respect of the health care provider strengthened the TB patients' adherence to treatment.

Former TB patients participating in the study strongly stressed that if patients did not understand the importance of complete adherence to TB treatment and refuse to follow the treatment plan, there should be legal compulsory actions forcing treatment for these patients to control the spread of TB disease and protect society. Participants also indicated that some financial support for regular TB patients from the State would also strengthen TB treatment adherence.

There are currently no laws in Armenia for compulsory TB treatment and no financial support from the State for regular TB patients and their families, though some financial support was provided to MDR-TB patients and their families.

In reality, no one in the family can be ultimately responsible for the TB patients to take their drugs...We don't give the medicine to the patient to take it home. They take the medicine right in our TB office in the presence of a nurse and me. We don't have permission to let patients take the drugs home. Moreover, when they forget to come to the polyclinic, we call them and ask them why they didn't come, what is the problem, and then we make a decision on what to do then.

Just in those situations when a patient really can't come to the polyclinic for his/her TB drugs we make special arrangements. For example, my patient's relative died and he had to leave Yerevan for a while. We received special written permission from the chief to provide him with TB drugs for one week. After his return he continues his treatment in the polyclinic, as usual.

TB health care provider 3.C.1 Focus group discussion, Yerevan

The family cannot do anything directly to make sure the TB patient takes the drugs, because the patient takes the tablets in the polyclinic; the family can never be sure that they really took the drugs.

TB health care provider 3.C.2 In-depth interview, Gyumri The best assurance for adherence to treatment is to give the drugs at the polyclinics.

TB patient 3.C.1 In-depth interview, Yerevan

Of course it would be great if the medicine is given at home to make the treatment easier for the patient, but the doctor should direct it; for example, with visits by the doctor or nurse – otherwise, it will not work...

If the doctor is really good (as my doctor was), he/she becomes a family member to some extent. The doctor can have a relationship with the patient such that the patient takes the medicine out of respect for the doctor.

Family member 3.C.1 Focus group discussion, Yerevan

Financial support is the best way to encourage the patient... I do not think that someone could play any substantial role in changing the behavior of the patient. If a patient is responsible, he will take the tablets without outside support, if a patient is irresponsible – nobody will force them to do something that they don't want to do. Among TB patients we have many criminals who ignore outside opinions and suggestions – it is a very difficult group of people to work with.

TB health care provider 3.C.2 In-depth interview, Gyumri

... With compulsory treatment [using the police] many more TB cases would be treated successfully and the spread of disease would be reduced.

TB patient 3.C.2 In-depth interview, Yerevan

Doctors should work with the police. We don't have an alternative. A non-adherent patient will start to infect other people. This kind of patient should be isolated and treated through the adoption of a special TB compulsory treatment law.

TB patient 3.C.1 In-depth interview, Yerevan

4. TB Patient Household Infection Control

Both FGD and in-depth interview participants indicated that for sputum smear negative TB patients that were in their ambulatory treatment phase, household infection control should be included in everyday household duties. Following hygienic standards including sneezing and coughing in disposable napkins, regular ventilation of rooms, disinfection of places where TB bacilli could survive for a longer time, and regular checkups for persons who had contact with a TB patient who was infectious at the time were mentioned as important components of infection control.

Though some study participants believed that isolation of TB patients from other household members would negatively affect relationships within the family, others reported that many patients isolate themselves from family to prevent the spread of infection. One health care provider even reported that she had a patient who placed an ultraviolet lamp in the house to protect other family members from infection.

Many study participants stated that, in a contrast to TB patients who take special care to protect the health of their family members, there were also TB patients who did not adequately protect the health of others. Study participants indicated that some of those TB patients behave in this fashion because they were unaware of the threat to other people, while others cared less if they infected others with TB, including sometimes their own children.

In the opinion of the majority of the study participants the responsibility for infection control in the household would be best carried out by the woman who did most of the housekeeping. Others thought that the person should be chosen by the family, while some study participants believed that family members should share equal responsibility for infection control.

If you isolate the TB patient in his home he will lose your trust. When you do your everyday household duties such as washing the dishes and cleaning the toilet with disinfectant, then you don't need to do any extra work to prevent the spread of TB.

Family member 4.1 Focus group discussion, Yerevan

TB patients should follow sanitary standards – keeping individual items such as towels, dishes, and clothes separated from other family members' items and regularly ventilating the house. There is no need to do anything because being sputum smear negative he/she cannot infect anybody.

TB patient 4.1 In-depth interview, Gyumri

To prevent other family members from acquiring TB, they should first learn how to disinfect the places where the TB bacilli could survive for a longer time, for example carpets, clothes, bedding of a patient, bathroom, towels, or dishes. Second – ventilate rooms where a patient is coughing and, of course, let in sunlight when possible. Another important thing is to teach the elementary standards of hygiene to cover the mouth while coughing or sneezing.

> Expert 4.1 In-depth interview, Yerevan

The most important thing is to wear a mask. I think that if the transmission is through the air, the masks are enough. A patient could also somewhat remove himself from other people. He can also sleep separately, because a patient may cough or sneeze during the night. Wearing a mask might be uncomfortable during sleeping. If a patient values the health of his family he

should make an effort to protect them.

TB patient 4.2 In-depth interview, Yerevan

I cared very much about protecting my family and friends... I separated all of my personal items and dishes until I successfully completed my treatment for TB and received confirmation that I was cured. I even avoided meeting with my relatives and friends during my treatment when possible.

> TB patient 4.3 In-depth interview, Yerevan

One of my patients bought an ultraviolet light for home to control the spread of TB infection, can you imagine?

TB health care provider 4.1 Focus group discussion, Yerevan

It is important to be open with everyone with whom you had close contact before and after the diagnosis, so they could also be screened for TB and if they have TB they can start treatment. I was diagnosed in Moscow and I informed about my TB disease all of those with whom I worked and lived at that time and asked them to go for checkups. I also told my family and relatives in Armenia after returning and beginning my treatment. Thank God, nobody was infected because of me.

> TB patient 4.1 In-depth interview, Gyumri

We always screen family members. We teach them to ventilate the house and keep their homes clean, put under the sun carpets and other things.

TB health care provider 4.2 Focus group discussion, Yerevan

If a patient doesn't want to do anything to prevent the spread of TB disease in the household, it is because he/she is not informed.

Family member 4.1 Focus group discussion, Yerevan

Some TB patients become very self-centered. However, we have other patients that completely isolate themselves to a point of being pathological.

TB health care provider 4.3 Focus group discussion, Yerevan

I had a patient that was sputum positive and stayed at home. I told him that he is contagious and can infect his three daughters; he responded that he got infected, so he will let his daughters also get infected – it did not matter to him. We worked with him for a long time; however, we couldn't change his ways. Later he died and his daughters developed TB.

Expert 4.2 Focus group discussion, Yerevan

Everybody should take responsibility for infection control, but it depends on the family dynamics. Each family could select a person for taking more responsibility, so it should be decided by each family.

TB health care provider 4.4 In-depth interview, Gyumri

I think [selection of a family member] the same person could take the primary responsibility for infection control who is the primary supporter for treatment adherence for the patient. Whoever it is, he/she should encourage the TB patient to have patience.

TB patient 4.1 In-depth interview, Gyumri

In Armenian families women are responsible for cleaning in the home. We explain to them what should be done to prevent the spread of disease and basically women take the responsibility.

Expert 4.2 Focus group discussion, Yerevan

All family members should take equal responsibility for infection control measures in the household.

TB patient 4.3 In-depth interview, Yerevan

5. Monitoring of the Household TB Infection Control Pilot Project

Only participants who were experts and TB health care providers, including doctors and nurses, were asked about how to monitor the pilot project. The participants suggested developing a monitoring form to be distributed among training participants to watch the quality of household trainings and to make sure that social workers are actually conducting the trainings. To measure the effectiveness of the household training, they recommended conducting baseline – follow -up tests.

The experts and health care providers recommended maintaining confidentiality of monitoring activities. Some participants opposed spot-checks through telephone calls to TB patients' families, because it might ruin the trust of the family in the social worker.

In addition, some study participants recommended using the medical record of TB patients to compare the success of adherence before and after training, as well as evaluating treatment outcomes.

...Patients can sign a paper when they receive their training materials including date, the topics of training, and identification number that would be given to every participant instead of using names [for confidentiality].

TB health care provider 5.1 Focus group discussion, Yerevan To monitor the project, you can use pre-post testing. A difference in the results will measure the effectiveness of the training... I think that calling families for checking whether they received the training is not the best approach, because by calling you may harm the trust in the social workers by the families.

> Expert 5.1 In-depth interview, Yerevan

A month following the education [Household TB Pilot Project training], an evaluation test should be conducted to understand whether the training participants learned the material. Moreover, training sessions and evaluation tests should be conducted by different people.

Expert 5.2 Focus group discussion, Yerevan

From treatment outcomes of TB patients who participated in the pilot study you can check the quality of the work by the social worker. If a patient is cured, it means that the social worker worked well with the family.

TB patient 5.1 In-depth interview, Yerevan

If patients who participated in the training did not take medicines properly before the training and changed their behavior after the training, with improved adherence to treatment, it will mean that the training was successful.

TB health care provider 5.1 Focus group discussion, Yerevan

There is some adherence percentage registered by the doctor in the journal for each TB patient. You can use this percentage by comparing it before and after training.

Expert 5.2 Focus group discussion, Yerevan

Conclusion from pre-intervention qualitative research

The main findings of this qualitative study that provided direction for conducting effective intervention among regular TB patients and their family members include:

- Most patients and their families are interested in learning more about TB
- The study team should fully understand the structure and the function of the families of TB patients and receive permission from the entire family before their participation in the program
- For effective counseling, trainers should be aware of the TB infectivity status (SS+/SS-) and the emotional status of the patient and his/her family members
- The best place for training is the homes of the TB patients
- Trainers should rigorously maintain the confidentiality of the training sessions
- Providing the families with some incentives will facilitate their participation

- The choice of the best candidates in the family for supporting the TB patient depends on the personal relationships and power structures within a family
- Training materials should include the following topics: modes of TB transmission and how to prevent it, common signs of TB and how it is diagnosed, the importance of completing TB treatment and the consequences if not completed, possible complications, the importance of frequent checkups for other family members, infection control, and latent TB infection treatment
- Training session should be conducted once or twice in the same month, last about one hour or so and include simple but thorough talks, flipchart presentations, brochures, and a question-answer session
- Major difficulties related to TB treatment adherence include the long duration of TB treatment, the side effects of medication, thinking that TB is cured after in-patient treatment, and problems with access to polyclinics
- Taking TB drugs should be under control and observation of health care providers
- For sputum smear negative TB patients that are in their ambulatory treatment phase, household infection control should be included in everyday household duties
- The responsibility for infection control in the household would be best carried out by a woman who does most of the housekeeping
- The training for regular TB patients and their families should be sustainable to be effective, thus it should be an integral part of the national TB program
- To watch the quality of household trainings and to make sure that the trainers are actually conducting the trainings a monitoring form should be developed and distributed among training participants
- To measure the effectiveness of the household training baseline follow -up tests have to be conducted
- To compare the adherence to treatment before and after the training [if possible], and evaluate treatment outcomes via the medical records of TB patients.

INTERVENTION 1

The findings from the document review and from the qualitative study informed and provided directions for the planning and implementation of the Household TB Pilot Project. The intervention included counseling sessions about the importance of 1) taking TB drugs regularly, 2) monitoring and reporting side-effects and symptoms, 3) monitoring and reporting of any TB symptoms among other family members and contacts for follow-up check-ups, 4) taking appropriate safety and prevention measures, and 5) providing psychological support for TB patients.

Training of Trainers (TOT)

Counseling team

The experts of the National TB Control Program and Global Fund Implementation Unit of the RA Ministry of Health emphasized the importance of providing professional psychological support to TB patients during the intervention. Given the expert opinion, sensitivity of the topic, the stigma of TB disease, and the importance of confidentiality for TB patients, the CHSR research team hired two TB nurses and two psychologists to work in the Household TB Infection Control Pilot Project. These specialists already have had an ongoing relationship with and trust of the TB patients and their family members and they took a training of trainers (TOT) course for counseling.

TB nurses and psychologists participated in one-day TOT which covered the aims of the study, recruitment of participants, assurance of confidentiality, the consent form, and the protocol of the household counseling sessions. Interactive teaching methods were used throughout the TOT.

The CHSR team developed a training package using educational materials from the US Center for Disease Control and Prevention (CDC), the World Health Organization (WHO) and the NTP of the Ministry of Health of Armenia. The main topics of the TOT module included: 1) History of TB, 2) TB Transmission, 3) Pathogenesis of TB, 4) TB Disease, 5) Diagnosis of TB, 6) Treatment of TB Disease, 7) Adherence to TB Treatment, 8) Drug-Resistant TB (DR-TB), 9) Infectiousness, 10) Infection Control, and 11) Psychological and Social Support for TB Patients (Appendix 3). During the TOT the CHSR research team and the trainers reviewed, discussed and finalized the counseling materials to assure their quality and relevance to the target population. Three CHSR expert trainers conducted the full-day TOT session. TOT sessions prepared training participants for answering questions posed by the TB patients and their family members during the counseling sessions. The trainers learned their role and specific methods in educating the patients and other household members about TB, the importance of reporting symptoms and taking TB medication as prescribed, managing of household infection control, and the necessity of the psychological support within the family of TB patients. In addition, the trainers were educated on how to conduct baseline – follow -up surveys of TB patients and their family members who participated in the counseling sessions.

The trainers received the Household TB Pilot Project Manual, brochures for TB patients and their family members (Appendix 4), leaflets, a flipchart, and TB brochures, developed by the CHSR research team for distribution to the families during the household counseling. At the end of the TOT session two teams of trainers, with a nurse and a psychologist in each team, were formed to conduct the educational and socio-psychological household counseling for TB patients and their family members in pilot sites.

Counseling of TB patients and family

The pilot project involved TB patients and their family members from Shirak, Kotayk and Aragatsotn marzes (Figure 1). Shirak and Kotayk marzes were selected for the household trainings based on their relatively high TB and MDR-TB notification rates, the number of TB patients (Table 2), feasibility, and the recommendations of NTP. Aragatsotn marz is located between Shirak and Kotayk marzes; it was feasible to include all the TB patients from this marz in the pilot project.

Figure 1. Map of the Republic of Armenia and Nagorno-Karabakh (blue line marks the Aragatsotn, Kotayk and Shirak marzes selected for the Household TB Pilot Project)



Table 2. Population size and TB statistics by marzes of Armenia, January 2011.^{24,43,44}

	Total population	TB notification rates	Number of	f TB patients
Marz	x 1,000	per 100,000	Regular TB	MDR TB
Aragatsotn*	142.4	37.4	41	48
Ararat	280.4	39.8	122	137
Armavir	285.9	44.3	150	159
Gegharkunik	242.4	35.5	86	90
Kotayk*	282.1	38.8	129	135
Lori	282.1	34.8	104	114
Shirak*	282.0	40.4	158	162
Syunik	152.9	87.6	160	163
Tavush	134.6	38.7	70	73
Vayots Dzor	56.0	32.3	19	20
Yerevan	1116.6	40.8	510	539

*Marzes selected for the pilot project.

After the TOT session in the American University of Armenia, one of the TB psychologists was tasked with calling all TB outpatient centers of Aragatsotn, Kotayk, and Shirak marzes that have been enrolled in the pilot project according to the list provided by the NTP, and introducing the project to the doctors of TB outpatient centers (Appendix 5).

All regular TB patients from Aragatsotn, Kotayk, and Shirak marzes, who at the time of the training were receiving ambulatory TB treatment and were able to understand Armenian were considered eligible to participate in the pilot household training project. Family members of

the selected TB patients, their friends, neighbors and relatives, who understood Armenian, were also eligible for the trainings.

TB physicians and nurses from the outpatient centers contacted their eligible TB patients and informed them about the trainings. With the permission from the TB patients, and using the information obtained through the outpatient centers about the days and hours when the patients would do their regular visits to the outpatient TB centers, the trainer prepared a calendar of patients' visits for each TB center. This calendar was divided among two teams of trainers for their visits to the outpatient TB centers and their first meetings with the TB patients in the selected three marzes (Appendix 6).

To protect the training teams from TB infection and to develop a profile of the TB patients and their families, some information on infectivity status of TB patients and their family structure was obtained from TB outpatient centers. TB doctors provided information about whether household members of the TB patient were aware of his/her TB disease. Data was also collected on TB patient diagnosis and disease status (SS+/SS- and regular TB/DR-TB), the number and outcomes of his/her previous TB treatments, number of TB patients in the household, and contact information. This information provided greater safety for the trainers who conducted counseling of TB patients and their family members.

Two teams of trainers worked in the project simultaneously. One of the teams began operations in the Kotayk marz, while the other worked in Aragatsotn marz. After completing activities in these two marzes, the teams began working in Shirak marz. Based on the schedule, the trainers visited the TB centers and met the regular TB patients individually. First, they presented the project and provided the consent form to the patients. After the patient consented to participate, trainers tried to understand the patient's needs and assess his/her emotional state and relations with family members using the interview guide for TB patients developed by the CHSR research team (Appendix 7).

If during the interview it became evident that all members of the patient's family knew about his/her disease and if the patient expressed the desire for all family members to receive the TB counseling, then the appropriate place, date and time was arranged with the patient for the counseling session. If the patient was unwilling for all family members to participate in the

counseling session, the trainer tried to find out who would be participating and set a convenient place, date and time for the counseling session.

Because of the stigma associated with TB, the need to protect confidentiality, and patients' preference, the majority of counseling sessions were conducted in the homes of TB patients, at the times when the visitors are least expected. Only few sessions were conducted in the TB outpatient centers, at the request of the TB patients and upon permission of the centers' administration and the TB physicians. All participants learned from the consent form that their participation was voluntary, that they could stop counseling at any time and refuse to discuss any topic or answer any of the questions, and that their anonymity and confidentiality were fully protected (Appendix 8).

To assure the high quality of counseling sessions, the CHSR research team performed regular spot-check visits and calls.

Hundred and fourteen households of TB patients were eligible to participate in the household counseling according to the eligibility criteria set by the CHSR research team. Twenty two of these households were in Aragatsotn marz, 38 in Kotayq, and 54 in Shirak. Of 114 TB patients, 66.7% agreed to meet the trainers at the outpatient TB centers. Table 3 presents the numbers and reasons for failure to contact or refusals when the trainer contacted the potential participants by telephone.

Calls					
Results	Aragatsotn (N=22)	Kotayk (N=38)	Shirak (N=54)	Total (N=114)	
	% (n)	% (n)	% (n)	% (n)	
Agreed to be contacted	90.9% (20)	71.1% (27)	53.7% (29)	66.7% (76)	
Refusal	(0)	5.3% (2)	(0)	1.8% (2)	
Not eligible for the counseling	(0)	7.9% (3)	46.3% (25)	24.6% (28)	
Deceased	4.6% (1)	5.3% (2)	(0)	2.6% (3)	
No contacts available	4.6% (1)	(0)	(0)	0.9% (1)	
Out of the country	(0)	10.5% (4)	(0)	3.5% (4)	

Table 3. The results of initial recruitment of potential participants through telephone calls

Table 4 presents the results of the second stage of recruitment for household counseling conducted by the two teams of trainers in TB outpatient centers. Of 76 TB patients from all three marzes who were approached by the trainers at TB centers, 72.4% agreed to participate

and permitted to contact their family members for the counseling, 15.8% refused to participate in the counseling session, and 11.8% were found to be not eligible for the study.

moutpatient 1D centers				
Results	Aragatsotn (N=20)	Kotayq (N=27)	Shirak (N=29)	Total (N=76)
	% (n)	% (n)	% (n)	% (n)
Agreed for counseling	40% (8)	88.9% (24)	79.3% (23)	72.4% (55)
Refusal	25% (5)	3.7% (1)	20.7% (6)	15.8% (12)
Not eligible for the counseling	35% (7)	7.4% (2)	(0)	11.8% (9)

 Table 4. The results of the face-to-face recruitment meetings with potential participants in outpatient TB centers

The total number of participants for the counseling sessions was 136. The teams of trainers were able to schedule counseling sessions with 55 TB patients and 81 family members in Aragatsotn, Kotayk, and Shirak marzes (Table 5).

Table 5. Participants of counseling sessions						
	Aragatsotn	Kotayk	Shirak	Total (N=136)		
Results	(N=26)	(N=61)	(N=49)			
	% (n)	% (n)	% (n)	% (n)		
TB patients	30.8% (8)	39.3% (24)	46.9% (23)	40.4% (55)		
Family members	69.2% (18)	60.7% (37)	53.1% (26)	59.6% (81)		

Table 5. Participants of counseling sessions

Two teams of trainers, each consisting of a psychologist and a TB nurse, conducted eight household counseling sessions for 26 participants in Aragatsotn marz, 24 counseling sessions for 61 participants in Kotayk marz, and 23 counseling sessions for 49 participants in Shirak marz. Overall the trainers conducted 55 household counseling sessions for 136 participants (55 TB patients and 81 family members) by November 2012 in the pilot sites.

The counseling sessions lasted for about 90 minutes on average. The material presented during the sessions was based on the AUA CHSR training manual (Appendix 3) and the TB flipchart developed by the NTP. During the counseling sessions, the trainers were using simple examples and comparisons in order to make the counseling sessions more interesting for the participants. They were encouraging participants to ask questions and engage in interactive discussions about TB. They were frequently verifying if the material was comprehensible and understandable to the trainees.

On average, each team of trainers conducted two to three counseling sessions per day. At the end of the sessions the trainers distributed TB brochures and mobile phone recharge cards to the participants, so that they could have written materials about TB and could contact the CHSR study team in case if they had questions. In addition, the trainers left a box of chocolate to TB patients and their family members as a sign of appreciation of their participation.

INTERVENTION 2

Training for nurses working in TB outpatient centers in Armenia

In addition to the TOT session for the teams of the Household TB Pilot Project trainers who conducted counseling in Aragatsotn, Kotayk, and Shirak marzes, CHSR organized a one-day "Educational and socio/psychological support for regular TB patients and their family members" TOT session for all TB nurses working in all 72 TB outpatient centers in Armenia. This session was organized to address the deficiencies in TB evidence-based knowledge and skill-sets for effectively working with TB patients and their families among TB nurses, which were highlighted during the household counseling sessions.

The team of trainers included three CHSR TOT expert trainers, who collaborated with the experienced TB psychologist and TB nurse, who participated in the TOT session in the past and gained extensive field experience during the pilot project in three marzes of Armenia. Specific examples from the pilot project were used during the TOT sessions for TB nurses. To ensure effective learning and communication of participants, CHSR organized three separate sessions with 17-18 nurses participating in each session.

The total number of nurses who participated in the TOT sessions was 52 nurses working in TB outpatient centers from all the marzes of Armenia. They participated in the "Educational and socio/psychological support for regular TB patients and their family members" TOT sessions improving their TB-related professional knowledge and acquiring new skill-sets for working with TB patients and their families. At the end of the training sessions participants evaluated a training course by filling out a feedback form (Appendix 9). All trainees received a training handouts and a certificate of course completion.

EVALUATION OF INTERVENTIONS 1 AND 2

Methodology

Intervention 1: Counseling of TB patients and their family members

<u>Study design</u>: The CHSR team conducted a self-administered baseline – follow -up knowledge and practice panel survey of all training participants to evaluate the influence of the Household TB Infection Control Pilot Project on participants' knowledge, treatment adherence, infectious control, communications with outpatient TB specialists, and socio-psychological support within the family of TB patients.

<u>Inclusion criteria:</u> TB patients and their family members from Aragatsotn, Kotayk, and Shirak marzes, who were enrolled in the household counseling sessions, were able to read and write in Armenian, and were 18 years old and above were eligible to participate in the baseline – follow -up evaluation surveys. These additional criteria meant that not all of the counseling session participants were eligible for the baseline – follow-up evaluation surveys.

<u>Survey Instrument:</u> The CHSR team developed two study questionnaires based on the CHSR counseling package and similar instruments used for other TB assessments. One survey instrument was used to collect information from TB patients and the other one from family members. Both questionnaires had two main sections on TB related knowledge and practice, and several questions on TB stigma and socio-demographic characteristics of the participants. To make baseline and follow-up data comparable the same questionnaires were used for the baseline and follow-up survey (Appendix 10). In addition to the survey instruments, the CHSR team developed a journal form in English and Armenian to calculate the response rates (Appendix 11).

<u>Data Collection and Entry:</u> The trainers conducted the baseline data collection right before the start of the household counseling session. One month after the counseling session, the follow-up data collection took place. To minimize the risk of interviewer bias, trainers who conducted the baseline data collection and counseling in certain households did not visit the same households for the follow-up data collection. Instead, they interviewed the TB patients and their family members where the counseling was provided by their colleagues from the other team. All the participants completed the self-administered questionnaires in private; mainly at home, with only a few completed in the TB outpatient centers, at the request of the patient.

The CHSR research team double-entered the data collected from TB patients and their family members into SPSS 16 statistical package and cleaned the data before the analysis.

Data Analysis: Data analysis was done using SPSS 16 and Stata 10 statistical software packages. Basic descriptive analysis (means, frequencies, odd ratios, and standard deviations) was carried out for the baseline and follow-up data. To test the differences in proportions between baseline and follow-up the McNemar Chi-Square test for two related samples was used. To test the difference between means of continuous variables at baseline and follow-up the paired-samples t-test was used. Two-samples independent t-test was used to test the difference in means between the TB patients and their family members.

To assess the level of knowledge of TB patients and family members about TB before and after the counseling session, the cumulative knowledge score was calculated based on 28 knowledge items in the questionnaire. The mean percent cumulative knowledge score was calculated based on the proportion of correct answers.

TB patients' treatment outcomes

Over the next four months after the intervention, in collaboration with the local TB outpatient centers of Aragatsotn, Kotayk, and Shirak marzes, the CHSR research team collected data on treatment outcomes of TB patients who started their ambulatory treatment in October-November-December (4th quarter) 2012 and who received household counseling in November-December 2012. This data was extracted from medical records of TB patients kept in TB outpatient centers.

To evaluate the true impact of the pilot project on the TB treatment outcomes, the research team compared TB treatment outcomes data from the study participants with the official NTP statistics on treatment outcomes of other TB patients from the same marzes who received their ambulatory treatments in October-November-December (4th quarter) 2011.

Intervention 2: TOT of outpatient TB center nurses

To evaluate the quality of the TOT sessions organized for 52 nurses of TB outpatient centers, the CHSR team developed a short questionnaire. This questionnaire included six evaluation questions scaled from one to five and one open-ended question for participants' suggestions and recommendations.

At the end of the training sessions nurses of TB outpatient centers, evaluated the training. Sixteen participants of the first training session gave only a verbal feedback and 36 participants of two other sessions completed the evaluation forms at the end of the sessions. The research team assured anonymity and confidentiality of the information provided by the TB nurses.

Results

1. Intervention 1: Counselling of TB patients and their family members

<u>Response rates</u>: Since the eligibility criteria for participation in the TB household counseling session and for participation in the baseline – follow -up surveys were different, some counseling session participants did not take part in the evaluation. Overall, 123 of 136 eligible counseling session participants (90.4%) completed the baseline survey. The response rate was 98.2% among TB patients and 85.2% among family members. Among those 13 participants (9.6%) who did not complete the baseline survey, 7.4% were not eligible to participate (were younger than 18 or could not read and write Armenian), and three (2.2%) refused to participate because they knew in advance that they could not participate in the follow-up (Table 6).

Results		Aragatsotn (N=26)	Kotayk (N=61)	Shirak (N=49)	Total (N=136)
		% (n)	% (n)	% (n)	% (n)
Completed survey		100% (26)	80.3% (49)	98.0% (48)	90.4%(123)
	TB patient	30.8% (8)	49.0% (24)	45.8% (22)	43.9% (54)
	Family member	69.2% (18)	51.0% (25)	54.2% (26)	56.1% (69)
Not eligible for sur	vey	(0)	14.8% (9)	2.0% (1)	7.4% (10)
	TB patient	(0)	(0)	100% (1)	10.0% (1)
	Family member	(0)	100% (9)	(0)	90.0% (9)
Refusal		(0)	4.9% (3)	(0)	2.2% (3)
	TB patient	(0)	(0)	(0)	(0)
	Family member	(0)	100% (3)	(0)	100% (3)

Table 6. Baseline survey participation

About 89% of baseline survey participants were also involved in the follow-up evaluation. Table 14 presents the numbers and reasons for refusal at the follow-up survey. Overall, 109 of 136 eligible participants (80.2%) completed the follow-up survey. Response rate was 94.6% among TB patients and 70.4% among family members. In addition to those who did not complete the survey at baseline, seven (5.7%) refused to participate and another seven were not available at the time of the follow-up evaluation (were out of the country or not at home) (Table 7).

Survey				
Results	Aragatsotn (N=26)	Kotayk (N=49)	Shirak (N=48)	Total (N=123)
	% (n)	% (n)	% (n)	% (n)
Completed survey	84.6% (22)	91.8% (45)	87.5% (42)	88.6%(109)
TB patient	36.4% (8)	51.1% (23)	50.0% (21)	47.7% (52)
Family member	63.6% (14)	48.9% (22)	50.0% (21)	52.3% (57)
Not available at the time of survey	15.4% (4)	(0)	6.3% (3)	5.7% (7)
TB patient	(0)	(0)	33.3% (1)	14.3% (1)
Family member	100% (4)	(0)	66.6% (2)	85.7% (6)
Refusal	(0)	8.2% (4)	6.3% (3)	5.7% (7)
TB patient	(0)	25.0% (1)	(0)	14.3% (1)
Family member	(0)	75.0% (3)	100% (3)	85.7% (6)

 Table 7. Follow-up survey participation among those who participated in the baseline

 survey

Socio-demographic characteristics

Sixty three percent of TB patients and 18% of family members who participated in the baseline – follow-up surveys were males. The mean age was 48.7 for the TB patients and 43.7 for the family members. Sixty six percent of TB patients and 75% of family members were married. The mean number of household members of the TB patients was 4.3. The majority of the participants in both study groups had complete or incomplete high school education (64% of TB patients and 68% of family members), and about 37% of patients and 32% of family members had professional/technical and university education. Almost 62% of the households monthly spent less than 100,000AMD (\$250), 37% spent between 101,000 and 300,000AMD (\$250-750), and only one household spent more than 301,000AMD (\$751) (Table 8).

Characteristics	TB pa	atients	Family members		
	mean	SD	mean	SD	
Age	48.7	13.2	43.7	16.0	
Number of family members	4.3	2.3			
	%	n (N=52 [#])	%	n (N=57 [#])	
Gender (males)	62.7	32	17.5	10	
Married	66.0	33	75.0	42	
Education					
School less than 10 years/ complete 10 years	63.5	33	68.4	39	
Professional technical education	19.2	10	15.8	9	
Institute/University	17.3	9	15.8	9	
Household monthly spending					
< 100,000 AMD	61.5	32			
101,00-300,000AMD	36.6	19			
> 301,000AMD	1.9	1			

Table 8. Socio-demographic characteristics of surveys participants

[#]*For some items N was different because not everybody responded to the questions.*

Knowledge

Tables 9 and 10 show the TB patients' and their family members' knowledge at baseline and follow-up. The proportions of correct answers increased for almost all questions in both study groups in one month after the counseling sessions were conducted. The statistically significant improvement in the proportion of correct answers was recorded for nine questions among TB patients and 11 questions among family members ($p \le 0.05$, McNemar exact tests).

The mean cumulative knowledge score for TB patients calculated based on 28 items significantly increased from 19.3 (ranging from 12 to 26, SD 3.7) at baseline to 21.9 (ranging from 12 to 28, SD 4.0) at follow-up (p<0.001). The mean percent cumulative knowledge score for TB patients increased from 68.9% at baseline to 78.2% at follow-up. The mean cumulative knowledge score for family members increased from 18.0 (ranging from 10 to 26, SD 4.2) at baseline to 21.7 (ranging from 13 to 27, SD 4.1) at follow-up (p<0.001). The mean percent cumulative knowledge score for family members increased from 64.3% at baseline to 77.5% at follow-up.

There was no statistically significant difference between the means for TB patients and their family members at both baseline and follow-up.

I able 9. Knowledge about 1 B among 1 B patient	Base		Follow	-	P-value ^{iv}
-	<u> </u>	<u>-32</u> n	<u> </u>	<u>-32</u> n	I -value
A person can get TB through:		[=51		=51	
The air when a person with TB coughs or sneezes	86.3	44	96.1	49	0.13
Direct contact with TB patients	51.0	26	41.2	21	0.36
A person cannot get TB through:	N	=51	Ν	[=52	
Handshakes	66.7	34	98.0	50	<0.01 **
Touching items in public places	56.9	29	80.4	41	0.01 **
Using the same sanitary utensils	54.9	28	92.2	47	<0.01 **
Sharing the same platter	47.1	24	92.2	47	<0.01 **
The signs of TB	N	[=52	N	[=52	
Cough, lasting longer than 3 weeks	57.7	30	73.1	38	0.13
Coughing up blood	76.9	40	75.0	39	1.00
Weight loss	84.6	44	86.5	45	1.00
Fever	65.4	34	73.1	38	0.39
Chest pain	61.5	32	69.2	36	0.45
Difficulty breathing/not enough air	59.6	31	65.4	34	0.63
Weakness	80.8	42	76.9	40	0.79
Sweating	82.7	43	73.1	38	0.27
A person in the infective stage of TB can prevent the spread of disease through:	N	[=52	N	[=52	
Immediate treatment	75.0	39	82.7	43	0.39
Ventilate the room frequently	75.0	39	84.6	44	0.27
Cover mouth and nose when coughing or sneezing	82.7	43	84.6	44	1.00
Wear a mask	73.1	38	53.8	28	0.02 *
Avoid using public transportation	44.2	23	30.8	16	0.02
A person in the infective stage of TB cannot		20	2010	10	0.17
prevent the spread of disease through:	Ν	=52	Ν	=52	
Avoiding shaking hands	65.4	34	98.1	51	<0.01 **
Washing hands frequently	73.1		53.8		<0.01 **
Trying to interact with people in confined areas	71.2	37	94.2	49	<0.01 **
Taking drugs that are prescribed by the		0,		.,	10101
doctor every day, in the presence of the doctor _	Ν	[=46	Ν	[=46	
or nurse is the best method of TB treatment	93.5	43	97.8	45	0.50
The consequences of not following the					
treatment scheme correctly	N=47		Ν	[=47	
Remaining seek for a longer period	80.9	38	89.4	42	0.39
Spreading tuberculosis to other people	74.5	35	76.6	36	1.00
Developing drug-resistant tuberculosis	55.3	26	76.6	36	0.04 *
Developing a more severe case of the disease	76.6	36	68.1	32	0.45
No changes	83.0	39	97.9	47	0.04 *
Mean cumulative knowledge score	19.2	2	21.6		<0.01 ***

Table 9. Knowledge about TB among TB patients, baseline/follow-up comparison

*For some items N was different because not everybody responded to the questions. *statistically significant difference, $p \le 0.05$ **highly statistically significant difference, $p \le 0.01$

 $^{\rm iv}$ McNemar paired-samples chi-square statistic of knowledge change from baseline to follow-up for TB patients $^{\rm v}$ Paired samples T-test

Items		eline =57 [#]	Follow	-	P-value ^{vi}
-	%	n	%	n	
A person can get TB through:	N	[=54	N	[=54	
The air when a person with TB coughs or sneezes	63.0	34	96.3	52	<0.01 **
Direct contact with TB patients	42.1	24	61.1	33	0.69
A person cannot get TB through:	N	[=54	N	[=54	
Handshakes	75.9	41	96.3	52	0.01 **
Touching items in public places	71.9	41	85.2	46	0.33
Using the same sanitary utensils	61.1	33	88.9	48	<0.01 **
Sharing the same platter	50.0	27	92.6	50	<0.01 **
The signs of TB	N	[=56	N	[=56	
Cough, lasting longer than 3 weeks	50.0	28	75.0	42	<0.01 **
Coughing up blood	58.9	33	62.5	35	0.80
Weight loss	62.5	35	83.9	47	<0.01 **
Fever	69.6	39	78.6	44	0.33
Chest pain	51.8	29	69.6	39	0.03 *
Difficulty breathing/not enough air	53.6	30	62.5	35	0.38
Weakness	64.3	36	76.8	43	0.21
Sweating	69.6	39	71.4	40	1.00
A person in the infective stage of TB can	N		N		
prevent the spread of disease through:		=55		[= 55	0.77
Immediate treatment	83.6	46	87.3	48	0.77
Ventilate the room frequently	69.1	38	76.4	42	0.65
Cover mouth and nose when coughing or sneezing	76.4	42	92.7	51	0.01 **
Wear a mask	54.5	30	60.0	33	0.70
Avoid using public transportation	29.1	16	26.2	28	0.45
A person in the infective stage of TB cannot					
prevent the spread of disease through:		[=55		[=55	×
Avoiding shaking hands	72.7	40	90.9	50	0.03
Washing hands frequently	36.4	20	54.5	30	0.02 *
Trying to interact with people in confined areas	76.4	42	96.4	53	<0.01 **
Taking drugs that are prescribed by the					
doctor every day, in the presence of the doctor _		=48		[=48	
or nurse is the best method of TB treatment	93.8	45	97.9	47	0.50
The consequences of not following the					
treatment scheme correctly		[=55		[=55	
Remaining seek for a longer period	78.2	43	83.6	46	0.63
Spreading tuberculosis to other people	70.9	39	70.9	39	1.00
Developing drug-resistant tuberculosis	52.7	29	63.6	35	0.21
Developing a more severe case of the disease	72.7	40	74.5	41	1.00
No changes	92.7	51	98.2	54	0.38
Mean cumulative knowledge score	18.	0	21.7		< 0.01 ***vii

Table 10. Knowledge about TB among family members, baseline/follow-up comparison

[#]For some items N was different because not everybody responded to the questions ^{*}statistically significant difference, $p \le 0.05$ ^{**}highly statistically significant difference, $p \le 0.01$

 vi McNemar paired-samples chi-square statistic of knowledge change from baseline to follow-up for TB patients vii Paired samples T-test

Additional analysis was done to measure positive changes in participants' knowledge. For TB patients the mean positive change was 4.9 (ranging from 1 question to 12 questions), while for the family members the mean positive change was 5.8 (ranging from 1 question to 14 questions).

Socio-demographic characteristics of the study participants such as age, education, marz of residence, and monthly spending were not associated with the level of the study participants' TB-related knowledge and the improvement in cumulative knowledge scores.

Stigma

Tables 11 and 12 show that the proportion of those who believed that TB does not negatively affect the relationships between TB patients and their family increased from 59.5% at baseline to 67.3% at follow-up for TB patients, and from 60.9% at baseline to 73.2% at follow-up for the family members. Despite substantial differences in percentages, these changes were not statistically significant – this could be due to lack of power to show the true difference as the numbers in the samples were 52 and 57.

There was a substantial increase in the proportion of TB family members who thought that TB patients did not want to hide their TB diagnosis from their family from 74.5% at baseline to 83.9% at follow up. This percentage did not change substantially among the TB patients.

Table 11. Stigma toward TB among TB patients, baseline/follow-up comparison						
Items	Baseline N=52 [#]	Follow-up N=52 [#]	P-value ^{viii}			
	% n	% n				
People with TB do not want to hide from their	N=42	N=42				
family members that they have TB	81.4 35	78.4 40	1.00			
TB does not negatively affect relationships	N=41	N=41				
between people with TB and their family	59.5 40	67.3 33	1.00			

[#]For some items N was different because not everybody responded to the questions.

viii McNemar pared-samples chi-square statistic of stigma change from baseline to follow-up for TB patients

Table 12. Stigma toward TB among family members, baseline/follow-up comparison					
Items	Baseline N=57 [#]		P-value ^{ix}		
	% n	1 % n			
People with TB do not want to hide from their	N=46	6 N=46			
family members that they have TB	74.5 35	83.9 47	1.00		
TB does not negatively affect relationships	N=46	6 N=46			
between people with TB and their family	60.9 28	3 73.2 41	1.00		

Table 12. Stigma toward TB among family members, baseline/follow-up comparison			
Items		Follow-up N=57 [#]	P-value ^{ix}
-	0/	0/	

[#]For some items N was different because not everybody responded to the questions.

In either TB patients or their family members, the cumulative knowledge score, and sociodemographic characteristics of the study participants such as age, education, marz of residence, and monthly spending, were not associated with the level of stigma among the study participants.

Practice

Baseline-follow-up evaluation showed that the proportion of TB patients who reported taking medication in the presence of a doctor or a nurse (DOT performance) increased from baseline to follow-up from 94.2% to 98.1%, while the proportion of family members who were aware of their TB patients' DOT performance increased from 93.0% at baseline to 98.2% at followup; however, the differences were not statistically significant. Despite substantial differences in percentages, these changes were not statistically significant – this could be due to lack of power to show the true difference as the numbers in the samples were 52 and 57.

Table 13 and Table 14 present the TB patients' and their family members' opinions about TB-related family support at baseline and follow-up.

The patients and their family members were asked to evaluate the family support on the scale from 1 to 5. A mean score assigned by the TB patients to their family support was 4.90 at baseline and 4.98 at follow-up, while the mean score assigned by family members was 4.78 at baseline and 4.81 at follow-up. The reported differences were not statistically significant.

The cumulative knowledge score and socio-demographic characteristics of the study participants such as age, education, marz of residence, and monthly spending were not associated with the level of family support reported by the study participants.

^{ix} McNemar pared-samples chi-square statistic of stigma change from baseline to follow-up for family members

two weeks) at baseline and tonow-up.	the per	specie		patie	11.5
Items		seline N=52 [#]	Follo ⁻ N	w-up N=52 [#]	P-value ^x
	%	n	%	n	
Family members supported TB patient with	Ν	=51	Ν	=51	
TB treatment	88.2	45	92.2	47	0.50
Providing good nutrition -		=50	Ν	=50	
	98.0	49	98.0	49	1.00
Encouraging to follow TB treatment	Ν	=48	Ν	=48	
Encouraging to follow TD treatment	93.8	45	95.8	46	1.00
Ensuring taking TB drugs in the presence	Ν	=50	Ν	=50	
of TB physician or nurse	94.0	47	98.0	49	0.63
Droviding morel support		=47	Ν	=47	
Providing moral support	93.6	44	97.9	46	0.50

Table 13. Family support for TB treatment (taking place at least once during the past two weeks) at baseline and follow-up: the perspective of TB patients

[#]For some items N was different because not everybody responded to the questions

Table 14. Family support for TB treatment (taking place at least once during the past two weeks) at baseline and follow-up: the perspective of family members

Items		seline N=57 [#]	Follo N	w-up I=57 [#]	P-value ^{xi}
	%	n	%	n	
Family members supported TB patient with	Ν	=47	Ν	=47	
TB treatment	87.2	41	91.5	43	0.75
Providing good nutrition	Ν	=50	Ν	=50	
Troviding good nutrition	100	50	98.0	49	1.00
Encouraging to follow TB treatment	Ν	=50	N	=50	
Encouraging to follow TB treatment	96.0	48	94.0	47	1.00
Ensuring taking TB drugs in the presence	Ν	=50	N	=50	
of TB physician or nurse	92.0	46	90.0	45	1.00
Droviding moral support		=51	N	=51	
Providing moral support	98.0	50	96.1	49	1.00

[#]For some items N was different because not everybody responded to the questions

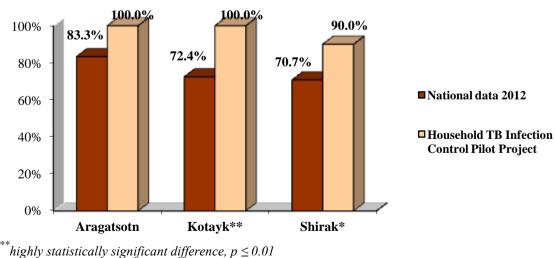
^x McNemar pared-samples chi-square statistic of practice change from baseline to follow-up for TB patients ^{xi} McNemar pared-samples chi-square statistic of practice change from baseline to follow-up for family members

2. TB patients' treatment outcomes

As an additional evaluation of the project, the research team in collaboration with the local TB outpatient centers, collected data on TB patients' treatment outcomes. Of 55 TB patients, who received counseling in November-December 2012, seven were still receiving their treatment by the time of reporting (mid April 2013).

Figure 2 shows percentages of successful treatment outcomes^{xii} of TB patients from Aragatsotn, Kotayk, and Shirak marzes who were in the ambulatory phase of TB treatment in 4^{th} quarter of 2011 and completed their treatment according to NTP reports, compared to successful treatment outcomes of TB patients who participated in counseling sessions and completed their treatment by April 2013 in each marz. The proportion of TB patients with treatment success among those who participated in Household TB Infection Control Pilot Project was significantly higher than the respective proportion of TB patients residing in Kotayk (p = 0.009) and Shirak (p = 0.09) marzes in 2011. Small number of observations in Aragatsotn (the data were available for seven TB patients who participated in the project and 12 patients who received ambulatory treatment in the 4th quarter 2011) did not allow for a meaningful statistical analysis in that region.





highly statistically significant difference, $p \le 0.01$ *marginally statistically significant difference, $0.1 \le p \le 0.05$

^{xii} WHO definition for successfully treated TB patient: a patient who was *cured* (a patient who was initially smear-positive and who was smear-negative in the last month of treatment and on at least one previous occasion) or who *completed treatment* (a patient who was initially smear- negative and who was smear-negative in the last month of treatment and did not meet the criteria for failure).

The comparison of combined data on all treatment outcomes for TB patients in all three marzes for the 4th quarter of 2011 to the treatment outcomes of TB patients who participated in the Household TB Infection Control Pilot Project shows statistically highly significant differences in success, default/failure, and death treatment outcome (Fisher's exact test p = 0.0004) (Table 15).

	Aragats		tayk, and Sh		
Treatment	NTP stat	istics	Pilot Proje	ct	P-value
outcome	N=82	2	N=48		Fisher's exact
	%	n	%	n	
Success	73.2	60	95.8	46	
Default/Failure	21.9	18	4.2	2	0.0004**
Death	4.9	4		0	

Table 15. Comparison of TB patients' treatment outcomes: the NTP statistics for the 4th quarter 2011 and the Household TB Infection Control Pilot Project

^{*}highly statistically significant difference, $p \leq 0.01$

3. Observations made by the follow-up evaluation teams on the impact of recipients' counselling

TB patients who participated in the counseling sessions shared their TB-related experiences with the team of trainers. During the sessions, many of them indicated that before developing TB they knew nothing about the disease and never considered the possibility that they would develop this disease. Moreover, counseling played an important role in improving the relationships within participants' families by providing factual knowledge and correcting misconceptions and myths associated with TB, leading to decline in stigma and fear of the disease inside the family.

Among participants there were families of extra-pulmonary TB patients who learned for the first time that these patients could not transmit TB through coughing. They were very relieved to learn this. A great number of participants were also relieved to learn that TB was not transmitted through bathroom towels and other personal items and kitchen wares and utensils. In one family where the father-in-law was in the ambulatory phase of TB treatment (SS-), the grandchildren and the daughter-in-law moved out of the house fearing TB infection. After participating in the counseling session, their fears were alleviated and they thankfully moved back home. In another family, grandfather under TB treatment was banned from communicating with his grandchildren by family members. There was another person

under treatment who was isolated in a separate room with his own personal items and eating wares. After the counseling sessions with family members and patients, both of these individuals were fully and happily reintegrated into their families.

A TB doctor advised the training team not to invite one of the patients to participate in the counseling session because that patient was refusing to complete his treatment and most probably would be unwilling to participate. However, the professional psychologist and the TB nurse from the training team convinced this patient not only to participate in the counseling session, but also to do follow-up checkups at the hospital after the session.

According to the trainers, by the end of each counseling session, patients talked much more freely and openly about their treatment practices and behaviors as well as DOT implementation. Trainers noticed that in some remote regions DOT was not practiced and TB drugs were distributed to the patients in quantities sufficient for administering independent drug intake at home.

One of the TB patients who participated in a counseling session was a nurse who worked in a TB hospital. She mentioned that she was very surprised to learn that she developed TB, because she used a surgical mask at work. During the counseling session, she learned that a respirator provides better protection than a surgical mask. After returning to work, she asked her chief nurse for a respirator: the chief nurse rejected the request, informing her that the surgical mask was sufficient for protection.

Based on the professional advice and information acquired during the counseling session, one TB patient applied for and was approved to receive financial aid from PAROS social support program. Another participant decided not to return to migrant work outside of Armenia that put him at higher risk for tuberculosis.

The study evaluators collected these stories during their follow-up survey visits to participant families. During these visits, participants expressed their gratitude to the counseling teams and stressed the program's importance and necessity.

In addition, the CHSR research team received many telephone calls from patients and their family members who wanted to express their gratitude for the counseling sessions. All

participants indicated that the counseling sessions were valuable, and almost all were very appreciative of the attention they received from the training teams, especially the psychological support. Some TB patients suggested expanding the program to include general population in addition to families of TB patients.

4. Intervention 2: Trainings for nurses working in the TB outpatient centers in Armonia

Armenia

Tables 16-22 present the results from evaluation of the training sessions for TB nurses.

Table 16. Usefulness of the training for nurses working TB outpatient centers			
	Frequency	Percent	Cumulative Percent
Excellent	36	100.0	100.0
Good	0	0.0	
Average	0	0.0	
Poor	0	0.0	
Very poor	0	0.0	
TOTAL	36	100.0	
Mean score (1= Very Pa	oor and 5= Excellent)		5.0

Table 17. Trainers' qualifications

	Frequency	Percent	Cumulative Percent
Excellent	36	100.0	100.0
Good	0	0.0	
Average	1	0.0	
Poor	0	0.0	
Very poor	0	0.0	
TOTAL	36	100.0	
Mean score (1 = Very	Poor and 5= Excellent	<i>t</i>)	5.0

Table 18. Quality of the training methods

	Frequency	Percent	Cumulative Percent
Excellent	34	97.2	97.2
Good	1	2.8	100.0
Average	0	0.0	
Poor	0	0.0	
Very poor	0	0.0	
TOTAL	36	100.0	
Mean score (<i>1</i> = Very Poor a	nd 5 = Excellent)		4.97

	Frequency	Percent	Cumulative Percent
Excellent	35	97.2	97.2
Good	0	0.0	97.2
Average	1	2.8	100.0
Poor	0	0.0	
Very poor	0	0.0	
TOTAL	36	100.0	
Mean score (<i>1</i> = <i>Very Poor ar</i>	d 5 = Excellent)		4.94

Table 19. Comprehensiveness of the training topics

Table 20. Importance of the training materials

	Frequency	Percent	Cumulative Percent
Excellent	33	91.7	91.7
Good	2	5.6	97.3
Average	1	2.8	100.0
Poor	0	0.0	
Very poor	0	0.0	
TOTAL	36	100.0	
Mean score (1= Very Poor an	nd 5= Excellent)		4.88

Table 21. Novelty of the training materials

	Frequency	Percent	Cumulative Percent
Excellent	32	88.9	88.9
Good	2	5.6	94.5
Average	2	5.6	100.0
Poor	0	0.0	
Very poor	0	0.0	
TOTAL	36	100.0	
Mean score (1= Very Poor at	nd 5= Excellent)		4.83

Table 22. Suggestions and recommendations from the nurse participants

Concerning the training program	Frequency
Organize trainings for TB nurses more frequently	12
Thanks to this training organizers	4
Organize TB trainings for the general population	2
Organize TB trainings in the regional TB outpatient centers	1
Concerning the National TB Control Program	
Insure payment for working on weekends and holydays in TB outpatient centers	13
Increase salaries of TB nurses	13
Implement mandatory treatment for TB patients	3
Provide TB outpatient centers with vehicles to transport and distribute medication	2

Discussion

The knowledge of TB patients and their family members about TB, including modes of TB transmission, common signs of TB, ways of TB prevention, proper TB treatment, and the consequences of not following the treatment plan, significantly improved after the 90 minutes household counseling sessions, with the TB patients and their family members. The most statistically significant positive changes in knowledge for both study groups were observed for the modes of TB transmission, prevention, and the consequences of not following the treatment plan.

In general, family members had a lower initial mean knowledge score than the TB patients, which was expected given that the persons with disease were often more knowledgeable about their condition than their family members. However, both groups reached similarly high knowledge scores after the intervention, indicating greater improvement in family members' knowledge. Since the family members were the primary target for building household support for the patient, this was a strong indication of the project's success.

The reductions in the TB-associated stigma reported by TB patients and their family members were not statistically significant. This might be explained by the general nature of the stigma questions used in the study, which were mainly directed towards stigma in the community and not inside the family, and might not be sufficiently sensitive to changes in the stigma within family. Moreover, the numbers for the statistical testing were low limiting the power to detect true differences.

The observations and feedback provided to the trainers during the follow-up visits suggested about substantial reduction in the stigmatization of TB disease within the families leading to improvements in their social practices. Some of the reported changes included allowing children and grandchildren to spend time with the smear negative TB patient after the intervention as compared to isolating them before the counseling (even though the patients were not infectious), and moving back to live with the TB patient in the same house after the counseling. Reduction in social isolation was broadly reported by the participating families and patients.

The evaluation showed only a slight improvement in the DOT practice by TB patients. The feedback and informal conversations with the training participants during the follow-up visits

and the training sessions led us to think that the improvement was likely larger than what was reported at the follow-up. For example, some patients told the trainers that their TB doctors at TB outpatient centers instructed them to report taking the drugs in the presence of a nurse or doctor, when in reality they were not. This might have resulted in the over-reporting of the DOT adherence at the baseline.

The findings demonstrated that families were highly supportive of TB patients at baseline and were even more supportive at the follow-up; however, the increase was not statistically significant. Since close family ties and strong family support are highly valued, respected, and commonly practiced in Armenia, particularly in the rural regions, this finding was expected. However, it is also possible that the study participants over-reported some of the indicators of support at baseline to impress the trainers, which might have led to smaller magnitude of change at the follow-up. While the counseling sessions were designed to equip the families with knowledge and skill-sets to improve the quality of support, the questionnaire might not have been sensitive enough to capture the changes in quality of support as compared to quantity.

The comparison of treatment outcomes for TB patients who participated in the household counseling sessions and those who did not, demonstrated the major longer-term success of the pilot project. Improved treatment adherence and success and significant reduction in default/failure rates will bring to reductions in TB death rates and reduce the likelihood of developing drug resistant TB.

Limitations

In the scope of this pilot project, the household counseling sessions were implemented only in Aragatsotn, Kotayk, and Shirak marzes of Armenia. The baseline-follow-up evaluation surveys for the counseling intervention included only those TB patients and their family members who participated in the sessions, met survey eligibility criteria, and consented to participate in answering the surveys, limiting the number of study participants for evaluation and reducing the statistical power of the analysis. Some of the questions on TB-related stigma in the study tool were not sufficiently sensitive to the intervention and might have measured general stigma in the community instead of stigma inside the TB-affected families.

Conclusion from the evaluation of the intervention

The main findings of the evaluation are the following:

- The overall mean cumulative knowledge score for TB patients and family members significantly improved from baseline to follow-up.
- Family members showed greater overall improvement in knowledge than TB patients.
- The proportion of study participants who felt that TB does not negatively impact relationships between people with TB and their families increased from 60% to 71% after the counseling sessions.
- Stigmatizing social practices within the families were reduced.
- Rates of TB treatment success significantly increased and default/failure and death rates significantly decreased among TB patients from Aragatsotn, Kotayk, and Shirak marzes who participated in the household counseling sessions (Pilot Project) compared to those TB patients who were not involved in the pilot project in the same marzes.

PILOT PROJECT CONCLUSION AND RECCOMENDATIONS

The Household TB Infection Control Pilot Project used multiple components, including document and literature review, and qualitative and quantitative research methods, for comprehensively assessing the current TB situation in Armenia and organizing an effective and appropriate intervention for TB patients and their family members to improve the TB treatment outcomes and reduce stigma inside the families.

This project showed that the knowledge of medical personnel on TB prevention and control was inadequate leading to scarce TB-related knowledge among TB patients, their family members, and the general population in Armenia. However, the large majority of TB patients and their families were interested in learning more about TB. The gap in knowledge on TB prevention and control among TB patients and their family members can be substantially reduced through the small-scale interventions involving household counseling by trained nurses and psychologists. These sessions can also enhance the understanding of the importance of completion of TB treatment by TB patients.

The counseling sessions can bring reduction in stigmatization of the TB patients in their families. Psychological support as an integral part of the household TB counseling can help TB patients and their families to keep stronger interpersonal relationships, and therefore, improve the TB treatment outcomes.

Maintaining a supply of TB drugs and taking TB drugs at home without observation by a clinical person (without DOT) was a common practice for TB patients living in remote rural areas. Household TB counseling sessions can substantially improve the treatment adherence of TB patients even if they take drugs at home, because families in Armenia in general, demonstrated supportive practices and behaviors toward family members with TB. All this could increase the rate of successful treatment outcomes among TB patients. This project demonstrated that conducting a single 90-minute household TB counseling session for households with TB patients is very cost-effective and could be implemented nationwide.

The main recommendations that derive from the qualitative research, the household TB counseling sessions, and the project evaluation surveys are listed below:

- Expand the household counseling of TB patients and their family members to all marzes of Armenia and Yerevan to increase TB knowledge, reduce TB related stigma, and improve the practices and behaviors towards TB treatment and infection control through the institutionalization of the household TB counseling program and its inclusion in the National TB Control Program.
- When planning the future household TB counseling programs, give the priority to more isolated regions where DOT is not adequately practiced, to improve TB treatment completion rates.
- Ensure the integration of psychological support for TB patients and their family members in the future household TB counseling programs and other communication efforts with TB patients during the outpatient phase of treatment.
- Continue to empower family members of TB patients to be engaged in household TB infection control and facilitating TB treatment adherence.
- Conduct regular refresher trainings among TB nurses and physicians working in TB hospitals and TB outpatient centers on the topics of TB prevention and control and patient counseling skills.
- Organize regular information-communication campaigns about TB for the general population in Armenia.

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APPENDIX 1: An example of a FGD guide in English and Armenian

Place:
Date:
Time:
Moderator:
Recorder:

- 1. To conduct effective training and address the patient's specific needs, what would help social workers to conduct effective trainings? What does the social worker need to know about the patient and from whom? *Probe:* health status of TB patient, knowledge of family members about his/her disease, willingness to participate in trainings, etc.
- 2. What are the barriers that social worker might face when conducting training of TB patients and his/her family members in their households?
- 3. In what format the TB training materials for TB patients and their family members could work the best? *Probe:* What effective communication techniques can help the social worker present new information to patients and their family members about TB?
- 4. Please list the topics that need to be addressed in the training materials for TB patients and their family members.
- 5. What are some of the difficulties TB patients have receiving treatment?
- 6. In your opinion, who in the family could be the best candidate for supporting adherence of TB patient treatment (taking pills)?
- 7. What could be done to encourage the adherence of TB patients to treatment in their households?
- 8. Do you think that the adherence of children to TB treatment is a problem? How can different strategies work for improving adherence in children? What are ways the social worker can help parents?
- 9. What is the best way to ensure that family members do help TB patients to adhere to treatment?
- 10. What is the best way to ensure that a TB patient adheres to treatment using the help of a family member?
- 11. What could be done in the households of TB patients to prevent other family members from acquiring TB?
- 12. In your opinion, what would TB patients be willing and able to do to keep others safe?
- 13. In your opinion, who in the family could be the best candidate for supporting TB infection control in the family of the TB patient?
- 14. What monitoring mechanisms could be used for the household training program implementation, what are the potential problems, and how often should the patients and their families be monitored?

Վայրը՝ Օրը՝ Ժամը՝ Վարող՝ Գրանցող՝

- Արդյունավետ կրթական ծրագիր իրականացնելու և ՏԲ ունեցող մարդկանց հատուկ կարիքներին արձագանքելու համար, ի՞նչ է անհրաժեշտ իմանալ սոցիալական աշխատողին և ո՞վ կարող է տրամադրել նրան այդ ինֆորմացիան։ *Փորձ. Հ*իվանդի կարգավիձակը, ընտանիքի անդամների տեղյակ լինելը նրա հիվանդության մասին, համաձայնությունը մասնակցել կրթական ծրագրին և այլն։
- Ի՞նչ խոչընդոտների կարող են հանդիպել սոցիալական աշխատողները ՏԲ հիվանդների և նրանց ընտանիքի անդամների հետ կրթական ծրագիրն իրականացնելիս։
- 3. Ի՞նչ ֆորմատով (ձևով) է անհրաժեշտ կառուցել կրթական նյութերը, որպեսզի դրանք լավագույնս արդյունավետ լինեն ՏԲ հիվանդներին և նրանց ընտանիքի անդամներին մատուցելու համար։

Փորձ. Ի՞նչ արդյունավետ շփման միջոցներ կարող են օգտագործել սոցիալական աշխատողները ՏԲ հիվանդներին և նրանց ընտանիքի անդամներին նոր տեղեկություններ հաղորդելու ընթացքում։

- Խնդրում եմ թվել բոլոր այն թեմաները, որոնց անհրաժեշտ կլինի անդրադառնալ ՏԲ հիվանդների և նրանց ընտանիքի անդամների համար կրթական նյութեր կազմելիս։
- 5. Ի՞նչ դժվարությունների են հանդիպում ՏԲ հիվանդները բուժում ստանալիս։
- Ձեր կարծիքով, ՏԲ հիվանդի ընտանիքի անդամներից ո՞վ մյուսներից ավելի լավ կնպաստի հիվանդի ՏԲ բուժման ընթացակարգին հետևելուն (դեղերը խմելուն)։
- Դ՞նչ կարելի է անել տան պայմաններում, որ խրախուսել ՏԲ հիվանդին դեղորայքը կանոնավոր ընդունել։
- 8. Արդյո՞ք դեղորայքի կանոնավոր ընդունելը խնդիր է նաև երեխաների համար։ Ինչպե՞ս տարբեր տեսակի մոտեցումները կարող են նպաստել դեղերի կանոնավոր ընդունելուն։ Ի՞նչ կարող է անել սոցիալական աշխատողը երեխայի ծնողներին օգնելու համար։

- 9. Ինչպե՞ս կարելի է համոզվել, որ ընտանիքի անդամները իսկապես օգնում են հիվանդին ՏԲ բուժումն ընդունել կանոնավոր։
- 10. Ինչպե՞ս կարելի է համոզվել, որ ՏԲ հիվանդը ընտանիքի անդամների օգնությամբ ՏԲ բուժումն ընդունում է կանոնավոր։
- 11. Ի՞նչ կարելի է անել ՏԲ հիվանդի տանը ընտանիքի մյուս անդամների վարակվելը կանխարգելելու համար։
- 12. Ձեր կարծիքով, ի՞նչ կցանկանա և ի՞նչ կկարողանա անել ՏԲ հիվանդը մյուսներին չվարակելու համար։
- 13. Ձեր կարծիքով, ՏԲ հիվանդի ընտանիքի անդամներից ո՞վ մյուսներից ավելի լավ կկատարի տան մեջ ՏԲ վարակի վերահսկման աշխատանքները։
- 14. Ի՞նչ մեխանիզմներ կարելի է կիրառել տան պայմաններում անցկացվող կրթական ծրագրի դիտազննման համար, ի՞նչ դժվարությունների կարող ենք հանդիպել և որքա՞ն հաձախ է պետք այցելել հիվանդներին և նրանց ընտանիքի անդամներին դիտազննելու նպատակով։

Շնորհակալություն մասնակցության համար

APPENDIX 2: AUA Institutional Review Board (IRB) approval



AMERICAN UNIVERSITY OF ARMENIA

07 June 2012

Varduhi Petrosyan, MS, PhD Director, Center for Health Services Research and Development American University of Armenia Yerevan, Armenia

RE: IRB Application Form

Dear Dr. Petrosyan

Institutional Review Board (IRB) for clinical studies at the American University of Armenia, reviewed your proposal entitled "Household TB Infection Control Project". The proposal was approved: your study appears to be based on comparable prior research and is directly related to your professional duties. The proposal was reviewed through an expedited review procedure and approved since additional safeguards have been included in the study to protect the rights and welfare of participants in compliance with 45 CFR 46.111 (b) and 45 CFR 46.110 of the Code of Federal Regulations.

Your proposal satisfies all IRB requirements:

- Risks to subjects are minimized by using procedures that are consistent with sound research design, and that do not unnecessarily expose subjects to risk.
- Risks to subjects are reasonable relative to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.
- The selection of subjects is equitable.
- Informed consent will be sought from each prospective subject.
- There are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

Should any change or any adverse event occur during the study period, please promptly keep us informed.

Sincerely,

Auch

Yelena Amirkhanyan, MD, MPH Chair, AUA IRB for Clinical Studies Tel: (374 10) 51 25 68 Fax: (374 10) 51 25 66 E-mail: yamirkh@aua.am

40 Marshal Bagramian Avenue Yerevan, 0019, Armenia Tel.: (37410) 512526, 512525 Fax: (37410) 512512 300 Lakeside Drive 5th Floor Oakland, CA 94612 Tel.: (510) 987-9452 Fax: (510) 208-3576

APPENDIX 3: Training package for the Training of Trainers (TOT) session

History of TB

TB is a widely spread infectious disease which has been known to humans since early times. In 1865 a French surgeon, Jean-Antoine Villemin, proved that TB was infectious, and in 1882 a German scientist named Robert Koch discovered the bacterium that causes TB. Only half a century has passed since the discovery of drugs for TB treatment. Before that, TB treatment was limited to sending people to sanatoriums and special convalescence homes. Many people who could not afford a sanatorium had no choice but to stay at home.

A breakthrough came in 1943, when an American scientist, Selman Waksman and one of his assistants, Albert Schatz, discovered an antibiotic that could kill TB bacteria and cure TB disease. Two more drugs were found between 1943 and 1952.

TB Transmission

The causative agent for TB is a rod-shaped bacterium, Koch's bacillus. TB is spread from **person-to-person** through the air. When a person with **infectious** TB disease coughs, sneezes or speaks tiny droplets with the TB bacteria can get carried through air and infect other people.

A person can become infected with TB if they breather the contaminated air. The disease is **transmitted** from the diseased person to the healthy person in this manner.

The spread of TB bacteria depends on several factors, such as: duration of exposure; the number of infectious people, concentration of people in closed areas and the susceptibility of certain people. Each person with active TB (bacillus transmitting patients) infects approximately 10-15 people throughout their lifetime if left untreated. One in every three people who are constantly in contact with TB infectious patients becomes infected. This is called latent TB infection (LTBI) and means that TB bacteria are in the body, but the body's immune system (Cells and tissues which protect the body from disease) is keeping the bacteria under control. Only about 5% of people with latent TB infection develop the disease immediately after infection. The remaining 95% enter a latent asymptomatic phase; these persons may develop the disease later when the bacteria overcome the immune system of the individual. Furthermore, only 10% of people with latent TB infection may develop TB disease throughout their lifetime and the risk is the greatest during the first two years after infection.

Pathogenesis of TB

When a person inhales air containing TB bacteria, most of the larger droplets remain in the nose and throat, where the TB bacilli are likely to die off. However, smaller droplets may reach the lungs, where TB infection is more likely to develop.

Some of the TB bacteria are killed in the lungs, but some may survive and multiply, entering the bloodstream and spreading through the body. TB disease usually develops in the upper portions of the lungs, but sometimes it can also develop in the kidneys, the brain, and bones. However, the body's immune system usually stops the growth of the agent, thus stopping the development of TB disease. However, the individual remains infected with TB bacteria, thus being a latent TB infection (LTBI) carrier.

TB Disease

A portion of people with TB infection will eventually develop TB disease.

The risk factors for the development of TB disease are:

- Previously having TB
- HIV infection
- Substance abuse such as drug use or consumption of more than 40 g of alcohol per day
- Smoking
- Malnourishment
- Low body weight (when the body weight is 10% or more below the ideal body weight)
- Overcrowded living conditions
- Prolonged therapy with corticosteroids and other immunosuppressive medication
- Organ transplant
- Silicosis an occupational lung disease
- Diabetes mellitus
- Severe kidney diseases
- Certain types of cancers, such as leukemia, Hodgkin's disease (malignant growth in the lymph nodes), or cancer of the brain and neck
- Certain intestinal conditions
- Vitamin D deficiency

The following are symptoms of TB disease:

- A cough lasting for three or more weeks
- Chest pain when breathing or coughing
- Coughing up sputum (phlegm from deep in the lungs) or blood
- Fever
- Chills
- Night sweats
- Weight loss
- Appetite loss
- Fatigue and general weakness

Diagnosis of TB Disease

The following four steps are used to diagnose TB disease in Armenia:

- 1. Medical history when the doctor learns every detail of the history of the disease, complaints, accompanying diseases, family history, etc. from the patient.
- 2. Physical examination when the doctor listens to the patient's heart, lungs, palpates the organs and assesses the overall condition of the patient.
- 3. Chest x-ray to identify pathological lesions in the lungs.
- 4. Bacteriological examinations when sputum is taken from the patient and subjected to laboratory analysis to reveal the presence of TB causing agents in the sputum.

The presence of any one of these symptoms should raise suspicions of TB; however a positive bacteriological culture is the only reliable proof of TB disease. A chest x-ray cannot confirm TB disease.

Diagnosis of TB Infection

Currently, the available methods of TB identification are the **Mantoux tuberculin skin test** (**TST**) and the **interferon-gamma release assays** (**IGRA**). The latter is used to test for

interferon gamma reaction in the presence of TB mycobacterium antigens. The Mantoux Tuberculin Skin Test is used to determine the reaction of skin to TB antigen. However, this test is not reliable and can provide false positive results if the patient has received BCG vaccination in the past. Table 1 shows the differences between TB disease and latent TB infection.

Latent TB Infection (LTBI)	TB Disease (in the lungs)					
Inactive tubercle bacilli in the body	Active tubercle bacilli in the body					
Chest x-ray usually normal	Chest x-ray usually abnormal					
Sputum smears and cultures are negative	Sputum smears and cultures may be positive					
No symptoms	Presence of symptoms					
Not infectious	Often infectious until treatment					

Table 1. Major similarities and differences between LTBI and TB disease

Close contacts are people who have had prolonged, close contact with a person who is known to have or suspected of having TB. All contacts must be examined.

Preventive treatment is organized at the regional TB cabinets:

- Mantoux positive contact children under the age of 15 Isoniazide treatment for a period of six months.
- Infants born to mothers with pulmonary TB Isoniazide treatment for 3 months, after which a Mantoux test is conducted and in the event of a negative result, BCG vaccination is done. An additional three months of preventive treatment is prescribed if the result is positive.
- HIV infected people treatment for six months when there are relevant indications.

Treatment of TB Disease

Treatment for TB cures the disease, prevents disability, protects the patient from death, and prevents the patient's family and the community from becoming infected.

TB disease is treated for at least six months; for some cases, treatment lasts longer. TB bacteria are mainly killed during the first eight weeks of treatment (during the initial intensive phase of treatment). However, treatment must be completed, as some TB bacteria can survive quite long. Therefore the initial intensive phase is followed by a continuation phase of treatment of at least four months. TB bacilli which have survived in the organism can cause a disease relapse if the patient fails to complete their treatment.

TB treatment includes taking such combinations of drugs to which the TB bacteria are susceptible. Treatment with a single drug can lead to the development of drug-resistant TB. The initial phase of treatment includes the following four drugs (Figure 1):

- Isoniazid (INH),
- Rifampin (RIF),
- Pyrazinamide (PZA), and
- Ethambutol (EMB)



Figure 1. Drugs used to treat TB disease. From left to right: Isoniazid, Rifampin, Pyrazinamide, and Ethambutol.

Controlling adverse reactions effects of TB medication

The adverse reactions to medication are concluded in table 2. These include allergic reactions, problems with vision, nausea, vomiting, stomach problems, etc.

	A dreaman Departian		Cianificance
Caused by	Adverse Reaction	Signs and Symptoms	Significance
			of Reaction*
Any drug	Allergic	Skin rash	Serious
Ethambutol	Eye damage	Blurred or changed vision	Serious
Isoniazid	Hepatitis	Abdominal pain,, darkened urine, 3 or	Serious
Pyrazinamide	-	more days of fatigue, fever, flulike	
Rifampin		symptoms, lack of appetite, nausea,	
r		vomiting, jaundiced skin or eyes	
		volinting, juundleed skin of eyes	
Isoniazid	Nervous system	Dizziness, tingling or numbness around	Serious
	damage	the mouth	
	Peripheral neuropathy	Tingling sensation in hands and feet	Serious
Pyrazinamide	Stomach upset	Stomach upset, vomiting, lack of	Serious
•	1	appetite	
	Increased uric acid	Joint aches, Podagra (rare)	Serious
Rifampin	Hemorrhage	Easy bruising, slow blood clotting	Serious
	Discoloration of	Orange urine, sweat, or tears	Minor
	body fluids		
	Sensitivity to the sun	Frequent sunburn	Minor

Table 2. Common adverse reactions to TB medication

*Patients should stop medication in the event of serious adverse reactions and consult a physician immediately. Patients can continue taking medication if they have minor adverse reactions.

Adherence to TB Treatment

Patients must take their anti-TB medication in a timely and consistent manner to prevent the spread and complications (development of drug resistant TB, more severe cases of the disease and death) of the disease and for treatment. This is called adhering to treatment. However, as patients are often required to simultaneously take multiple medications for

months on end, it is impossible to be completely certain that they will adhere to the treatment throughout the entire course.

There are many ways to encourage patients to adhere to treatment. The most effective strategy is **directly observed therapy (DOT)**. DOT means that a health care worker is always present when the TB patient takes their dose of prescribed medication. As it is impossible to know which patients will adhere to their treatment and which will divert from the schedule, this method of treatment should be considered for all patients. The DOT method is especially important to use for all children and adolescents.

Interrupted or incomplete treatment occurs when the patient is unable to or refuses to take the prescribed TB medication. One of the most important issues of TB monitoring is the taking of prescribed medication; non-compliance can have serious consequences. TB patients who have interrupted or not completed their treatment can:

- Recover late or develop more severe forms of the disease
- Infect others with TB
- Develop and spread drug-resistant TB
- Die as a result of interrupted treatment

Reasons for Non-adherence

The main reasons causing difficulties in taking TB medication are listed below:

- Often patients think that stopping taking their medication is the correct choice once they stop feeling bad. TB symptoms can disappear during the initial phase of treatment (the first eight weeks). However, some TB bacteria may survive, causing disease relapse and development of drug-resistant TB, unless treatment is continued for at least another 4 months.
- The long duration of the disease and the side effects caused by multiple medications can lead to interruption or incomplete treatment.
- Sometimes patients don't understand the treatment plan completely, such as how to take the medication, or the necessity for a long treatment period. This is why they often fail to comply with their treatment and lack motivation in sticking to the prescribed treatment plan.
- Some patients have their own personal beliefs and approach to TB disease and its treatment. In such cases it is possible for patients to not trust or follow the advice and prescriptions of their TB cabinet doctors, as they become fearful and worried. Some patients may try hiding the fact that they have TB from those around them, by avoiding treatment.
- Some patients are incapable of clearly understanding and following the advice and prescriptions of health-care workers. Elderly patients with limited mobility, individuals with other diseases, patients with substance abuse or mental health problems, and young children are particularly at risk for problems with adherence.
- Lack of access to health care can also be a barrier to successful completion of TB treatment with full adherence. Special efforts are necessary to reach and provide TB treatment for patients who don't have a permanent address or means of transportation.
- Employed patients may have difficulty paying regular visits to the TB cabinet to take their medication if their working hours conflict with clinic hours.
- If the patient and health care worker fail to establish a trusting relationship, it can influence the patient's adherence to treatment. There is a higher probability that the patient will cooperate with the doctor, follow the given instructions and advice, if they

trust and have confidence in them. Patients may also be more likely to be interested in treatment in such cases, as well as discuss questions and concerns about the treatment with their doctor.

• Finally, daily issues of greater importance, such as unemployment, drug abuse, alcohol abuse, homelessness, presence of other diseases (E.g. HIV/AIDS) may also be the reason for patients to lack motivation in adhering to their treatment. Taking TB medication correctly cannot be a priority for these patients.

An individual approach is necessary for each patient, as they may have their personal reasons for non-adherence. Patients make the decision of whether or not to take their TB medication every day. Their decisions often depend on the level of support they get from health care workers, social workers and family members.

Drug-resistant TB (DR-TB)

Regular TB is TB that can be cured by first-line anti-TB drugs. When the TB bacilli display resistance to any first-line anti-TB drugs, they are considered drug-resistant TB (DR-TB). DR-TB is treated by second-line anti-TB drugs. DR-TB includes mono-resistant TB, poly-resistant TB, multi-drug resistant TB (MDR-TB) and extensively drug resistant TB (XDR-TB). TB is mono-resistant when the Drug Susceptibility Test (DST) reveals resistance of the bacilli to one of the five first-line drugs. Poly-drug resistant TB is resistant to two or more anti-TB drugs but not to both Isoniazid and Rifampicin (the two most effective first-line anti-TB drugs) simultaneously. MDR-TB is resistant to both isoniazid and rifampicin. XDR-TB is resistant to Isoniazid and Rifampicin, all fluoroquinolone drugs, and at least one of three injectable second-line anti-TB drugs (Capreomycin, Kanamycin and/or Amikacin). Some forms of XDR-TB are untreatable.

Drug-resistant TB is transmitted in the same way as regular TB. There are two means of acquiring drug-resistant TB disease. Primary drug-resistance is when someone is infected by a strain of drug-resistant TB from contact with an infectious drug-resistant TB patient and develops the disease. Secondary drug-resistance occurs when someone with regular drug-susceptible TB develops drug-resistant TB, due to interruption or lack of completion of their treatment plan. When regular TB patients do not take all of their drugs or if they take the drugs less often than prescribed, they can develop secondary drug-resistant TB.

The symptoms for drug-resistant TB are the same as regular TB. However, the treatment of drug-resistant TB is more expensive, longer, less effective and has more side-effects.

Infectiousness

Only people with TB disease are considered to be infectious, while those who have latent TB infection (LTBI) are not infectious —they cannot spread TB to others. Except for laryngeal TB, extra-pulmonary TB is rarely infectious; however, extra-pulmonary TB transmission can occur through aerosol droplets and during procedures such as autopsies and tissue/organ irrigation. The main factors leading to infection from patients with TB are presented in Table 3.

Undiagnosed, or unsuspected TB patients are the primary risk for TB transmission to the general population. In general, young children with pulmonary TB disease are less likely to be infectious than adults, as children are sometimes unable to produce sputum when they cough, or they may have small numbers of the causative agent. However, transmission of TB bacilli from children to others is not impossible.

Factors Associated with Non-infectiousness	Factors Associated with Infectiousness
No cough	Presence of a cough
No cavity in the lung	Cavity in the lung
No acid-fast bacilli on sputum smear	Acid-fast bacilli on sputum smear
Extra-pulmonary TB	TB of the lungs, airway, or larynx
Receiving adequate treatment for 2 weeks or longer	Not receiving adequate treatment
Are not subjected to cough-inducing procedures	Subjected to cough-inducing procedures (e.g., bronchoscopy, sputum induction, and administration of aerosolized medications)
Negative sputum cultures	Positive sputum cultures

Table 3: Infectiousness of People Known to Have or Suspected of Having TB Disease*

The infectiousness of a TB patient is directly related to the number of tubercle bacilli that are expelled into the environment. Depending on the environment, these tiny particles can remain suspended in the air for several hours. M. tuberculosis is transmitted through the air; infection by touching the patient and using their personal things is not possible. Infection occurs when a person inhales M. tuberculosis, which travels to the mouth or nasal passages, upper respiratory tract, and bronchi and reach the alveoli of the lungs. The more TB bacteria patients expel into the air in water droplets, the more likely they are to infect others with TB. The following factors determine the probability of TB transmission:

• Coughing

The more sputum (phlegm from deep in the lungs) their coughing creates, the more TB bacteria patients expel into the air.

• Lung cavities

A TB patient may produce large amounts of TB bacteria in a cavity in the lung caused by TB, which can then be expelling into the external environment.

• TB disease location

Usually, only people with TB disease of the lungs (pulmonary TB) or the respiratory passages (airway or larynx) are infectious, because they can cough out the TB bacteria into the air from these sites. In general, those who have TB loci in other organs cannot infect other people.

• Not covering mouth and nose when coughing

Infectious TB Patients who do not cover their mouth and nose properly while coughing are more likely to expel TB bacteria into the air.

• Sputum smear positive TB

A sputum (phlegm from deep in the lungs) sample is taken from the mouth of a patient to determine whether or not they are infectious. The patient is considered smear positive and can infect other people through coughing If TB bacteria are found in the sputum. Consequently, a patient is considered smear negative and unlikely to infect other people if no TB bacteria are discovered in the sputum.

- Not receiving appropriate TB treatment or poor adherence to treatment Inadequate treatment or poor adherence extends the period of infectivity and delays recovery.
- Some environmental factors

The probability of Mycobacterium Tuberculosis transmission can be increased by some environmental factors. These include space (exposure in small, enclosed areas),

ventilation (inadequate local or general ventilation that results in insufficient dilution or removal of infectious droplets), specimen handling (improper specimen handling procedures that may further dispersion of the infectious droplets), and atmospheric pressure (high atmospheric pressure in the infectious patient's room causes M. tuberculosis organisms to flow to other areas).

Risk of infection increased when a person is in close contact with TB patients for longer periods of time. Family members, roommates, friends, and co-workers are often at greater danger of infection, as they are often closer to the patient. There's a lower risk of infection with TB for those who spend less time in contact with a TB patient.

Infection control

The best way to stop transmission is to isolate infectious persons from other people and to start them on standard TB medication as early as possible. Infectiousness declines very rapidly after starting the appropriate treatment and adhering to the treatment. However, the speed of decline of infectiveness varies for different patients. Some patients may remain infectious for weeks or even months. Patients with drug-resistant TB may not respond to treatments with main medication (first line) and remain infectious until they receive effective treatment.

The spread of TB bacilli is stopped and their concentrations in the air decreased through controlling the environment. This includes **Ventilation and Sunlight/Ultraviolet germicidal irradiation (UVGI)**, which kills off TB bacilli. **Ventilation** is the movement of air in a confined area and the replacement of air inside the building with outside air. When fresh air enters the room, it dilutes the concentration of TB bacilli in the air, which were extracted during coughing; moreover, it can dry bacilli faster (killing the TB bacteria). There are two types of ventilation: **natural Ventilation and mechanical Ventilation**

Natural ventilation relies on cross ventilation in a building designed for good air exchange; for example, the use of open doors and windows to bring in air from outside. Natural ventilation can be used in places that do not have a central ventilation system. **Mechanical ventilation** refers to the use of equipment to circulate and move air in a building. Mechanical ventilation should be used in hospitals, specialized TB hospitals and other health-care institutions, which are intended for confirmed and suspected TB patients.

Sunlight is a natural source of ultraviolet radiation that kills TB bacteria. TB bacteria in the air are killed by special ultraviolet lamps that give off ultraviolet light.

Respirators and surgical masks These are mechanical ways for reducing the risk of TB transmission in the environment. Understanding the difference between respirators and surgical masks is of utmost importance. Respirators are intended to protect health-care workers, family members, social workers and other people from inhaling TB bacilli. This can protect these individuals from becoming infected with TB when in contact with an infectious patient (Figure 2).



Figure 2. The respirators in this photograph are specifically designed to filter bacteria.

Surgical masks (Figure 3) are designed to stop particles from being spread (exhaled) into the air by the person wearing them when they breathe, talk, cough, or sneeze. Persons who are suspected or confirmed of having infectious TB can wear a surgical mask to prevent them from expelling infectious particles into the environment.



Figure 3. Patient wearing a paper mask. This mask is designed to stop droplets from being spread by the patient.

Good cough hygiene:

Good cough hygiene includes the following measures:

- Covering the nose and mouth when coughing or sneezing
- Using tissues, face masks or scraps of cloth to cover the mouth and nose
- Disposing of tissues, cloths or masks used to wipe respiratory secretions in a nearby dustbin.

How to reduce the risk of exposing others to TB during the infectious stage

- Socializing in outdoor (and not indoor) spaces during the infectious period (or until sputum smear-negative) preferably in sunlight
- Wear respirators and masks whenever outdoor contact is impossible
- Avoiding crowded transportation, if possible
- Providing the patient with a separate room at home
- Ventilate the patient's room very frequently, by opening doors and windows
- It is necessary to adhere to good cough hygiene
- Encourage the patient and those who are in frequent and close contact with them to quit smoking, as it increases the probability of TB infection by a few times.
- Encourage people working as stone processors to wear masks.

Physicians consider TB patient to be noninfectious when they meet <u>all</u> of the following criteria:

- They have received appropriate treatment for two weeks or longer,
- Their symptoms have decreased (for example, they are coughing less and they no longer have a fever)
- They have three consecutive sputum smear negatives results taken with 8-24 hour intervals (at least one of the samples must have been taken early in the morning).

Psychological and social support for TB patients

Some socio-psychological factors can affect the patient during treatment, thus interfering with, or assisting, treatment adherence. The majority of patients live in difficult social conditions; moreover, TB disease puts a further strain on these families. Many patients are unable to work or fulfill other social roles during treatment, due to symptoms of the disease and side effects of the medication. As a result of giving up or postponing important activities or goals, including work and education, many patients feel frustrated and 'useless'. Furthermore, the social stigma associated with TB can have negative consequences on patients and their families, including social rejection, discrimination and shame.

It is important to better understand what socio-psychological factors are affecting patients, to be able to provide appropriate social and psychological support.

- Poverty.
- Stigma and discrimination.
- Alcoholism and/or drug abuse.
- Difficult social conditions, including overcrowding.
- Unemployment.
- Migration.
- Lack of national socio-economic support systems

During treatment, the socio-mental support of family, relatives and people close to the patients are extremely important. This is an important factor in adhering to the prescribed treatment, recovering and thus limiting the risk of spread of TB in the environment.

How should relatives and close friends support TB patients?

- Encourage the patient to adhere to the concept of a healthy lifestyle and nutrition. Make sure the patient does not smoke and abuse alcohol. Ensure a smoke-free environment at home.
- Ensure that the infectious patient (BK+) does not interact with people in a closed, unventilated area; wear a mask in the event of such cases.
- Ensure personal and cough hygiene.
- Ensure proper and regular ventilation of the house.
- Encourage the patient to adhere to the prescribed treatment
- Ensure that medication is taken regularly, in the presence of a health-care provider.
- Ensure that the patient contacts the doctor if they begin feeling bad while on medication.
- Ensure that in case of symptoms (complaints) the other family members contact the doctor immediately.
- Ensure that people who have been in contact with the patient (people close to them, relatives, friends, etc) undergo medical examinations.
- Provide mental support to the patient.
- Ensure peaceful conditions within the family

APPENDIX 4: TB brochure



Հայաստանում տուբերկուլոզի ախտորոշումը և բուժումն INAKIICE

Ժամանակին բժշկի դիմելու և բուժմանը ճիշտ հետևելու դեպքում տուբերկույոզը ԼԻՈՎԻՆ ԲՈՒԺԵԼԻ Ի

Ի՞նչ է տուբերկուլոզը

Տութերկուլոգը (SP) վարակիլ հիվանդություն է որհ հայուցիչը տուբերկուրդի բացիլն է ՏԲով կարող վարակվել ցանկացած մարդ։ ՏԲ-և ժառանգական hhdmhnnpnih)b

Ինչպե՞ս են վարակվում տուբերկուլոցով

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Վարակի դեպրում մարդու իմուհիտետը (օրգահիզմի անողական համակարգը) կարող է մեջել SP բացիլներին տարիներ լաբունակ և թուղլ չտալ, որ հիվահդություն առաջանա։ ՏԲ բացիլով վարակվում են pumbpy, umhuib bpmbghg dam 18 % -p dam b unusularid warphpharing hhduluparpjarlip: Parij իվահիտեաց, բրոնիկ հիվակդությունները (օր. շաբարային դիարետը, սիրտ-անոթային համակարգի հիվանդությունները և աղը), ոլ լիարժեր սնունդը, ծիմեր, ալկոhalf impurgmented a bedamaringsph odoradabarda

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Տուբերկուլոգի ախտորոշումը (դիագնոգը)

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- Հնարավորինս համախ ահափայորը հրադահարն
- ՏԲով հիվանդը հազայիս, փոչտալիս կամ ծիծաղելիս բերանը և բիթը պետբ է փավի անձևուցիկով, թայիսիզարմա րակ խսկաղվե

· Վարակիչ հիվահդները



(ՅՅ+ հիվանդները) պետք է խուսափծն շրջապատի մարդկանց հետ փակ Հուսափծն շրջապատի մարդկանց հետ փակ չփվեն բացօրյա տարածընհրում, ցանկայի է արհի մառագալթեերի առկայությամբ, բանի որ ՏԲ բայիվշերը hward synthered in a state in a second state of the second s

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խործրդով այլ դեղեր (օր.՝ ախոիբիոտիկներ) չխմել,՝ SP դեղ երը խմել ը ժշկի կամ բուժըրո չև երկայությամբ

Badebb mampanin biparisonal dam demine spational անպարհան պետը է դիմել բուժող բժշկին՝ միայն նա կարող է որոշիլ դաղարեցնել բուժումը, թե ոլ

ՏԲ դեղերի անկանոն ընդունումը կամ բուժումը կիստ թողծելը կարող է **առաջոցծել դեղուկայուն ՏԲ։** Դեղակարուն ՏԲ-և պահանջում է ավելի ուժեղ դեղերի օգտագործում և ավելի ծրկար ժամանակով։ Սակայն որոչդեպընրում նովնիսկ այդ ուժեղ դեղնրը լեն օգնում, և ՏԲ-ն կարող է թարդանալ և ընդհանրապես լբուժվել հատկապես, երբ խովոռում են դեղերի ընդունման nhdhda

Ինչպե՞ս պետք է լինի բարեկամների ն մտերիմների աջակցությունը ՏԲ հիվանդին

Ընտանիքի անդառները պետք է՝ հետևեն հիվանդի դեղերի կանո-նակոր ընդուննանը բուծաշխո-առղի ներկայությամբ,

bhahhh, np hhimhap ajalh եգծվիր վայնեն ատարանուն» հանձելու վայա ժժտնու nhuperd,



հետհեհե, որ վարակիչ հիվահոր (884- հիվածոր) աղ ածմանց հետ չջիմի փակ չօդափոխվող տարածրերում, իսկ ջինաեղեպրում[րի դիմա],

հետևեն հիվանդի ահձևակուն և հազի հիգիեհային (հազայիսկում վաշտալիս հիվանդը փակի բեշանը), Դետհեն տան կանոհավոր օգավտիոնանը,

հետևեհ, որ բնատեկրի մյուս անդաքները անքիջապi դիւենթծչկի որևէգուհգտաներունենալուդեպրում,

klashih, np bhilufugh hinn gehnuf nebisgan duqugh (մտերիմները, հարազատները, ընկերները) անցնեն by half of a second second



Arminian Medical Fund

APPENDIX 5: Patients appointment dates setting form in English and Armenian

Hello. May I speak to the outpatient TB center physician? Could you spare five minutes of your time?

My name is...... I am the National Tuberculosis Control program psychologist. As you know, the American University of Armenia Center for Health Services Research and Development, with support of the NTP, is implementing an educational project for patients with regular tuberculosis and their family members. During the first stage of the project, you have provided the list of regular TB patients in your outpatient TB center. We are starting the next part of the project now, during which the project personnel must meet with the patients at the outpatient TB centers and set appointments for educational trainings with them. For this purpose, I would like to learn when and at what times (with what frequency) do these patients (mentioned in the list) visit you to receive medication. How can we meet with them? Are there any worries or additional information concerning these patients that you would like to inform us about?

Thank you in advance for your support.

Բարև Ձեզ: : Ես կարո՞ղ եմ խոսել_ՏԲ կաբինետի բժշկի հետ: Կարո՞ղ եք ինձ 5 րոպե տրամադրել:

Իմ անունն է ______: Ես Տուբերկուլոզի ազգային ծրագրի (ՏԱԾ) հոգեբանն եմ: Ինչպես գիտեք Հայաստանի ամերիկյան համալսարանի Առողջապահական ծառայությունների հետազոտման և զարգացման կենտրոնը ՏԱԾ-ի աջակացությամբ իրականացնում է կրթական ծրագիր ռեգուլյար տուբերկուլոզով հիվանդների և նրանց ընտանիքի անդամների համար: Ծրագրի առաջին փուլում Դուք տրամադրել եք Ձեր ՏԲ կաբինետի ռեգուլյար ՏԲ հիվանդների ցուցակը: Այժմ սկսվում է ծրագրի հաջորդ փուլը, որի ընթացքում ծրագրի աշխատակիցները պետք է ՏԲ կաբինետում հանդիպեն հիվանդների հետ և նրանց հետ կրթական դասընթաց անցկացնելու պայմանավորվածություն ձեռք բերեն: Այդ նպատակով կուզեի իմանալ երբ և որ ժամերին (ինչ հաՃախականությամբ) են Ձեզ մոտ գալիս այս (թերթիկում նշված) հիվանդները դեղորայքը ստանալու նպատակով: Ինչպե՞ս կարելի է նրանց հետ հանդիպել: Կա՞ն արդյոք ինչ-որ մտավախություններ կամ լրացուցիչ տեղեկություններ այս հիվանդների վերաբերյալ, ինչի մասին կուզենայիք ինձ տեղյակ պահել:

Նախօրոք շնորհակալություն աջակցության համար

Patient ID	Marz	City/vi llage	Outpatient TB center	TB Patient's name, surname and date of birth	Pulmonary /Extra- pulmonary	BK+/BK- Latest result	TB patient address, telephone number	Number of TB patient's family members/ how many know of the disease	Date/time of first meeting in outpatient TB center	Training ap	pointment o	letails
										Place	Day	Time
00101												
00201												
00301												
00401												

APPENDIX 6: Outpatient TB centers visit schedule and counseling session appointment form in English and Armenian

Հիվանդի ՏՀ	Մարզ	Քաղաք /գյուղ	ՏԲ կաբինետ	Հիվանդի անուն ազգանունը/ ծննդյան ամսաթիվը	Թոքային /արտաթո քային	ԲԿ+/ԲԿ- Վերջին արդյունքը	ՏԲ հիվանդի հասցեն, հեռ. համարը	ՏԲ հիվանդի ընտանիքի անդամների թիվը/ովքեր են տեղյակ հիվանդության մասին	օրը/ժամը	Դասընթաց պայմանավ մանրամաս	որվածությ	_
								uuultu		Վայր	Ор	Ժամ
00101												
00201												
00301												
00401												

APPENDIX 7: Consent form and guideline for TB patient's needs and mental state assessment in English and Armenian

Hello. Are you Aram? My name is..... I am a nurse. My name is..... I am a psychologist.

We work for the American University of Armenia Center for Health Services Research and Development, which is conducting this project together with the Ministry of Health. We are working with TB patients and their family members from three marzes: Kotayk, Aragatsotn and Shirak. We organize meetings with the patients, become acquainted and learn about their needs, after which we organize a counseling session for them and their family members. During these sessions we present TB transmission methods, prevention, treatment and the importance of support from family members. This counseling will help better protect your and your family from tuberculosis.

Guideline:

- Tell us a little about yourself. What do you do? Do you work anywhere? If yes, what work do you do? Who lives in your house? Are you married? Do you have children? How many?
- Outside of your family members and family, who do you often share confidences with? Have you told anyone from your family or outside of your family about your disease? If not, then why? If yes, then how did they take this news? Do you know from whom you became infected? Did any of your family members have TB prior to your illness? Have members of your family been tested for TB after you became ill? Has TB been identified in any one of them? Are they receiving treatment now or not? If not, then why?
- What topics would be of particular interest to you during the TB counseling session? What would you like to hear about during counseling? Would you like to have your family members participate in the counseling session as well? Who from your family would be especially interested in participating? If you do not wish so, what are the reasons? If you do wish so, then when and where can we conduct the counseling session? It will last approximately 1 hour.

Բարև Ձեզ: Դուք ե՞ք։ Իմ անունն է Ես բուժքույր եմ: Իմ անունն է Ես հոգեբան եմ:

Մենք աշխատում ենք Հայաստանի ամերիկյան համալսարանի Առողջապահական ծառայությունների հետազոտման և զարգացման կենտրոնում, որը Առողջապահության նախարարության հետ իրականացնում է այս ծրագիրը: Մենք աշխատում ենք երեք մարզերի՝ Կոտայքի, Արագածոտնի և Շիրակի ՏԲ հիվանդների և նրանց ընտանիքների անդամների հետ: Մենք հանդիպումներ ենք ունենում հիվանդների հետ, ծանոթանում ենք, պարզում ենք նրանց կարիքները, ապա կրթական փոքրիկ դասընթաց ենք անցկացնում նրանց և նրանց ընտանիքի անդամների համար: Դասընթացի ընթացքում ներկայացնում ենք ՏԲ-ի տարածման եղանակները, կանխարգելումը, բուժումը և ընտանիքի անդամների աջակցության կարևորությունը: Այս դասընթացը կօգնի ավելի Ճիշտ պաշտպանել Ձեզ և Ձեր ընտանիքի անդամներին ՏԲ-ից:

<u>Ուղեցույց.</u>

- Մի փոքր պատմեք ձեր մասին։ Ինչո՞վ եք զբաղվում։ Որևէ՞ տեղ աշխատում եք։ Եթե այո, ի՞նչ գործ եք անում։ Ո՞վ է բնակվում Ձեր տանը։ Ամուսնացած եք, Ունե՞ք երեխաներ, քանի՞սն են։
- Ու՞ մ հետ եք հաՃախ կիսվում Ձեր ընտանիքի անդամներից կամ ընտանիքից դուրս։ Ձեր հիվանդության մասին պատմե՞ լ եք որևէ մեկին, Ձեր ընտանիքում կամ էլ` ընտանիքից դուրս։ Եթե ոչ` ինչու՞ ։ Եթե այո, ապա նրանք ինչպե՞ ս ընդունեցին այդ լուրը։ Գիտեք, թե ումի՞ ց եք վարակվել։ Մինչ Ձեր հիվանդանալը ընտանիքի անդամներից որևէ մեկը ունե՞ ր ՏԲ։ Ձեր հիվանդանալուց հետո, Ձեր ընտանիքի անդամները հետազոտվե՞ լ են ՏԲ-ի համար։ Ինչ-որ մեկի մոտ ՏԲ հայտնաբերվե՞ լ է։ Հիմա բուժում ստանու՞ մ է, թե` ոչ։ Եթե ոչ, ինչու[°]:
- ՏԲ դասընթացի ժամանակ հատկապես ի՞նչ թեմաներ Ձեզ ավելի կհետաքրքրեն, ի՞նչ կցանկանայիք լսել այդ դասընթացի ընթացքում։ Կցանկանա՞ք, որ Ձեր ընտանիքի անդամները նույնպես մասնակցեն այդ դասընթացին, հատկապես Ձեր ընտանիքի անդամներից ո՞վ հետաքրքրված կլինի մասնակցել։ Եթե չեք ցանկանում, որո՞նք են պատձառները։ Եթե ցանկանում եք, որտե՞ղ և ե՞րբ կարող ենք անցկացնել դասընթացը։ Այն մոտավորապես տևելու է 1 ժամ։

APPENDIX 8: Consent form for the counseling session and baseline – follow -up surveys of TB patient and family in English and Armenian

Hello. Are you Aram? My name is I am a nurse. My name is I am a psychiatrist.

We work for the American University of Armenia Center for Health Services Research and Development, which is conducting this project together with the Ministry of Health. We are working with TB patients and their family members from three marzes: Kotayk, Aragatsotn and Shirak. We organize meetings with the patients, become acquainted and learn about their needs, after which we organize counseling sessions for them and their family members. During these sessions we present TB transmission methods, prevention, treatment and the importance of support from family members. This counseling session will help better protect yourself and your family from tuberculosis.

We had made an appointment with *Aram* for this meeting. Is that ok? The counseling session will last approximately one hour. It's more like a conversation, during which we will tell you about TB; in turn, you can raise issues concerning this disease which worry you and we will start a discussion on these.

Before proceeding, we want to provide you with questionnaires which you have to fill out individually. The questions refer to TB disease. You will be approached again by our staff members one month after this discussion, and will be asked to fill in the same questionnaire again. Nobody is going to know about your responses, and we are not going to discuss them. This is just for us and is only conducted to help evaluate our work and understand the effectiveness of our education program. Your name or any other data will not be noted on the questionnaire. In the event that you are not comfortable with any of the questions, you can refuse to respond to it or move on. Your participation in this project or in filling in the questionnaire is completely voluntary.

If you have no objections, may we start?

Thank you

Բարև Ձեզ: Դուք *Արա՞մն* եք: Իմ անունն է: Ես բուժքույր եմ: Իմ անունն է; Ես հոգեբան եմ:

Մենք աշխատում ենք Հայաստանի ամերիկյան համալսարանի Առողջապահական ծառայությունների հետազոտման և զարգացման կենտրոնում, որը Առողջապահության նախարարության հետ իրականացնում է այս ծրագիրը: Մենք աշխատում ենք երեք մարզերի` Կոտայքի, Արագածոտնի և Շիրակի ՏԲ հիվանդների և նրանց ընտանիքների անդամների հետ: Մենք հանդիպումներ ենք ունենում հիվանդների հետ, ծանոթանում ենք, պարզում ենք նրանց կարիքները, ապա կրթական փոքրիկ դասընթաց ենք անցկացնում նրանց և նրանց ընտանիքի անդամների համար: Դասընթացի ընթացքում ներկայացնում ենք ՏԲ-ի տարածման եղանակները, կանխարգելումը, բուժումը և ընտանիքի անդամների աջակցության կարևորությունը: Այս դասընթացը կօգնի ավելի ձիշտ պաշտպանել Ձեզ և Ձեր ընտանիքի անդամներին ՏԲ-ից:

Մենք պայմանավորվել էինք *Արամի* հետ այս հանդիպման համար: Կարելի[°] է: Դասընթացը կտևի մոտավորապես մեկ ժամ: Այն ավելի շուտ լինելու է փոքրիկ զրույց, որի ընթացքում մենք ձեզ կպատմենք ՏԲ-ի մասին, Դուք էլ ձեր հերթին կարող եք հիվանդության հետ կապված ձեզ հուզող բոլոր հարցերը բարձրացնել և հենց դրանց շուրջ էլ քննարկում կծավալենք:

Նախքան սկսելը, մենք ուզում ենք Ձեզ հարցաթերթիկներ տալ, որպեսզի ինքնուրույն լրացնեք: Հարցերը վերաբերվում են ՏԲ հիվանդությանը: Զրույցից 1 ամիս հետո մեր աշխատակիցները ևս մեկ անգամ ձեզ կայցելեն ու կխնդրեն, որ նույն հարցաթերթիկը նորից լրացնեք: Ձեր պատասխանների մասին ոչ ոք չի իմանալու, Ձեր պատասխանները չենք քննարկելու: Սա զուտ մեզ համար է և արվում է այն նպատակով, որպեսզի գնահատենք մեր աշխատանքը և հասկանանք, թե ինչքանով է մեր կրթական ծրագիրը արդյունավետ եղել: Ձեր անունը կամ որևէ տվյալներ չեն նշվելու հարցաթերթիկի վրա: Եթե ինչ-որ հարցեր ձեզ դուր չգան, կարող եք չպատասխանել կամ անցնել առաջ: Ձեր մասնակցույունը այս դասընթացին կամ հարցաթերթիկ լրացնելու հարցում լրիվ կամավոր է:

Եթե դեմ չեք, կարո՞ղ ենք սկսել:

Շնորհակալություն

APPENDIX 9: Feedback form in English and Armenian

Please give a feedback on how important was this training to you by evaluating it in a scale of 1 to 5 (where 1 is very poor, 2 - poor, 3 – average, 4 – good, and 5 – excellent) through the following criteria:

Level of this training usefulness at work for outpatient TB centers nurses	1	2	3	4	5
Level of integrity of the training topics	1	2	3	4	5
Level of importance of the provided materials	1	2	3	4	5
Quality of methods used to provide training information	1	2	3	4	5
New knowledge gathering opportunity	1	2	3	4	5
Level of trainers' qualification	1	2	3	4	5
Suggestions and recommendations					-

Խնդրում ենք գնահատել 1-5 սանդղակի միջոցով (որտեղ 1 ամենացածր գնահատականն է, 5 ամենաբարձր), թե որքանով էր Ձեզ համար դասընթացն արդյունավետ հետևյալ չափանիշներով՝

Դասընթացի օգտակարությունն աշխատանքի համար	1	2	3	4	5
Թեմաների ամբողջականությունը	1	2	3	4	5
Հաղորդած ինֆորմացիայի կարևորությունը	1	2	3	4	5
Նոր գիտելիքներ ձեռք բերելու հնարավորությունը	1	2	3	4	5
Նյութի մատուցման ձևը	1	2	3	4	5
Դասավանդողների պատրաստվածությունը	1	2	3	4	5

Առաջարկներ

APPENDIX 10: Questionnaire for TB patient in English and Armenian

1.	Pre/post - project	2.	ID
3.	Marz	4.	City/village
5.	Date	6.	Team #

Instructions on filling in the form. Carefully read the questions as well as the instructions written under the questions in italic. Choose your preferred response to each question, and draw a circle around it. Note that after choosing certain responses to some questions you must skip one or more questions. The number of the question you have to skip to is pointed out in front of the relevant response.

	Demographic informati	on				
1.	Sex			1.	Male	
	Mark one response only			2.	Female	
2.	How old are you?					
3.	What is your marital status?			1.	Married	
	, j			2.	Separated/Divorced	
	Mark one response only			3.	Widowed	
				4.	Single	
4.	Indicate the highest level of	educa	ation that	1.	School (less than 10 years)	
	you have received.			2.	School (10 years)	
				3.	Professional technical education (10-13 years)	
	Mark one response only			4.	Institute/University	
5.	How many people live at yo	ur ho	ouse?			
	(include yourself)					
	Answer the following question	ons re	elating to t	ube	rculosis. Carefully read the instructions written in italic	
	under each question.					
6.	How can a person get	1.	By being	in c	ontact with TB patients	
	infected with TB?	2.	By greeti	ng a	TB patient with a handshake	
		3.			air when a person with TB coughs or sneezes	
	Choose all the answers	4.			e same platter	
	that you think are correct.				e same sanitary utensils	
		6.	•	<u> </u>	various objects in public places (doorknobs, handles in	
		_	transport,		.)	
		7.	Other		D 100 1	
_					Difficult to answer	
7.	What are the signs of TB?	1.			g longer than 3 weeks	
		2.	Bloody c		1	
	Choose all the answers	3.	Weight lo			
	that you think are correct.	4 .	Elevated		perature	
			5. Chest pain			
		6. 7	Weaknes		eathing/not enough air	
		7. 8.	Sweating			
			All of the		N/A	
			Other			
					Difficult to answer	
		00.	DO HOU KI	UW/		

diately begin treatment							
l shaking hands							
mouth and nose when coughing or sneezing							
Wash hands frequently							
late the room frequently							
Wear a mask							
Try interacting with people in confined areas							
l using public transportation							
(note):							
t know/ Difficult to answer							
remedies, eg. Herbal medication, good nutrition, butter, etc							
ig at home, without using any medication							
Treatment with medication purchased from pharmacies							
g drugs that are prescribed by the doctor every day, in the presence							
doctor or nurse							
emain sick for a longer period							
pread tuberculosis to other people							
levelop drug-resistant tuberculosis							
levelop a more severe case of the disease							
won't be any significant changes							
the above							
of the above							
that you think are correct.7. None of the abovePlease read the following beliefs and choose one answer for each one of them.							
e one answer for each one of them.							
rom 1. I completely agree							
rom 1. I completely agree 2. I agree							
Tom1. I completely agree2. I agree3. I neither agree, not disagree							
Tom1. I completely agree2. I agree3. I neither agree, not disagree4. I do not agree							
Tom1. I completely agree2. I agree3. I neither agree, not disagree4. I do not agree5. I completely disagree							
 Fom 1. I completely agree 2. I agree 3. I neither agree, not disagree 4. I do not agree 5. I completely disagree 88. Do not know/ Difficult to answer 							
Tom 1. I completely agree 2. I agree 3. I neither agree, not disagree 3. I neither agree, not disagree 4. I do not agree 5. I completely disagree 88. Do not know/ Difficult to answer hips 6. I completely agree							
rom1. I completely agree2. I agree3. I neither agree, not disagree4. I do not agree5. I completely disagree88. Do not know/ Difficult to answerhips6. I completely agree7. I agree							
rom1. I completely agree2. I agree3. I neither agree, not disagree4. I do not agree5. I completely disagree88. Do not know/ Difficult to answerhips6. I completely agree7. I agree8. I neither agree, not disagree8. I neither agree, not disagree							
rom1. I completely agree2. I agree3. I neither agree, not disagree4. I do not agree5. I completely disagree88. Do not know/ Difficult to answerhips6. I completely agree7. I agree8. I neither agree, not disagree9. I do not agree							
rom1. I completely agree2. I agree3. I neither agree, not disagree4. I do not agree5. I completely disagree88. Do not know/ Difficult to answerhips6. I completely agree7. I agree8. I neither agree, not disagree9. I do not agree10. I completely disagree							
rom1. I completely agree2. I agree3. I neither agree, not disagree4. I do not agree5. I completely disagree88. Do not know/ Difficult to answerhips6. I completely agree7. I agree8. I neither agree, not disagree9. I do not agree							
rom1. I completely agree2. I agree3. I neither agree, not disagree4. I do not agree5. I completely disagree88. Do not know/ Difficult to answerhips6. I completely agree7. I agree8. I neither agree, not disagree9. I do not agree10. I completely disagree88. Do not know/ Difficult to answer							
rom1. I completely agree2. I agree3. I neither agree, not disagree4. I do not agree5. I completely disagree88. Do not know/ Difficult to answerhips6. I completely agree7. I agree8. I neither agree, not disagree9. I do not agree10. I completely disagree88. Do not know/ Difficult to answer							
Yom 1. I completely agree 2. I agree 3. I neither agree, not disagree 3. I neither agree, not disagree 4. I do not agree 5. I completely disagree 88. Do not know/ Difficult to answer hips 6. I completely agree 7. I agree 8. I neither agree, not disagree 9. I do not agree 10. I completely disagree 88. Do not know/ Difficult to answer							
rom1. I completely agree2. I agree3. I neither agree, not disagree4. I do not agree5. I completely disagree88. Do not know/ Difficult to answerhips6. I completely agree7. I agree8. I neither agree, not disagree9. I do not agree10. I completely disagree88. Do not know/ Difficult to answer							
Yom 1. I completely agree 2. I agree 3. I neither agree, not disagree 3. I neither agree, not disagree 4. I do not agree 5. I completely disagree 88. Do not know/ Difficult to answer hips 6. I completely agree 7. I agree 8. I neither agree, not disagree 8. I neither agree, not disagree 9. I do not agree 10. I completely disagree 88. Do not know/ Difficult to answer Hosis treatment 70 1. Yes 1. Yes							
rom1. I completely agree2. I agree3. I neither agree, not disagree4. I do not agree5. I completely disagree88. Do not know/ Difficult to answerhips6. I completely agree7. I agree8. I neither agree, not disagree9. I do not agree10. I completely disagree88. Do not know/ Difficult to answer							
Yom 1. I completely agree 2. I agree 3. I neither agree, not disagree 3. I neither agree, not disagree 4. I do not agree 5. I completely disagree 88. Do not know/ Difficult to answer hips 6. I completely agree 7. I agree 8. I neither agree, not disagree 8. I neither agree, not disagree 9. I do not agree 10. I completely disagree 88. Do not know/ Difficult to answer Hosis treatment 70 1. Yes 1. Yes							
rom1. I completely agree2. I agree3. I neither agree, not disagree4. I do not agree5. I completely disagree88. Do not know/ Difficult to answerchips6. I completely agree7. I agree8. I neither agree, not disagree9. I do not agree10. I completely disagree88. Do not know/ Difficult to answer							

15.	What was the reason for not tak medication in the presence of the nurse? Choose all those choices that you suitable.	e doctor or the	 I was feeling well I forgot There was no time Some issues with transportat Doctor's advice I did not trust the treatment I was dissatisfied by the heat The long duration of treatmet Side effects of medication I have already competed the Other 	lth wo ent treati	ment		tude				
16.	 Have your family members supported you with your tuberculosis treatment during the past two weeks? Mark one response only 						 Yes No -> Go to Q18 				
17.	If yes, how would you rate that highest, and 1 is the lowest?	support on a sca	le of 1-5, where 5 is the	1	2	3	4	5			
18.	During the past two weeks have	ve your family	members at least once:								
A	Made sure that you receive good	l nutrition?		1. Yes			2. No				
B	Encouraged you to follow your	treatment respon	nsibly?	1. Y	es		2. N	lo			
С	Made sure that you drink your n	nedication in the	e presence of the doctor or nurse	1. Y	es		2. N				
D	Supported you mentally?			1. Y	es		2. N	lo			
	On average, how much money does your family spend monthly? Mark one response only	 From 101,0 From 201,0 Above 301 	00 to 100,000 AMD 000 to 200,000 AMD 000 to 300,000 AMD								

Thank you for your participation

1. Նախածրագրային/հետծրագրային

8. Մարզ _____

10. Ամսաթիվ_____

Յուցումներ հարցաթերթիկը լրացնելու վերաբերյալ. Նախ ուշադիր կարդացեք հարցերը, ինչպես նաև հարցերի տակ շեղագրով գրված ցուցումները: Ապա ընտրեք յուրաքանչյուր հարցի Ձեր նախընտրած պատասխանը՝ այն վերցնելով շրջանակի մեջ: Ուշադրություն դարձրեք, որ որոշ հարցերի համար կոնկրետ պատասխանը ընտրելուց հետո պետք է մեկ կամ մի քանի հարց բաց թողնել: Այդ պատասխանի դիմաց գրված է, թե որ հարցին պետք է անցում կատարել:

	Ժողովրդագրական տվյալներ								
19.	Նշեք Ձեր սեոը		3. Տղամարդ (արական)						
	Նշեք միայն մեկ պատաս	խան	4. Կին (իգական)						
20.	Քանի՞ տարեկան եք:								
21.	Նշեք Ձեր ամուսնական ւ	[իմակը:	1. Ամուսնացած						
			2. Բաժանված						
	Նշեք միայն մեկ պատաս	խան	3. Ամուսինը/կինը մահացած						
			4. Չամուսնացած						
22.	Նշեք Ձեր ամենաբարձր Լ	լրթական	1․ Թերի միջնակարգ (10 տարուց պակաս)						
	աստիձանը:		2. Միջնակարգ (10 տարի)						
			3. Միջին մասնագիտական (10-13 տարի)						
	Նշեք միայն մեկ պատաս	խան	4․ Բարձրագույն (ինստիտուտ/համալսարան)						
23.	Քանի՞ հոգի է ապրում Չ	եր տանը							
	(հաշվեք նաև Ձեզ):								
	Պատասխանեք հետևյալ հ	հարցերին, որ	ոնք վերաբերում են տուբերկուլոզ հիվանդությանը:						
	Ուշադիր կարդացեք յուրվ	սքանչյուր հա	ւրցին կից նշված շեղագիր (թեք գրված) ցուցումները:						
24.	Ինչպե՞ս կարելի է	1. Հիվանդի	ւ հետ շփվելով						
	վարակվել	2. Հիվանդ	ին ձեռքով բարևելով						
	տուբերկուլոզով:	3. Օդի միջ	ոցով, երբ հիվանդը հազում է կամ փռշտում:						
		4. Նույն ա	փսեից ուտելով						
	Հնտրեք բոլոր այն	5. Նույն հի	ւգիենիկ պարագաներից օգտվելով						
	պատասխանները, որոնք	6. Հասարակական վայրերում տարբեր իրերի դիպչելով (դռան							
	համարում եք Ճիշտ:	բռնակներ, տրանսպորտ և այլն)							
		7. Ujj							
		88 . Չգիտեմ/ ։	ղժվարանում եմ պատասխանել						

Ժողովրդագրական տվյալներ

7. SZ_____

9. Գյուղ/քաղաք_____

25.	Որո՞նք են տուբերկուլոզի նշանները: <i>Ընտրեք բոլոր այն</i> պատասխանները, որոնք համարում եք Ճիշտ:	 Երեք շաբաթից ավել տևող հազ Հազ արյունով Քաշի կորուստ Բարձր ջերմություն Ցավ կրծքավանդակում Դժվարացած շնչառություն/օդի պակասը Թուլություն Քրտնարտադրություն Քոլորը Այլ 88. Չգիտեմ/Դժվարանում եմ պատասխանել
26.	Ինչպե՞ս կարող է տուբերկուլոզով հիվանդը վարակիչ լինելու փուլում թույլ չտա, որ տուբերկուլոզը տարածվի: <i>Ընտրեք բոլոր այն</i> պատասխանները, որոնք համարում եք Ճիշտ:	 Անմիջապես սկսի բուժվել Խուսափի ձեռքով բարևելուց Հազալիս կամ փոշտալիս ծածկի քիթն ու բերանը Հաձախակի լվանա ձեռքերը Հաձախակի օդափոխի սենյակը Դիմակ (մասկա) հագնի Աշխատի շփվել մարդկանց հետ փակ տարածքներում Խուսափի հանրային տրանսպորտ նստելուց Այլ (նշեք): 88. Չգիտեմ/ դժվարանում եմ պատասխանել
27.	Ո [°] րն է տուբերկուլոզի բուժման ամենալավ միջոցը: Խնդրում եմ ընտրել լավագույն մեկ միջոց:	 Տնական միջոցները, օր.՝ դեղաբույսեր, լավ սնունդ, կարագ, և այլն Առանց դեղեր ընդունելու հանգիստ ռեժիմով տանը մնալը Դեղատներից (<i>ապտեկայից</i>) գնված դեղերով ինքնուրույն բուժվելը Բժշկի տված դեղերը ամեն օր բժշկի կամ բուժքրոջ ներկայությամբ ընդունելը Այլ
28.	Ի՞նչ կարող է պատահել, եթե տուբերկուլոզով հիվանդը ձիշտ չհետևի իր բուժման սխեմային: <i>Ընտրեք բոլոր այն</i> պատասխանները, որոնք համարում եք Ճիշտ:	 Ավելի երկար ժամանակ կմնա հիվանդ Կտարածի տուբերկուլոզն այլ մարդկանց Ձեռք կբերի դեղակայուն տուբերկուլոզ Ձեռք կբերի հիվանդության ավելի ծանր ձևեր Առանձնապես ոչինչ չի փոխվի Բոլորը Ոչ մեկը

Խնդրեմ կարդացեք հետնյալ պնդումները և յուրաքանչյուր պնդման համար ընտրեք մեկ տարբերակ

		1	
29.	Տուբերկուլոզ ունեցող մարդիկ ուզում են	1.	Լիովին համաձայն եմ
	թաքցնել իրենց ընտանիքի	2.	Համաձայն եմ
	անդամներից, որ հիվանդ են	3.	Ոչ համաձայն եմ, ոչ էլ՝ ոչ
	տուբերկուլոզով:		Համաձայն չեմ
		5.	Բացարձակ համաձայն չեմ
		88	. Չգիտեմ/ դժվարանում եմ պատասխանել
30.	Տուբերկուլոզ ունեցող մարդկանց մոտ	1.	Լիովին համաձայն եմ
	հիվանդությունը վատ է ազդում	2.	Համաձայն եմ
	ընտանեկան հարաբերությունների	3.	Ոչ համաձայն եմ, ոչ էլ՝ ոչ
	վրա:	4.	Համաձայն չեմ
		5.	Բացարձակ համաձայն չեմ
		88.	. Չգիտեմ/ դժվարանում եմ պատասխանել

Մի քանի հարցեր Ձեր տուբերկուլոզի բուժման վերաբերյալ:

31.	Վերջին երկու շաբաթվա ընթացքում եղե՞լ են օրեր, երբ դուք առնվազն մեկ անգամ բաց եք թողել դեղերի ընդունումը բուժքրոջ կամ բժշկի ներկայությամբ:		Այո Ոչ –><i>Անցեք հարց 16-ին</i>
32.	Վերջին երկու շաբաթվա ընթացքում քանի [°] անգամ եք բաց թողել դեղերի ընդունումը բուժքրոջ կամ բժշկի ներկայությամբ::		
33.	Ո՞րն էր բուժքրոջ կամ բժշկի ներկայությամբ դեղերի ընդունումը բաց թողնելու պատձառը: Նշեք բոլոր այն տարբերակները, որոնք հարմար եք համարում:	2. 3. 4. 5. 6. 7. 8.	Լավ էի զգում Մոռացա Ժամանակ չկար Տրանսպորտի հետ կապված խնդիրները Բժշկի խորհրդով Բուժմանը չէի վստահում Դժգոհ էի բուժաշխատողների վերաբերմունքից Բուժման երկար ընթացքը Դեղերի կողմնակի ազդեցությունները
			Բուժումն արդեն ավարտել եմ Այլ

34.	Վերջին երկու շաբաթվա ըն	1. Ujn							
	օգնե՞լ են տուբերկուլոզի բո	ւժման հարցում:							
			2 . Ոչ <i>–>Անցեք հարց</i>						
	Նշեք մեկ տարբերակ		18-ին						
35.	Եթե այո, ինչպե՞ս կգնահաս	Եթե այո, ինչպե՞ս կգնահատեիք այդ օգնությունը 1-5 բալով, որտեղ							
	5-ը ամենաբարձրն է, իսկ մե								
36.	Վերջին երկու շաբաթվա ընթացքում Ձեր ընտանիքի անդամները գոնե մեկ անգամ								
u	Հետևե՞լ են, որ Դուք լավ սն	1. Այո			2. Ոչ				
F	Խրախուսե՞լ են, որ Դուք պս	1. Այո			2. Ոչ				
q	Հետևե՞լ են, որ դեղերը խմեյ	1. Այո			2. Ոչ				
դ	Օգնե՞լ են Ձեզ հոգեպես:	1. Այո			2. Ոչ				
37.	Միջինում, ամսական ամեն ինչի վրա ինչքա՞ն փող է ծախսում Ձեր ընտանիքը: <i>Նշեք մեկ տարբերակ</i>	1. 50 000 դրամից քիչ 2. 51 000 – 100 000 դրամ 3. 101 000 – 200 000 դրամ 4. 201 000 – 300 000 դրամ 5. 301 000 դրամից ավել 88.Չգիտեմ/հրաժարվում եմ պատասխանել			·				

Շնորհակալություն մասնակցության համար

APPENDIX 11: Journal form in English and Armenian

	City/ Village		Marz	Date	
	Patient ID		Team #	Team #	
Participant Name/Surname	ID	Patient or family relation with them	Initial questioning result	Post-project questioning result	Training result
	 Refusal Incomplete Not applica 	t was not at home			 Complete participation Partial participation No participation

	Գյուղ/ քաղաք		Մարզ		_ Ամսաթիվ	
	Հիվանդի ՏՀ		Թիմի N	Թիմի N		
Մասնակցի անունը/ազգանունը	SZ	Հիվանդ կամ նրա հետ հարազատական կապը	Ելակետային հարցման արդյունքը	Հետծրագրային հարցման արդյունքը	Դասընթացի արդյունքը	
	 8. Հարցման 9. Մերժում 10. Անավարտ 	 ւծ հարցազրույց ենթական տանը չէր ո հարցազրույց ը ենթակա չէ (փոքր է 18	<u> </u> ៣.)		4. Լրիվ է մասնակցել 5. Մասնակի է մասնակցել 6.Ընդհանրապես չի մասնակցել	