IMPLEMENTATION OF DOTS STRATEGY FOR TUBERCULOSIS CONTROL IN THE REPUBLIC OF MOLDOVA. FROM THEORY TO PRACTICE: OPINIONS OF MEDICAL PERSONNEL

Master of Health Thesis Project Utilizing Professional Publication Framework

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October 2005

AKNOWLEDGEMENTS

I would like to express my deepest gratitude to my advisers Drs. Grace Sullivan and Varduhi Petrosyan who helped me to find the right path of my research through their valuable comments and help.

I am also very thankful to my local advisor Dr. Valeriu Crudu for his continuos support.

I am very proud to be one of the first international graduates of the American University of Armenia and I am very thankful to Dr.Haroutune Armenian and entire Public Health Faculty for the knowledge they shared with us.

I would like to thank Open Society Institute and Soros Foundation-Moldova for providing financial support.

I am also thankful to the OSI fellows and also to my classmates for their intelligence, patience and willingness to help.

ABSTRACT

Tuberculosis (TB), an ancient disease once believed to have Background. disappeared from the World Health Organization (WHO) European Region, affects more people today than two decades ago. Currently, more than three-quarters of the TB cases in the European Region occur in the Former Soviet States, where the TB rates more than doubled in the last 10 years. To combat TB, the WHO has recommended adoption of a strategy called Directly Observed Treatment Short Course (DOTS). TB is a significant public health problem in the Republic of Moldova with high prevalence and important social and economic consequences. According to the data provided by the Department of Statistics from the Public Health Center of the Ministry of Health, the incidence of TB in Moldova has increased in the last 12 years by 98%. In order to address this problem in 2001 the Government adopted the National Program of Tuberculosis Control in the Republic of Moldova for the years 2001-2005 based on DOTS strategy. The Program objectives are to achieve a rate of detection of at least 70% of smear positive patients and to cure 85% of new cases of pulmonary tuberculosis, microscopic positive at the moment of the diagnostic. This study assessed the opinions of the medical personnel about the performance of the DOTS strategy in the Republic of Moldova.

Methodology. The qualitative research was conducted in the family doctors centers from three regions with different incidence of tuberculosis. In-depth interviews were conducted with family doctors and phtiziopulmonologysts. These were two main categories of specialists involved in the National Tuberculosis Program implementation: family doctors, who work at the initial stage of identification and continuation treatment and specialized medical doctors, engaged in TB diagnosis and specialized services for TB patients. A desk review of relevant documents and reports, the WHO reports, guides and recommendations regarding DOTS implementation at international and local level were identified and analyzed during this research.

Results. After the content analysis of the in-depth interviews, it could be concluded that most of the respondents considered that the results obtained during 2003-2005 in the fulfillment of the DOTS strategy implementation in the Republic of Moldova were satisfactory at this moment, taking into account the economic situation of the state. Most of the respondents considered that lower achievements of DOTS program were due to economic crisis, massive migration, poverty of the population, insufficient financing of the health care system.

Conclusions: In the opinions of participants in this study implementation of DOTS strategy in Moldova was a step forward in combating alarming proportions of TB in the Republic of Moldova. For further successful implementation of the National Tuberculosis Control program and improving the performance of the program in the Republic of Moldova several strategies should be elaborated: strengthen primary health care, especially at local level; motivate young TB specialist as well as experienced staff; provide pretreatment counseling trainings for medical personnel; and develop appropriate social system support for TB patients.

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1. INTRODUCTION

Tuberculosis (TB) is a major public health problem worldwide and its control continues to elude the brightest minds and to challenge the human and economic resources of countries around the world [1]. In spite of the fact that more than one hundred years passed after the establishment of the pathogenic agent of tuberculosis, this disease remains a medical and social problem of major importance. The World Health Organization (WHO) estimated that one third of the world's population is infected with TB and that two million deaths occur each year from this disease [2]. Worldwide, tuberculosis is the second largest contributor among infectious diseases to adult mortality [3].

Responding to this situation, the WHO recommends a cost-effective strategy known as Directly Observed Treatment Short Course (DOTS). DOTS strategy is a management package that ensures effective diagnosis and treatment of infectious cases [4]. On March 24, 1997, the Director-General of the World Health Organization declared "the DOTS strategy for TB control represents the most important public health breakthrough of the decade, in terms of lives which will be saved" [4].

2. BACKGROUND/LITERA TURE REVIEW

2.1 History of DOTS

The essential principles of DOTS are the products of India's long and distinguished tradition of tuberculosis research. From 1955 to 1958, India conducted a national survey, which documented the burden of tuberculosis and the urgent need for a tuberculosis control program [5].

In the 1950s and 1960s, studies at the Tuberculosis Research Center (TRC) in Chennai, demonstrated the efficiency and safety of home treatment of tuberculosis

patients without any additional risk of disease to close contacts [6]. The problems of poor compliance to treatment of patients were identified and the necessity and feasibility of supervised administration of every dose of treatment to tuberculosis patients demonstrated. Studies have shown that about one-third of patients receiving self-administered treatment do not adhere to treatment [7]. It is impossible to predict which patient will take the medicines regularly. Directly Observed Treatment (DOT) is necessary at least in the initial phase of treatment to ensure adherence and achieve sputum smear conversion [8].

In the 1960s, studies at the National Tuberculosis Institute in Bangalore, documented the efficacy and feasibility of case detection by sputum smear microscopy even at the peripheral health institutions [9].

The principles of DOTS were combined into a powerful treatment system that ensured monitoring, supervision, and accountability for every patient started on treatment and demonstrated that this system could provide effective TB treatment, affordable for developing countries [9].

2.2 The Components of DOTS

The success of the DOTS depends on the implementation of five main components: 1) Government commitment to sustained TB control activities; 2) case detection by sputum smears microscopy among symptomatic patients self-reporting to health services; 3) standardized treatment module of six to eight months for at least all sputum smear-positive cases with directly observed therapy (DOT) for at least the initial two months; 4) a regular, uninterrupted supply of all essential anti-TB drugs; 5) a standardized recording and reporting system that allows assessment of treatment results for each patient and of the TB control program performance overall [10].

2.3 Global Applications of DOTS

The DOTS strategy has been implemented successfully in many countries. Several studies reported a rapid decrease in both tuberculosis and multidrug resistant form of TB among HIV infected patients in the United States [11,12].

Murraay *et al.* reviewed experiences in Malawi, Mozambique and Tanzania, documenting cure rates of 86-90% [13]. Effective program have been established and have continued to function well even in the context of civil war. Application of universal DOT and subsequent adoption of short-course chemotherapy were associated with a substantial decline in tuberculosis in Cuba, to a level below that of many industrialized countries [14].

In Beijing, DOT was implemented in 1978 and short course chemotherapy was introduced in 1988 [16]. Prevalence of smear-positive tuberculosis in Beijing decreased form 127 per 100,000 in 1979 to 16 per 100,000 population in 1990, a decrease of 17% annually [15].

The World Bank assisted project in China had remarkable success [16]. More than 3 million patients undergone sputum examinations and more than 515,000 smear positive patients were treated, with cure rates of more than 93% in 1997. The failure rate in previously treated patients fell progressively from 18% to 6% in the initial years of the program. The program in China currently covers a population of 800 million [17].

Bangladesh had excellent success in DOTS implementation, with coverage of more than two-thirds of the country and cure rates above 80% [18]. The impact of TB control program was quite considerable in Peru; after a decade of implementation of DOTS, the TB morbidity droppe d down by 35%, the incidence by 42%, the incidence of smear positive cases by 40% and the mortality rates decreased from 21% to 11%.

DOTS in South-East Asia has prevented more than 200,000 TB cases, saved more than 100,000 lives, and saved more than US\$500 million [19].

In India, more than 500,000 patients have been put on treatment; more than 80,000 lives have been saved (4500 lives every month) and more than 1 million infections have been prevented [19].

The World Bank ranked the DOTS strategy as one of the most cost-effective of all health interventions. DOTS cures 8 out of 10 patients treated and it has now been implemented in more than 180 countries [20].

2.4 Implementation of DOTS in the Republic of Moldova

2.4.1 General information on the country

Moldova's transition to a market-based economy since gaining independence in 1991 has been slow and difficult: significant internal political divisions within successive governments delayed structural reforms. The cumulative decline of the economy during 1990-2000 exceeded 60% (second only to Tajikistan among transition economies) [21, 22]. Moldova is a low -income country, with a Human Development Index (HDI) of 0.681 (on the 115th position out of 177 countries) [21]. Behind these data are a poor qualit y of governance, a high level of corruption, and multi-dimensional poverty (rooted in acute differentiation of income, unemployment, out-migration of labor force, brain-drain etc.), registering highest rates in small towns and rural areas [22]. About 600,000 people, or 37% of the total active population, left the country searching employment abroad [23].

2.4.2 The Health Care System

The system has three levels: Republican institutions at national level, "rayon" and municipal institutions at the intermediate level, and ambulatories and polyclinics at the local level. Most services are governmental, except for a private sector in

dentistry and ophthalmology and to a lesser extent in specialized fields such as gynecology, dermatology and urology. There are also some private clinical laboratories and a private pharmacy sector. According to the Reports of the Department of Statistics it is estimated that the number of GPs amounts to 90% of the estimated need for GPs and that of nursing staff 92% [24]. In 2003 the allocations from the state budget for the health sector was 3.1% of Gross Domestic Product (GDP), increasing from 2.3% of GDP in 2002. This allowed for per capita expenses of approximately 18 USD, up from approximately 12 USD in 2001 [25].

In January 2004 a system of obligatory health insurance was launched in Moldova. However, children (< 18 years), the elderly (> 62 years for men and 57 years for women), pregnant women, handicapped, police and military personnel and employees of the Ministry of Justice are exempted from payment to the Insurance Fund and are fully covered by the State. Otherwise, an employee contributes 2% of his/her salary for health insurance and the employer pays an equal amount for a total of the equivalence of 4% of the annual wage. Those self-employed (e.g. farmers) buy into the Insurance Fund with an annual sum, which in 2004 amounted to approximately 40 USD. Those officially registered as unemployed are not insured but are covered by the state budget for certain services, such as medical emergencies, TB and some other national programs (HIV, etc). These exemptions are partially covered by external donors. Migrant workers can buy into the insurance scheme in the same manner as the self employed.

The Insurance Fund partly covers a "minimum package" of health services, which includes primary health care and hospital services according to estimated costs per diagnosis. Patients must pay for services, which are not included in the minimum package.

2.4.3 Epidemiology of TB in Moldova

TB is a significant public health problem in Moldova with high prevalence and important social and economic consequences. International experts are concerned about the dynamics of medical statistics, which identifies Moldova as a center of TB contagion and spread. For the last decade the Republic of Moldova has one of the highest rates of recently detected cases of tuberculosis in Europe, after Kazakhstan, Kirghiztan, Romania and Russia (figure 1) [26]. According to the data provided by the Department of Statistics of the Center of Pubic Health the incidence of TB in Moldova has increased in the last 12 years by 98.0% and in 2004 affected 128 per 100,000 of the population (figure 2). In prisons the incidence is ten times higher than the country average and was 1,112 per 100,000 population in 2003 [27]. The mortality due to tuberculosis increased by 6.2% (17 per 100,000) in 2003 compared to 2002 (figure 3). According to the estimations of WHO tuberculosis experts, who repeatedly visit the republic, the official data are the visible part of the iceberg, the real data estimated as at least twice higher [27].

2.4.4 The National Tuberculosis Program (NTP)

In order to address these problems and improve the situation, in 2001 the Government adopted the National Program of Tuberculosis Control in the Republic of Moldova for the years 2001 -2005 (*Order No 180 dated 10-August 2001* and *Decision No. 559 dated 28-June 2001*). The goal of this Program is to stop the epidemics of tuberculosis, to control tube rculosis in the Republic of Moldova by reducing the incidence and mortality indices in parallel with reduction of the infection spread and prevention of multi-drug resistant forms of TB. The Program objectives are to achieve a rate of detection of at least 70% of smear positive patients and to cure 85%

of new cases of pulmonary tuberculosis, microscopic positive at the moment of the diagnostic [28].

The Program implementation began on November 1, 2001 in three pilot areas: Chisinau and two former counties - Lapusna and Orhei; in 2002 included the Edinet Balti, Soroca judets; in 2003 – Ungheni, Chisinau, Lapusna, Cahul, Tighina, Taraclia judets, TAU "Gagauzia", and the Transnistria region of Moldova, and in 2004 was implemented throughout the country.

The first phase of the Program was financed by international organizations such as WHO, Global TB Drug Facility and also by grants coming from Sweden and the Netherlands. These funds allowed purchasing an important quantity of medicines that covered fully the requirements of hospitals. The American Alliance for Health (AIHA) allocated funds for laboratory equipment, and supplies in order to develop the laboratory network for sputum microscopy. Caritas Luxemburg has supported DOTS implementation (including drug supply) in the penitentiary system. Implementation of DOTS within the penitentiary system in 2000 preceded implementation in the civil system starting in 2001.

The NTP uses a multi-sectoral approach involving the Ministry of Health (MoH), the Ministry of Justice (MOJ), the Ministry of Internal Affairs (MOIA) and collaborates with various non-governmental organizations (NGOs) and international partners.

The Central Unit of the NTP is located in the Phthisiopulmonology Institute (PPI) in Chisinau, with a Director and Manager (Coordinator). Diagnosis and treatment of TB is implemented at the national, "raion"/municipality, and local levels.

A patient with TB symptoms is detected at local level - ambulatory, and subsequently directed to the rayon level - the family doctors center, where the

phthysiopulmonologist¹ examines him/her and requests a lab test to determine if TB is present. At the rayon level, in the family doctors center (the former policlinics) there are 2 phtisiopulmonologysts that provide specialized TB services (lab tests and xrays) and consultation. Affiliated to phiziopulmonologyst's office, there is a center for microscopy, which performs smear microscopy – these services are not available in ambulatory centers in villages. Patients with TB are hospitalized for the intensive TB treatment in Phtisiopulmonologyc Institute or Phtiziopulmonologyc hospitals that are located one in Chisinau and one in Vorniceni. After 2-3 months of intensive treatment, the patients return for the follow-up ambulatory directly observed treatment. The private sector is not involved in TB control activities.

A person with signs and/or symptoms of TB is exempted from payment at the peripheral level, i.e. for consultation and acid-fast bacilli (AFB) microscopy. When referred to the specialized TB service for consultation, the patient has to pay for the first interview since out-patient TB services are only partially included in the Insurance Fund. At this level AFB microscopy and x-ray examination and anti-TB treatment is free of charge but the patient must pay for other examinations such as tomography, bronchoscopy if these are indicated. When a patient has been diagnosed with TB, treatment and follow up visits are free of charge. However, the cases of multidrug resistant TB (MDR-TB) are not covered by DOTS and second line medication is not free of charge for these patients.

The case definitions are the same as recommended by the WHO: "New cases," "relapses,", "return after default,", and "treatment after failure" distinguishing between smear positive and smear negative cases. There is quarterly reporting of cases, progress and outcome to the NTP (aggregated statistics) in line with WHO

¹ Doctors that provide consultation and specialized services for TB patients

recommendations. There is also a parallel system with nominal reporting to the Center for Public Health, but it is planned to combine the two reporting systems in the future.

The network of AFB microscopy is fully expanded with 56 microscopy centers. Bacteriological confirmation of TB cases is improving in Moldova. In 2003 > 50% of TB cases (pulmonary new and relapses) were AFB sputum smear positive in 17 of 34 territories implementing DOTS in 2003 (excluding in Transnistria where DOTS was implemented only at the end of the year). This is important progress when compared to 9% confirmation (by AFB microscopy) countrywide in 1996 [26].

The empiric treatment regimen in *new smear positive TB* (Category I treatment) is a four-drug regimen administered on daily basis in the intensive phase (in exceptional cases intermittently three times a week). As a rule treatment in intensive phase is administered in hospital. Exceptions to this are allowed if the patient for some reason prefers ambulatory treatment. In this case, a health worker administers directly observed treatment (DOT) at a health facility close to the patient's home. This is done in coordination with the corresponding "rayon" health center. The intensive phase of treatment is prolonged for a third month if sputum smear is positive at the end of two months. The continuation phase of treatment is administered on ambulatory basis three times a week for a total duration of treatment of six months.

Through the implementation of DOTS strategy and aiming to achieve the Millennium Development Goals, the Ministry of Health of the Republic of Moldova strives to achieve a detection rate of 70% of smear positive patients and a cure rate of 85% of new cases of pulmonary tuberculosis, microscopic positive. Currently the

achievement of these targets is estimated at 65,5% cure rate and a 45-50% for the detection rate.

The family doctors and phtiziopulmonologysts are the key stakeholders involved in the National Tuberculosis Program implementation. The family doctors work at the initial stage of identification and continuation treatment and specialized medical doctors engaged in TB diagnosis and intensive treatment. Receiving feedback from these two main categories of specialists might be very useful for the authorities from the Ministry of Health in the stage of elaboration of the NTP for the next period of 2006-2010. A qualitative research is needed first in order to reveal the main areas and issues regarding DOTS strategy implementation and then the next step would be a quantitative research on a basis of a questionnaire.

3. PURPOSE OF THE STUDY

This qualitative research was conducted in order to find out the opinions of medical personnel about the performance of the DOTS strategy in the Republic of Moldova.

The goal of this research is to investigate medical personnel's opinions on the DOTS strategy and to collect the major concerns and problems that appeared during DOTS strategy implementation and the solutions for improvement of program performance.

Research objectives

1. To establish to what extend the medical personnel are informed about DOTS strategy.

2. To identify the major issues that appeared during DOTS strategy implementation.3. To collect and analyze the opinions and recommendation for improvement of program performance.

4. METHODS AND MATERIALS

4.1 Study population and areas

The qualitative research was conducted during June-July 2005 in the family doctors centers and ambulatories from regions with different incidence of tuberculosis: most prevalent, least prevalent and median in terms of incidence of TB in Moldova. Semi-structured in-depth interviews were conducted with doctors from three regions (rayons): Ialoveni rayon with high incidence of tuberculosis - 135 per 100,000; Criuleni rayon with middle incidence of tuberculosis - 95 per 100,000, and Anenii Noi rayon with relatively low incidence - 82 per 100,000 [24]. In all three regions implementation of DOTS strategy started in 2003. Study population included family doctors and phtiziopulmonologysts. The choice of these groups of key informants allowed to collect a range of opinions from two main categories of specialists involved in the National Tuberculosis Program implementation: family doctors, who work at the initial stage of identification and continuation treatment and specialized medical doctors engaged in TB diagnosis and intensive treatment. Inclusion criteria were the following: respondent had to be certified Family Physician working at the position of Family Physician' as well as to be certified Phtiziopulmonologyst working at the position of the Phtiziopulmonologyst and be willing to participate in the study.

4.2 Study setting

From June to July 2005 the interviews were performed in family doctors centers and ambulatories from three regions: Ialoveni, Criuleni and Anenii Noi. The appointments with doctors were made before the interview. Data collection was performed in "rayon" Center of Family Doctors with phtyziopulmonologysts and family doctors that provide medical services in "rayon" Center of Family Doctors and

also family doctors that provide medical services in the ambulatories in villages were interviewed.

4.3 Study design

The qualitative research was considered the most suitable in order to fill the gap of information about medical personnel opinions and concerns about DOTS strategy implementation in Moldova. In-depth interviews were considered the most appropriate method of data collection in order to allow free emerging of new viewpoints.

4.4 Sample size

The total number of participants was 18. Using snowball method of selection 6 persons were identified from each rayon: one phtiziopulmonologyst and 5 family doctors. The interview guide was pre-tested during discussions with several family doctors from family doctors centers from Chisinau and a sample size of 18 persons was considered sufficient for data collection for a qualitative study.

4.5 Research instrument

The interview guide was developed in order to initiate the discussion with key informants and allow free emerge of ideas and cover the main domains of interest (Appendix 2). The interview guide was based on probe questions in order to: initiate discussion and receive feedback from main stakeholders involved in DOTS strategy implementation; establish to what extent medical personnel are informed about DOTS strategy; to understand the major concerns and problems that appeared during DOTS strategy implementation and what would be the solutions for improving the program performance. The duration of the interviews varied between 45-60 min, and they were tape recorded and transcribed verbatim.

5. ETHICAL CONSIDERATIONS

The Institutional Review Board Committee on Human Research within the College of Health Sciences of the American University of Armenia reviewed and approved the study. The study possessed no risk for participants. Oral consent to participation and tape recording was obtained before each interview (Appendix 3).

6. RESULTS

6.1 Awareness of the medical personnel about DOTS strategy

In all three regions implementation of DOTS strategy started in 2003. All phtiziopulmonologysts and family doctors mentioned the importance of all key components of DOTS strategy for its implementation: Governments commitment to long-term TB control as well as an uninterrupted supply of all essential anti-TB drugs; a standardized recording and reporting system that allows assessment of treatment results for each patient and of the TB control program performance overall as well as directly observed treatment.

All family doctors and phtiziopulmonologysts would suspect tuberculosis and recommend passing lab test to the patients that have cough more that 3 weeks, have fever, and other symptoms according to WHO recommendations and guidelines. The family doctors and phtiziopulmonologysts emphasized that sputum microscopy is the primary tool to diagnose tuberculosis and chest X-ray is a complementary tool when sputum smears are negative according to DOTS principles. However, all phtiziopulmonologysts told that they feel more comfortable when radiological examination is used for diagnostic confirmation. Moreover, many doctors that took part in this research recalled with nostalgia the time when going to the doctor was compulsory.

"During Soviet rule Moldova was considered one of the leaders in the treatment of tuberculosis. The small country had the services and infrastructure allowing it to detect the disease and treat it. All family members had to do it; there were mobile radiographic units posted in front of blocks of apartments and schools and doctors checked everybody. The same went for factories, companies and big institutions, where workers had to pass periodical check-ups. Sick persons were detected immediately and treated by the state." In-depth interview N1

However, all the respondents mentioned that implementation of DOTS

strategy was a step forward in combating alarming proportions of TB in the Republic

of Moldova.

"When this program started, I was concerned, and even suspicious about this strategy. But now I may say that it was a very good and appropriate decision to implement DOTS strategy in the context of economical, political situation and all the issues in health care system." In-depth interview N3

All doctors involved in the study, consider that it is essential that a health worker observe patients swallowing their medicines. TB patients must be provided complete treatment and be monitored to ensure cure. Sputum is examined during and at the end of treatment to ensure that a patient is free of TB bacilli. The recording and reporting system rigorously monitors and evaluates progress made while treating and curing each patient.

"Many years of life are saved if the disease is properly treated and in the absence of complicating factors such as drug resistance, the great majority of patients are cured by a six-moth course provided that treatment is given under the supervision to ensure that patients receive all doses of drugs under the scheme of treatment." In-depth interview N5

All specialized doctors – phtiziopulmonologysts expressed 100% probability for a new case patient to be cured of tuberculosis when all the recommendations according to the DOTS strategy are followed, versus 85-100% probability expressed by family doctors. "DOTS is an effective strategy- the only effective strategy we have at present for TB control. With increased commitment we can meet this challenge, prevent deaths due to TB, reduce ill health and enhance the quality of life in the Moldova. The time to act is now." In-depth interview N7

All phtiziopulmonologysts mentioned that they receive useful information, continuous instructions through trainings and seminars regarding DOTS issues. All family doctors also told that they received useful guidelines for primary health care providers, such as "Key aspects regarding DOTS strategy" and "Guideline for Tuberculosis Control for Primary Health Care Providers" elaborated by the Ministry of Health and international experts.

6.2. Major issues that appeared during DOTS strategy implementation

During conversations, the family doctors and phtiziopulmonologyst expressed their concerns about epidemiology of TB in Moldova and lower performance of DOTS program than was expected. Most of the respondents considered that this was due to the economic crisis, massive out-migration, poverty and insufficient financing of the health care system.

Moldova's alarming TB indicators reflect the deterioration of the health care system since the breakup of the Soviet Union in the early 1990s. Once the socioeconomic decline aggravated, tuberculosis reached alarming proportions.

"The situation was even worse in early stage of program implementation. There were such problems as shortages with drugs, low quality of sputum microscopy, poor reporting and monitoring system." In-depth interview N11

In the family doctors' center in the rayon, instead of 2 phtiziopulmonologysts that should be in every family doctor's center, there was only one specialist. This is frequent phenomenon, as due to the low wages many doctors have migrated aboard to look for a better-paid job. The number of young specialists in the rural areas is low. "One of my children is the last year student at the Medical University, and I asked him if he wants to be a phtiziopulmonologyst as I am for 35 years, and you know what he said? My son told me that it is notprestigious at all to be a phtiziopulmonologyst in nowadays. Well, telling the truth, I was deeply offended." In-depth interview N12

The phtiziopulmonologysts that participated in this research were around retirement ages.

" I have a large family to support, two of my children are students and two are in the primary school, so it is very difficult for me to make both ends meet. I would have leave the country to find a job abroad, but I am old for that." In-depth interview N18

All the respondents were dissatisfied with the low salaries; everybody mentioned that with the burden of work that is required from Family Physicians and Phtiziopulmonologysts the reimbursement is inadequate and unfair. The phtiziopulmonologysts and family doctors mentioned such factors as high level of fluctuations of personnel because of low wages.

Also family doctors, especially from villages complained that the working conditions were difficult, their offices are old, under-equipped, and had not been renovated for a long time. In one village, there was no running water system available at the ambulatory, just well water. In other village, because of a very small waiting room, the patients have to wait outside of the ambulatory.

Most of the doctors mentioned the necessity to change the way of thinking of tuberculosis patients in terms of responsibility and the level of their cooperation during treatment, especially at the outpatient stage. Usually after getting relief of symptoms through several weeks of treatment many patients are tempted not to complete the treatment. Incomplete treatment leads to reappearance of symptoms and continued transmission of disease.

The doctors emphasized the fact that the majority of the patients with

tuberculosis were from socially vulnerable groups of the population.

"Due to lack of money, sick people don't go to the doctor and end by infecting relatives and friends who spread the disease further. Often TB patients don't have money to cover travel expenses from the village to the rayon's family doctors center." In-depth interview N2

"Many TB patients are heavy drinkers and it is very difficult to deal with them. I wish that forced/compulsory treatment of tuberculosis had been available in order to protect non-infected persons but this contradicts the human rights of the patients. " In-depth interview N7

6.3 Recommendations for improvement of program performance.

All family doctors emphasized that a better communication is needed among

relevant stakeholders in relation to DOTS implementation.

"I think it would be more efficient if I will receive a phone call from the hospital that will inform me about the date when the patient from my region is going back home for outpatient treatment. Sometimes it takes several days before I am informed about that." In-depth interview N4

Many interviewees mentioned that they would benefit from on-going training

and communication within the NTP.

"I think that for some patients pretreatment counseling is the most important step to help them to realize the benefits of adhering closely to the treatment regimen. Once they understand those benefits, they take the initiative to follow the requirements of the treatment. So, I think is important that doctors spend a reasonable amount of time counseling. I think that would be very useful to organize training courses on communication and counseling skills for family doctors." In-depth interview N10

Most of the family doctors suggested that it would be very helpful to provide

some food packages and hygienic sets in order to motivate and increase patient's

compliance to the treatment.

"To maximize patient's compliance such incentives as free bus tokens, free meals, and arrangements for housing and other social services should be provided. The local authorities should be more active and contribute to that." In-depth interview N9 "I think that for successful treatment not only medication regimen is important for patients, but also adequate food supply as it used to be during Soviet period." In-depth interview N13

7. DISCUSSIONS

This qualitative research revealed that the lower performance of DOTS program in opinions of the medical personnel is due to economic crisis, massive migration, poverty of the population and insufficient financing of the health care system. These findings are consistent with the results of other researches that have been performed in Moldova. The KAP survey conducted by American Alliance for Health determined that at least in every tenth Moldovan family there were or is cases when a family member has had or has symptoms of tuberculosis. The greatest % of them saw a doctor. Those that haven't, did that either because of lack of money or because they considered feeling better [29]. Although many medicines are available in the country, most of them remain beyond the reach of the poor.

It is officially estimated that migrant workers constitute around 37% of the working-age population [30]. It was estimated early in the implementation of the DOTS strategy for tuberculosis control in Mold ova that as much as 20% of defaulting in the program could be explained by the character of migration – many migrants are returning periodically to the country and then leave again, some leave for good [26].

Attitude of the main stakeholders is also very important factor that influence success of program implementation. A qualitative research conducted in Russia revealed the negative attitude of key stakeholders to change due to inadequate understanding of DOTS; perceived 'defectiveness' of the 'externaly developed' DOTS strategy and the standardized nature of the treatment regimen[31]. From the results revealed by the qualitative research about the opinions of medical personnel in

the Republic of Moldova, it could be concluded that family doctors and especially phtiziopulmonologysts possess a strong commitment and positive attitude toward the implementation of DOTS in the country. Besides, all family doctors and phtiziopulmonologyst demonstrated a good knowledge about DOTS aspects.

However, based on the results of this research, it is clear that a more comprehensive understanding of DOTS by both TB specialists and Primary Health Care (PHC) providers especially from the rural area is needed to improve the quality of provided services. It is necessary to strengthen the teamwork and referral system between TB and PHC services as well as the mechanisms of monitoring and evaluation, supervision and quality control. All these elements built together to a comprehensive approach will contribute to the improvement of early diagnosis and better TB case management.

There are some concerns expressed by doctors, such as low salaries of medical personnel and as a result low motivation for young specialist, irresponsible patients, but most of them are related to the economical situation of the country. The data of this research could be used for further quantitative research on the basis of a questionnaire.

Limitations of the study are typical for qualitative research, especially the subjectivity of data. The interviews and the analysis of the data were done by one researcher. Another limitation of this study was that the participants that were involved in this research were only from three regions, some additional issues might be in the other regions. These limitations were due to financial and time constraints.

8. CONCLUSIONS AND RECOMMENDATIONS

In the opinions of the participants in this study, the performance of the DOTS program during 2003-2005 was considered sufficient, taking into consideration the economic situation of the country. For further successful implementation of NTC program and improving the performance of the program in the Republic of Moldova several strategies should be taken into consideration in the elaboration of NTC program for the period of 2006-2010:

- Capacity building at local level: to provide villages with adequately furnished and equipped ambulatories, which will enhance the provision of high quality of health care in rural areas in Moldova
- Stakeholder motivation, as well as motivation of young TB specialist and experienced staff in order to increase commitment of the medical personnel to the NTC.
- 3. Strengthen the teamwork and referral system
- Provide training for medical personnel about pretreatment counseling in order to improve communication skills.
- 5. Develop appropriate social system support for TB patients.

This qualitative research revealed that most of the respondents considered implementation of DOTS strategy as a step forward in combating alarming proportions of TB in the Republic of Moldova. Although there are some concerns expressed by doctors, such as low salaries of medical personnel and as a result low motivation for young specialist, irresponsible patients, but most of them are related to the economical situation or ther issues rather than on the DOTS strategy itself.

8. REFERENCES

- 1. WHO, DOTS Expansion Plan to stop TB in the WHO European Region 2002-2006, 2002
- 2. WHO, Global Tuberculosis Control, 2002.
- 3. WHO, Europe and Eurasia Regional Tuberculosis Evaluation, Regional Report, 2003
- 4. World Health Organization, Report on the Tuberculosis Epidemic, WHO/TB/97.224., Geneva, 1997
- 5. Indian Council of Medical Research, Tuberculosis in India A Sample Survey 1955-1958. Special Report Series No.341, , New Delphi, p.1, 1959
- 6. Tuberculosis Chemotherapy Center, Madras. A concurrent comparison of home and sanatorium treatment of pulmonary tuberculosis patients in south India. *Bull World Health Organization 21:51, 1959*
- 7. Fox, W. Self-administration of medicaments. A review of published work and a study of the problems. *Bull Int Union Tuberc 31:*307, 1962.
- 8. Baily, G.V.J., Savic, D., Gothi, G.D., Naidu, V.B. and Nair, S.S. Potential yield of pulmonary tuberculosis cases by direct microscopy of sputum in a district of south India. *Bull World Health Organ 37:* 875, 1967.
- Chaulk, C.P., Moore-Rice, K., Rizzo, R. and Chaisson, R.E. Eleven years of community-based directly observed therapy for tuberculosis. *JAMA 274:* 945, 1995.
- 10. World Health Organization, *Tuberculosis Programme: Framework for Effective Tuberculosis Control.* WHO/TB.94.179., Geneva, 1994.
- Frieden, T.R., Sterling, T., Pablos-Mendez, A., Kilburn, J.O., Cauthen, G.M. and Dooley, S.W. The emergence of drug resistant tuberculosis in New York City. *N Engl J Med 328:* 521, 199319.
- Frieden, T.R., Fujiwara, P.I., Washko, R.M. and Hamburg, M.A.Tuberculosis in New York City – Turning the tide. *N Engl JMed 333*: 229, 1995.
- Murraay, C.J.L., Dejonghe, E., Chum, H.J., Nyangulu, D.S., Salomao, A. and Styblo, K. Cost effectiveness of chemotherapy for pulmonary tuberculosis in three sub-Saharan African countries. *Lancet* 338: 1305, 1991.
- 14. Gonzalez, E., Arma, L. and Alonso, A. Tuberculosis in the republic of Cuba: Its possible elimination. *Tuberc Lung Dis* 75: 188, 1994.
- 15. Zhang, L.X. and Kan, G.Q. Tuberculosis control program in Beijing. *Tuberc Lung Dis* 73: 162, 1992.

- China Tuberculosis Control Collaboration. Results of directly observed short course chemotherapy in 112, 842 Chinese patients with smear positive tuberculosis. *Lancet 347:* 358, 1996.
- Dai, X.C. and Duanmu, H.J. Directly Observed Treatment, Short-Course (DOTS) in China. (Abstract) Nineteenth Eastern Region Conference of the International Union against Tuberculosis and Lung Disease, Singapore, 5-8 September, 1997.
- Kumaresan, J.A., Md. Ahsan Ali, A.K. and Parkkali, L.M.Tuberculosis control in Bangladesh: Success of the DOTS strategy. *Int J Tuberc Lung Dis 2:* 992, 1998
- 19. Murraay, C.J.L., Dejonghe, E., Chum, H.J., Nyangulu, D.S., Salomao, A. and Styblo, K. Cost effectiveness of chemotherapy for pulmonary tuberculosis in three sub-Saharan African countries. *Lancet 338*: 1305, 1991.
- 20. Alianta Americana pentru Sanatate, Curs de instruire pentru lucratorii asistentei medicale primare, Notiuni generale despre Tuberculoza, Întrebari cheie cu privire la Programul DOTS, AIHA Moldova, 2004
- 21. United Nations Development Program (UNDP), Human Development Index, 2005 Global Human Development Report, <u>www.hdr.undp.org</u>
- 22. WB, Poverty Assessment in Moldova report, 2004
- 23. Reports of Department of Migration, Moldova, 2004
- 24. Reports of the Department of Statistics, Center of Public Health, MoH, Moldova, 2004
- 25. Ministry of Health, Application to the WHO Green Light Committee for approval of a DOTS-Pilot Project in The Republic of Moldova, 2005
- 26. American Alliance for Health, Strengthening Tuberculosis Control in Moldova, Assessment Report, 2004
- 27. Ministerul Sanatatii al Republicii Moldova, Institutul de Ftiziopulmonologie, Programul National de Control al Tuberculozei, Îndrumar pentru controlul tuberculozei pentru furnizorii de asistenta medicala primara, 2004
- Ministry of Health, Order No. 180 dated on August 10, 2001: Concerning the Implementation of the National Program of Tuberculosis Control in the Republic of Moldova for the years 2001-2005, Moldova
- 29. American Alliance for Health, KAP survey: Tuberculosis in Moldova: Knowledge, Attitude and Practice in Population Behavior, 2004
- 30. Migration in the Republic of Moldova, CBS-AXA study, supported by IOM, EC, and IMF, 2004
- 31. Atun R.A, Baeza J, Drobniewski F, Levicheva V, Coker RJ. Centre for Health Management, Tanaka Business School, Imperial College London, UK. Implementing WHO DOTS strategy in the Russian Federation: stakeholder attitudes.

Appendix 1 Interview guide in Romanian

- 1. Va rog sa-mi comunicati de cît timp activati în calitate de medic.
- 2. În ce an strategia DOTS a fost implementata în regiunea D-ra?
- 3. Ati primit informatie suplimentara, instruire referitor la DOTS?
- 4. Credeti ca ati mai avea nevoie de ceva informatie, instruire suplimentara?
- 5. Ce credeti despre componentele cheie ale Programului?
- 6. Cum credeti, daca un pacient, caz nou, a urmat toate instructiunile conform programului DOTS, care este probabilitatea acestui pacient sa fie tratat de TB?
- 7. Care din pacientii noi care se adreseaza la D-ra, îi veti suspecta la TB?
- 8. Care este metoda de diagnostic al TB?
- 9. În opinia D-ra, programul si-a atins obiectivele propuse?
- 10. Care sunt problemele majore cu care va confruntati la moment în implementarea programului?
- 11. Ce credeti ca ati schimba în acest program?
- 12. Care credeti ca ar fi metode eficiente de a fortifica complianta pacientilor cu tuberculoza la tratament?
- 13. Care credeti ca va fi impactul implementarii acestei strategii pe viiror asupra incidentei si mortalitatii tuberculozei?
- 14. Ce credeti despre utilitatea acestei strategii?
- 15. Ce credeti despre nivelul cooperarii între serviciile specializate TB si medicina primara în regiunea D-ra?
- 16. Ce credeti despre importanta sensibilizarii populatiei referitor la TB?
- 17. Din convorbirea noastra înteleg....(sumarul continutului interviului). Sunteti de acord cu aceasta? Credeti ca toate momentele le -am înteles corect? Aveti ceva sa mai adaugati la ceia ce am vorbit?

Appendix 2 Interview Guide in English

1. Tell me please how long you have been working as a doctor.

2. When did DOTS strategy implementation begin in your region?

3. Did you receive a good orientation about Directly Observed Treatment Shortcourse strategy?

4. Do you need additional information about DOTS strategy?

5. Let's talk about key components of DOTS strategy.

6. Tell me please, if a patient (new case) has followed all the treatment recommendations according to DOTS strategy, in your opinion, what is his/her

probability to be cured of tuberculosis?

7. From your new patients, whom you will suspect that is having tuberculosis?

8. What is the proper diagnostic method of tuberculosis?

9. In your opinion, have the program achieved its objectives?

10. Tell me please, the major problems that are emerging in TB control activities at this stage of Program implementation.

11. Tell me please, what would you change in this program?

12. What is in your opinion the most effective way to increase the compliance of the TB patients to the treatment?

13. In your opinion what would be the impact on the incidence and mortality of TB the further implementation of DOTS strategy in Moldova?

14. What about the utility of this strategy?

15. What do you think about the level of cooperation between TB services and primary health care in your region?

16. What do you think about the importance of raising public awareness about TB?

17. From speaking with you today, I understand that....(summarize interview content). Do you agree with this? Are there any points that I have not understood

correctly?

18. Would you like to add anything else that we haven't talked about?

Appendix 3 Consent form in Romanian

American University Of Armenia

Institutional Review Board # 1/Committee On Human Research College Of Health Sciences Subcommittee For Student Theses

CONSENT FORM

Buna ziua, eu ma numesc Olesea Nedera. Sunt studenta la Universitatea Americana din Armenia. Cercetarea "Implementarea strategiei DOTS în Moldova. De la teorie la practica, opinia personalului medical" va fi prezentata în calitate de teza în cadrul programului de masterat în sanatate publica al Universitatii Americane din Armenia. Scopul acestei lucrari este analiza opiniilor personalului medical referitor la rezultatele programului DOTS în Moldova.

Este decizia D-ra de a participa sau nu la acest studiu. Puteti sa renuntati în orice moment. Participarea D-ra la studiu în nici un fel nu va va afecta serviciul D-ra. Nu am nevoie de datele D-ra personale sau oricare alta informatie care ar putea favoriza identificarea D-ra. Cu alte cuvinte se va face tot posibilul pentru respectarea confidentialitatii informatiei pe care o s-o oferiti D-ra. Daca participati în acest studiu nu vor fi beneficii materiale pentru D-ra. Daca va hotarîti sa participati, convorbirea noastra va dura în jur de 45-60min. Doriti sa participati? (Daca da, atunci, continuam). Pe parcursul discutiei noastre, daca doriti sa finisati, atunci va rog sa ma infor mati. Aveti întrebari?

Appendix 4 Consent form in English American University Of Armenia Institutional Review Board # 1/Committee On Human Research College Of Health Sciences Subcommittee For Student Theses

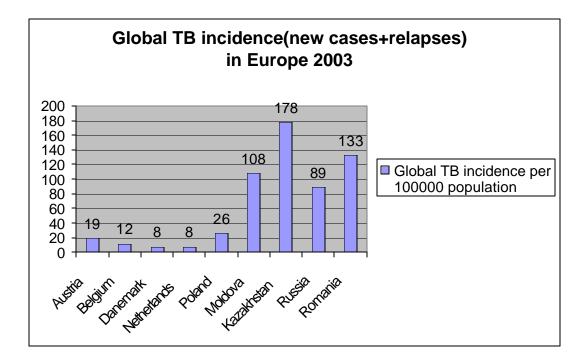
CONSENT FORM

Hello, my name is Olesea Nedera. I am MPH student at the American University of Armenia. The research project "Implementation of Directly Observed Treatment Short Course in Moldova. From theory to practice: opinions of medical personnel" will be presented as thesis paper within the framework of the Master of Public Health program at the American University of Armenia. The goal of the research is an analysis of medical personnel's opinions on the DOTS achievements.

It is your decision whether or not to be in this study. You can stop being in this study at any time. Whether or not you are in the study will not affect your job. I do not need your name or any information that will link you with the information I am going to collect. In other words, every effort will be made to protect the confidentiality of the information you provide. There will be no monetary benefits for you if you participate in this project. If you do choose to participate, to answer the questions will take about 45-60 minutes. Would you be willing to participate (If response is affirmative, continue). If at any time during the discussion you wish to stop, please inform me and we will not continue. Do you have any further questions?

Figure 1 Global TB incidence in Europe 2003

(WHO, Global Tuberculosis Control, 2003)



(Reports of the Department of Statistics, Center of Public Health, Ministry of Health)

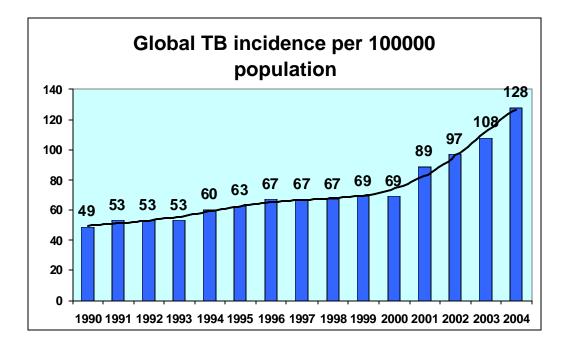
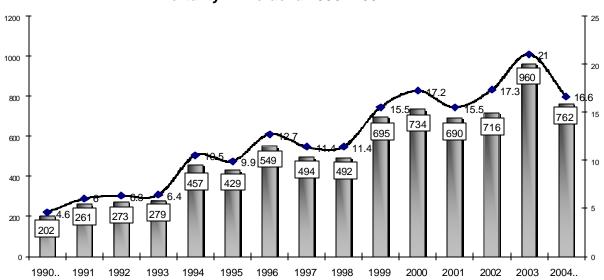


Figure 3 TB Mortality in the Republic of Moldova 1990-2004

(Reports of the Department of Statistics, Center of Public Health, Ministry of Health)



TB Mortality in Moldova 1990 - 2004