

National Strategic Plan for the Control of Tuberculosis in Romania, 2015-2020

Turning the tide against multi-drug resistance TB (MDR-TB)

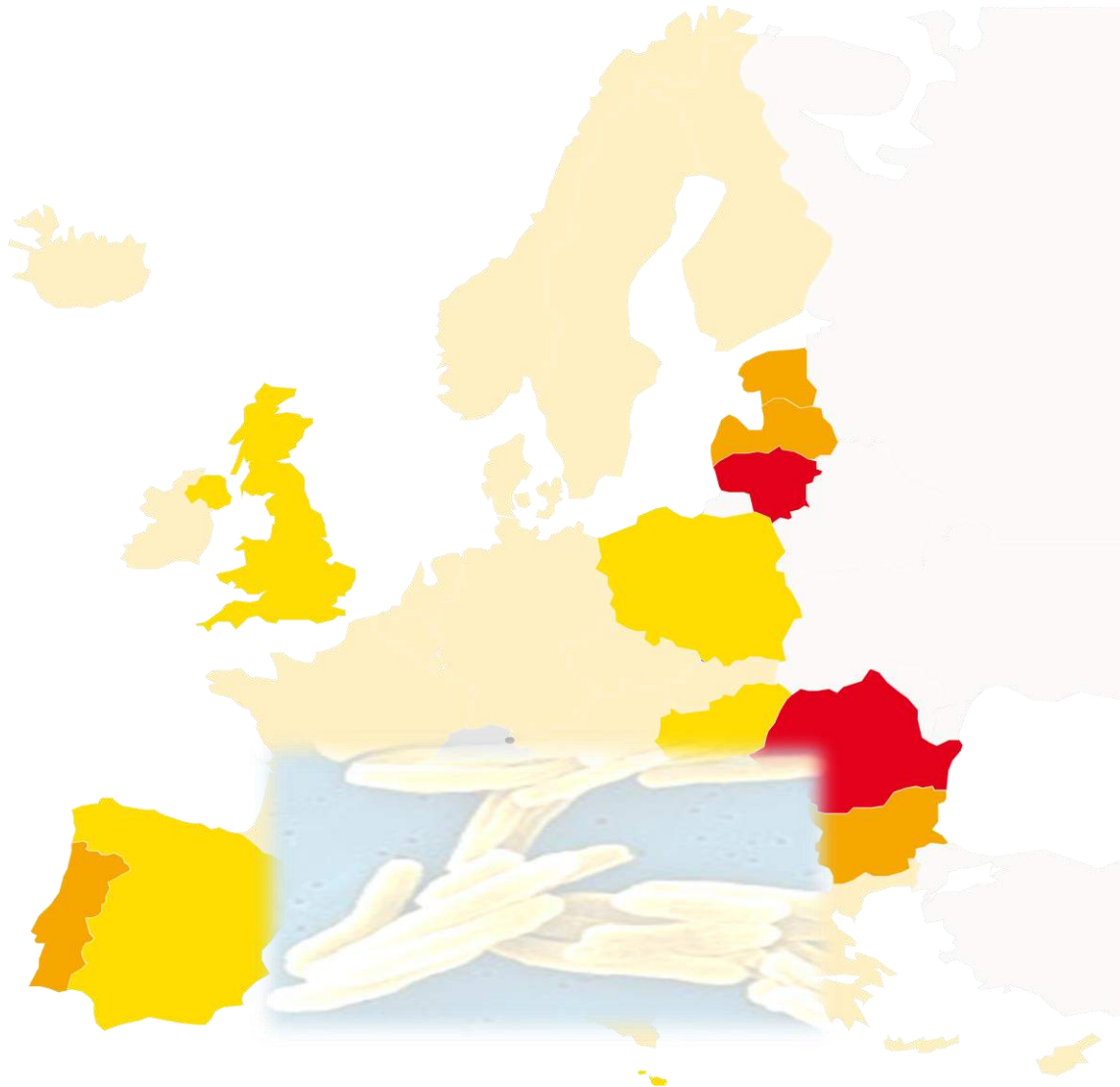


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The 2015-2020 National Strategic Plan for Tuberculosis Control presents the Government of Romania's priorities to address the public health challenge of tuberculosis (TB). The plan outlines our strategies to respond to unmet needs and sustain recent gains. Through these efforts, Romania will move closer towards TB elimination by 2050.

TB adversely impacts the lives of thousands of Romanians, in particular, on our most vulnerable citizens, rural, poor, and homeless citizens. The preventable death of over 1000 Romanians each year from TB is unacceptable. To address this problem, we must also *turn the tide against multi-drug resistance TB (MDR-TB)* by ensuring universal access to the most effective treatment regimens and supportive interventions.

Romania must also do more to prevent drug resistance from occurring by rapidly and accurately diagnosing MDR-TB and supporting patients to successfully complete therapy. Given the adverse and often fatal outcomes when TB strikes persons living with HIV (PLHIV), we must also take all steps to prevent TB in PLHIVs and to expeditiously identify and treat co-infection.

To protect the health of all Romanians requires making TB control a priority issue not simply through declarations, but with well-resourced actions. Financial and technical support has been provided by our international donors and partners, such as the World Health Organization and the Global Fund to Fight AIDS, Tuberculosis, and Malaria (GFATM), and more recently through new commitments from the Norwegian government and the European Union, but Romania must also increase its commitments. These resources, together with the tireless contributions of Romanians, will sustain our recent achievements and close critical gaps for controlling this disease.

This plan presents both a long-term vision, and identifies innovative strategies, to be implemented over the next five years to combat TB. The plan represents the government's commitment to take legislative and political action to reduce the TB burden. To support this plan, the government will also need to secure that resources for universal access to MDR-TB treatment and other innovative strategies are made a priority in our national health budget. The strategies presented in this plan will be led by the Ministry of Health and the National Tuberculosis Program, but should also guide local action. Through the combine efforts of all Romanians concerned with public health – doctors, nurse, patients and families - significant progress can be expected.

Prime Minister of Romania
September 2014

Preface

The National Strategic Plan for Tuberculosis, 2015-2020 was designed through a collaborative process led by a working group comprised of representatives from the Ministry of Health, the National Tuberculosis (TB) Program and the World Health Organization (WHO) along with various other governmental and non-governmental organizations. The plan sets TB control strategies based on Romania's current epidemiological and program needs and incorporates recommendations from a recent international program review of TB. The strategies and interventions presented in this document are intended for resource planning and policy setting. While the plan was developed to address the most pressing national resource needs for TB control, it can also guide planning and decision making at the district and local level.

The current plan builds upon past efforts and strategic plan experiences for TB which began in 1997 when Romania piloted the WHO DOTS Strategy reaching country-wide implementation by 2005¹. Following this, the country adopted the revised six point Stop TB Strategy through as part of its revised "Tuberculosis National Strategic Plan, 2006-2010". This plan was updated after 2010 under the drafted "Tuberculosis National Strategic Plan, 2013-2017". As part of this draft plan, the NTP established its aims to reduce mortality, morbidity and transmission of TB until it is no longer a national public health problem specifying as its following primary targets to be achieved by 2017: 1) reduce by 50% TB prevalence and mortality (2002 baseline); 2) maintain a case detection rate of new smear-positive pulmonary TB cases over 70%; and 3) maintain the treatment success rate among new pulmonary TB sputum-positive cases of 85%. The major areas of interventions corresponded to the six components of the Stop TB Strategy:

Stop TB Strategy

1. Pursue high-quality DOTS countrywide and enhancement
2. Address TB-HIV, MDR-TB and the needs of poor and vulnerable populations
3. Contribute to health system strengthening
4. Increase engagement all care providers in TB infection control
5. Empower people with TB and communities in order to fight TB
6. Enable and promote research

Romania subsequently drafted a separate strategic plan for MDR-TB, the "National plan to prevent and control M/XDR-TB, 2012-2015, officially launched in October 2012, but implementation was delayed due to the lack of financial resources. As part of the current national strategy, 2015-2020, MDR-TB activities have been incorporated into the current overall plan.

¹ The five elements of DOTS strategy are: 1) Political commitment with increased and sustained financing; 2) Case detection through quality-assured bacteriology; 3) Standardized treatment, with supervision and patient support; 4) An effective drug supply and management system, and; 5) Monitoring and evaluation system, and impact measurement

Abbreviations

AFB - Acid Fast Bacilli
ART – Antiretroviral treatment
C (+/-) - Culture (positive/negative)
CDC - Centers for Disease Control and Prevention
DOT – directly observed treatment
DRS – Drug resistance surveillance
DS-TB – Drug susceptible TB
DST – Drug susceptibility testing
ECDC – European Center for Disease Control and Prevention
EQA - External Quality Assessment
FLD - First-line anti-tuberculosis drugs
FLDST – First-line drug susceptibility test
FM -Fluorescent Microscopy
GDF – Global Drug Facility
GFATM – Global Fund to Fight AIDS, Tuberculosis and Malaria
GLC – Green Light Committee
GOR – Government of Romania
HIV – Human immune deficiency
HRD Human Resource Development
IC – Infection control
INH - Isoniazid
LED - Light Emitting Diode
LPA - Line Probe Assay
M&E - Monitoring and Evaluation
MDR-TB – Multi drug-resistant tuberculosis
MoH – Ministry of Health
MOJ – Ministry of Justice
NHL - National Health Laboratories
NRL – National reference laboratory
NSP – National Strategic Plan
NTP – National Tuberculosis Program
NTRL - National Tuberculosis Reference Laboratory
PLHIV - People Living with HIV
PMDT – Program management of drug-resistant tuberculosis
RAA – Romanian Angel Appeal
RMP - Rifampicin
SCMS - Supply and commodities management system
SAT – Self-administered treatment
SLD – Second-line anti-tuberculosis drugs
SLDST – Second-line drug susceptibility test
SOP - Standard Operating Procedure
SNRL - Supra-National Reference Laboratory
SS+ - Sputum Smear Positive
SS- -Sputum Smear Negative
TB – Tuberculosis
WHO – World Health Organization
XDR-TB – Extensively drug-resistant tuberculosis

I. Executive Summary

Romania made great strides to identify and treat drug-susceptible cases of TB. As a result of recent efforts, Romania dropped to 66th place in terms of global TB and achieved the following progress to control TB disease:

- TB mortality rate fell from 10.8 per 100,000 (2002) to 5.3 cases per 100,000 (2013);
- Treatment success rate for new smear-positive TB cases has exceeded 80% since 2005 reaching 86% in 2012 and 86% for smear-negative and extra-pulmonary TB cases, and;
- TB incidence declined from a peak of 142.2 cases per 100,000 (2002) to 79.9 cases per 100,000 (2012).

Romania reported 12,860 new TB cases a year in 2013, the highest incidence in the EU/EEA region and the fifth-highest rate within the WHO Euro region (after Kazakhstan, Moldova, Georgia and Kirgizstan), and 3,851 total retreatment cases. Recent progress is now threatened by the on-going spread of drug-resistant TB, which reflects system failures to adequately manage a TB case through completion of treatment. The country has an estimated 800 - 1200 new multi-drug resistant (MDR-TB) cases per year, but detects only 66% of cases. Out of the cases Romania does find only an estimated 40% receive recommended regimens.

A. Challenges and Constraints for TB Control

A number of challenges and constraints have impeded progress for TB control from lack of critical medications to insufficient program resources. These issues contribute to ongoing transmission, unfavourable treatment outcomes, and growth of MDR-TB. To sustain recent progress and prevent the MDR-TB from worsening, Romania needs to tackle these major challenges:

1. Unavailability of rapid testing for MDR-TB resulting in timely and accurate diagnosis²;
2. Poorly managed second-line treatment, apart from Global Fund MDR-TB treatment cohort due to unavailable second-line drugs (SLDs);
3. Unreliable drug supplies caused by decentralized procurement;
4. Costly, and often unnecessary, hospitalization of TB patients consuming limited resources;
5. Insufficient infection control in hospitals and laboratories exposing patients, families and health care workers to higher risk of contracting TB;
6. Poor Directly Observed Therapy (DOT) during outpatient treatment for both sensitive and resistant TB cases
7. Limited social support for patients with TB, insufficient psychological support provided to TB patients, and;
8. Insufficient scale-up of prevention and education activities in poor and vulnerable populations.
9. TB screening, diagnosis and treatment in high risk groups insufficiently addressed
10. Insufficient trained workforce for TB control and no systematic method to develop personnel skills and capacities

² According to the WHO estimates for Romania, an average of 2.9 percent of new and 11.6 percent of previously treated TB cases had MDR-TB in 2011, which corresponds to more than 1,000 MDR-TB cases. Eleven percent of MDR-TB cases were estimated to have XDR-TB meaning more than 110 XDR-TB cases should have been diagnosed in Romania in 2011.

Romania's Ministry of Health (MoH), through its National Tuberculosis Program (NTP), sets TB control guidelines, policies and conducts major TB initiatives, but currently lacks sufficient resources to universally test, diagnose and treat all MDR-TB cases. While, Romania has benefited from resources from the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM), European Union and several bilateral grants, most recently from the Government of Norway, these funds and commitments provide a temporary, external solution to resource needs. Greater financial commitment by the Government of Romania (GOR) is required for a long-term sustainable resolution to resource needs. To address these gaps and plan for high impact solutions, Romania has developed a new National Strategic Plan for TB Control, 2015-2020 (NSP).

B. Strategic Objectives and Interventions

To turn the tide against MDR-TB and sustain recent TB control progress, the GOR has established the following ambitious objectives which it will pursue over the next five years (2015-2020):

- *Objective 1 - Ensure universal access to rapid diagnosis methods for DS-TB and M/XDR-TB by 2020*
- *Objective 2 - Diagnose at least 85% of all estimated DS-TB and MDR-TB cases*
- *Objective 3 - Successfully treat at least 90% of new culture positive TB cases and 85% of all retreatment cases by 2020.*
- *Objective 4 - Successfully treat 75% of MDR-TB cases by 2020.*
- *Objective 5 - Reduce overall TB mortality rate to 4.3 per 100 000 population by 2020.*
- *Objective 6 - No affected families facing catastrophic costs due to tuberculosis³.*
- *Objective 7 - Case notification rate of all forms of TB per 100,000 population - bacteriologically confirmed plus clinically diagnosed, new and previously treated cases will decrease from 73 in 2013 to 46.59 cases per 100 000 population by 2020.*
- *Objective 8 - Improve health system capacity to control TB.*

The National Strategic Plan for TB (NSP) is based on the following three pillars:

- Integrated Patient-Centered Care and Prevention
- Bold Policies and Supportive Systems
- Innovative Research and Evidence-based Strategies

³ Out-of-pocket expenditure on health care exceeding 40% of discretionary household expenditure has been defined by WHO as a catastrophic level. The threshold for catastrophic total cost (including indirect costs) has not yet been established.

II. Introduction

The National Strategic Plan for Tuberculosis, 2015-2020 (NSP) presents the vision, goals and objectives for the diagnosis, treatment, and prevention of TB in Romania building upon recent achievements and responding to ongoing challenges. The NSP reviews the epidemiology of TB, describes how TB disease is managed, diagnosed and treated, and details the major needs and gaps impeding TB control progress, in particular, those impeding the timely diagnosis and effective treatment of MDR-TB. Following the situational analysis presented in Section III, a series of strategic objectives and interventions based on the pillars of Integrated Patient-Centered Care and Prevention, Bold Policies and Supportive Systems, and Innovative Research and Evidence-Based Strategies are introduced in Section IV to sustain recent progress, to align the country with international goals, and make significant strides to improve TB diagnosis and treatment outcomes and move Romania forward towards TB elimination. An M&E, TA and budget plan provides further details regarding the how Romania will strategically combat this disease over the next 5 years and specific targets, indicators and proposed intervention activities it will pursue.

A. Vision, Goals and Strategic Objectives

To address the problem of TB, the GOR establishes the following vision, goal and major objectives for TB control. Pursuit of these targets will align Romania's control program with international standards for the diagnosis and treatment of TB and improve the quality of life for Romanians over the next five years.

Vision: *Eliminate TB as a public health problem in Romania by 2050.*

Goal: *Achieve dramatic reductions in TB incidence and mortality by 2020.*

The Government of Romania will pursue this goal through the following **major objectives**:

- *Objective 1 - Ensure universal access to rapid diagnosis methods for DS-TB and M/XDR-TB by 2020*
- *Objective 2 - Diagnose at least 85% of all estimated DS-TB and MDR-TB cases*
- *Objective 3 - Successfully treat at least 90% of new culture positive TB cases and 85% of all retreatment cases by 2020.*
- *Objective 4 - Successfully treat 75% of MDR-TB cases by 2020.*
- *Objective 5 - Reduce overall TB mortality rate to 4.3 per 100 000 population by 2020.*
- *Objective 6 - No affected families facing catastrophic costs due to tuberculosis⁴.*
- *Objective 7 - Case notification rate of all forms of TB per 100,000 population - bacteriologically confirmed plus clinically diagnosed, new and previously treated cases will decrease from 73 in 2013 to 46.59 cases per 100 000 population by 2020.*
- *Objective 8 - Improve health system capacity to control TB.*

⁴ Out-of-pocket expenditure on health care exceeding 40% of discretionary household expenditure has been defined by WHO as a catastrophic level. The threshold for catastrophic total cost (including indirect costs) has not yet been established.

B. Pillars

Greater action and investment is required to reduce the burden of TB disease on the population of Romania, to prevent ongoing transmission, and to rapidly diagnosis and treat drug-susceptible TB. This document presents a call to action to scale up core TB prevention and control activities and to implement new diagnostic and treatment capacities to meet the growing challenge of MDR-TB and ongoing burden of TB within vulnerable populations.

To ensure that these actions are effective, the 2015-2020 NSP for TB will be based upon three pillars and pursue a series of key intervention areas:

- **Integrated Patient-Centered Care and Prevention**
- **Bold Policies and Supportive Systems**
- **Innovative Research and Evidence-Based Strategies**

1. Integrated Patient-Centered Care and Prevention

The initial pillar recognizes that TB care and prevention services should be based on integrated patient-centered care. The NTP needs to ensure provision of high-quality tuberculosis care and prevention across the health system. Romania needs to sustain effective diagnosis and treatment systems while embracing new strategies and technologies for universal access to drug susceptibility testing. Effective diagnosis and treatment for children are also required. To advance its ambitious objectives, the GoR needs to provide additional outreach services to underserved and vulnerable populations; and to embark on systematic screening and preventive treatment of relevant high-risk groups – all in partnership with relevant stakeholders.

2. Bold Policies and Supportive Systems

The second pillar encompasses bold policies and supportive systems that demonstrate the TB control is an important public health priority. To deliver effective TB diagnosis and care the GoR must provide sufficient resources and take action to develop and implement the major reform aimed on changing the current system of care for TB cases from in-patient to out-patient care, which will result in reduction of hospitalization cost while redirecting more resources to ambulatory and patient-centered care.

The MoH and the NTP must engage and coordinate initiatives with other public health programs public, nongovernmental and civil society organizations, communities and patient associations as well as family doctors. Interventions are required to address medical and non-medical needs of those ill with tuberculosis. To move towards TB elimination and sustain recent achievements, the Government must ensure a well-resourced, organized and coordinated health system with sufficient human and other resources.

3. Innovative Research and Evidence-Based Strategies

The third pillar recognizes that progress in tuberculosis control is constrained not only by the lack of new tools to better detect, treat or prevent tuberculosis but also by the weaknesses of health systems in delivering optimal diagnosis and treatment with existing tools and strategies. Ending the tuberculosis epidemic will require substantial investments in the development of novel diagnostic, treatment and prevention tools, and for ensuring their accessibility and optimal uptake alongside better and wider use of existing technologies. This will be possible only through increased investments and effective engagement of partners and the research community to conduct research that explores policy options, identifies best practices, and provides evidence for decision-making.

The following the key interventions that will be conducted during the NSP:

1. Integrated Patient-Centered Care and Prevention

- 1.1. Develop universal access to rapid diagnostic methods and universal drug-susceptibility testing
- 1.2. Improve the timeliness and accuracy of diagnosis of TB
- 1.3. Effectively treat TB patients by following WHO-treatment recommendations
- 1.4. Improve treatment outcomes for MDR-TB and XDR-TB patients by following WHO-treatment recommendation
- 1.5. Improve patient support and case holding systems
- 1.6. Prevent transmission of TB through vaccinations, targeted screenings, and infection control
- 1.7. Ensure collaborative tuberculosis/HIV activities

2. Bold Policies and Supportive Systems

- 2.1 Ensure adequate resources for tuberculosis care and prevention
- 2.2 Strengthen the capacity of the National TB Program for TB control
- 2.3 Develop human resource capacity for TB care and prevention
- 2.4 Establish centralized procurement and distribution of first, second and third-line anti-TB medications
- 2.5 Establish infection control standards and requirements for healthcare facilities
- 2.6 Engage and facilitate involvement of impacted communities and civil society organizations in TB control
- 2.7 Support the involvement of public section and family doctors and community workers to provide ambulatory and community-based TB care and services

3. Innovative Research and Evidence-Based Strategies

- 3.1. Ensure a dynamic and effective TB surveillance system
- 3.2. Develop epidemiological and research capacity for TB control
- 3.3. Conduct operational and epidemiological research to improve TB control

C. Strategic Interventions

Over the next five years, Romania will develop and implement a major reform aimed on changing the current system of care for TB cases from in-patient to out-patient care, which will result in reduction of hospitalization cost while redirecting more resources to ambulatory and patient-centered care (provision of treatment supervision, peer support, and enablers, to encourage adherence to the lengthy treatment process, etc.).

Also Romania will invest in rapid, quality-assured diagnostic methods to improve the accuracy and timeliness of TB detection and provide greater access to anti-tuberculosis medications, in particular, second-line treatment regimens for drug resistant cases.

Through the screening of high-risk populations, in conjunction with improved infection control practices in healthcare and laboratory settings, Romania will detect cases earlier and prevent ongoing transmission of the TB bacteria.

These actions will be supported by developing and formalizing TB control guidelines based on best practices and international norms, improving drug procurement process, and by building the capacity of providers, allied health professionals, and healthcare facilities to carry out critical TB functions.

To ensure that overall system is functioning, the TB surveillance system will be modernized and program implementation will be routinely monitored and evaluated to assess quality, identify barriers and document impact.

Finally, the potential for even greater program achievements will be assisted by engaging multiple stakeholders (government, civil society and international partners) to improve program coordination, identify best practices, resolve implementation barriers, and obtain technical support.

Pursuit of this comprehensive, and ambitious, plan will turn the tide against MDR-TB and move Romania closer to its goal of TB elimination.

By pursuing these objectives and interventions, Romania will seek to achieve the following impacts on TB Control (Table 1).

Table 1. Impact Indicators and Targets

Interventions	Indicators	Baseline	Year of baseline	2015	2016	2017	2018	2019	2020
Impact Indictors	TB mortality rate	5.3	2013	5.52	5.49	5.20	4.91	4.65	4.30
Outcome indicators	Case notification rate of all forms of TB per 100,000 population - bacteriologically confirmed plus clinically diagnosed, new and previously treated cases	72.99	2013	82.12	82.12	73.91	65.04	57.23	49.79
	Case notification rate per 100,000 population - bacteriologically confirmed, new and relapse cases	45.11	2013	49.70	49.71	44.74	41.73	36.73	31.95
	Treatment success rate - bacteriologically confirmed new TB cases	86%	2012	86%	87%	87%	88%	88%	90%
	Treatment success rate bacteriologically confirmed relapses	57%	2012	60%	65%	70%	75%	80%	85%
	Treatment success rate of MDR-TB: Percentage of bacteriologically confirmed drug resistant TB cases (RR-TB and/or MDR-TB) successfully treated	20%	2010	50%	55%	60%	65%	70%	75%

III. Situational Analysis

Tuberculosis (TB) disease is caused by bacteria (*Mycobacterium tuberculosis*) that most often affects the lungs, but can affect other organs and parts of the body. It spreads from person to person through the air. When people with pulmonary TB cough, sneeze or spit, they propel the TB germs into the air. A person only needs to inhale only a few of these germs to become infected. When a person develops active TB disease, the symptoms (*cough, fever, night sweats, weight loss*) may be mild for many months. This can delay seeking care, and result in transmission of the bacteria to others. People ill with TB can infect up to 10-15 other people through close contact over the course of a year. Without proper treatment up to two thirds of people ill with TB will die. Fortunately, TB is both curable and preventable when diagnosed in a timely manner and properly treated.

A. Recent Achievements

The National TB Control Program (NTP) in Romania has made remarkable progress to detect and treat tuberculosis (TB). As a result of dedicated action, and through following a national DOTS strategy based on the WHO STOP TB Strategy⁵, Romania achieved the following:

- Case detection of TB regularly exceeds the international target of 75%;
- TB incidence declined from its a peak of 142.2 cases per 100,000 (2002) to 79.9 cases per 100,000 in 2012;
- Treatment success rates for new smear-positive TB cases regular exceeded 80% since 2005, reaching 86% in 2012 (for 2011 cohort), and 86% for smear-negative and extra-pulmonary TB cases, and;
- TB-related deaths fell from 10.8 (2002) to 5.3% in 2013.

B. Critical Challenges

Despite these remarkable gains, Romania continues to experience some of the highest rates of TB for European (EU)/EEA countries reporting nearly 13,000 new cases every year (12,866 in 2013) and 1,136 Romanians TB-related deaths. Looming over this situation is the growing problem of multi-drug resistant TB (MDR-TB) and other challenges which threaten to undo TB control recent gains at a terrible human and financial cost.

Some of the significant challenges that will require a dedicated response and resolution during the next five years include addressing the following:

1. Unavailability of rapid testing for MDR-TB that creates a time lag between the request for drug sensitivity testing and availability of results⁶;

⁵ The 2006-2015 Stop TB Strategy was based on six major components: 1) pursuing high quality DOTS expansion and enhancement; 2) addressing TB/HIV, MDR-TB and other challenges; 3) contributing to health system; 4) strengthening; engaging all care providers; 5) empowering patients and communities; and 6) enabling and promoting research.

⁶ According to the WHO estimates for Romania, an average of 2.9 percent of new and 11.6 percent of previously treated TB cases had MDR-TB in 2011, which corresponds to more than 1,000 MDR-TB cases. Eleven percent of MDR-TB cases were estimated to have XDR-TB meaning more than 110 XDR-TB cases should have been diagnosed in Romania in 2011.

2. Poorly managed second-line treatment outside the limited number of patients in the Global Fund-treatment cohort due to missing second-line drugs (SLDs) on the Romanian market;
3. Unreliable drug supplies caused by decentralized procurement;
4. Costly, and often unnecessary, hospitalization of TB patients;
5. Insufficient infection control in hospitals and laboratories exposing patients, families and health care workers to higher risk of contracting TB;
6. Poor DOT during outpatient treatment for both sensitive and resistant TB cases
7. Limited social support for patients with TB, insufficient psychological support provided to TB patients, and;
8. Insufficient scale-up of education and prevention activities among poor and vulnerable populations (homeless, rural populations, and Roma)
9. TB screening, diagnosis and treatment in high risk groups insufficiently addressed
10. Insufficient trained workforce for TB control and no systematic method to develop personnel skills and capacities

C. Epidemiology

Within Romania, the major TB indicators are declining mostly due to the increased diagnosis and access to treatment for the majority of drug-susceptible TB (DS-TB) cases , but in terms of infectious disease TB has ranked as the leading category of disease (see Table 2).

Table 2 Number of Infectious Disease Cases

Categories of infectious diseases	1990	2010	2011	2012
	Number	Number	Number	Number
Rubella	10947	351	4398	20812
Tuberculosis	14997	15941	14543	13997
Measles	4690	193	4737	7450
Viral hepatitis	74745	4518	3449	4438
Influenza	11927	1600	3133	1917
Scarlet fever	4526	1659	3016	1817
Syphilis	5375	2326	2209	1702
Dysentery	7382	259	385	357
Whooping cough	817	29	85	83

Source: National Institute for Statistics

Global incidence for TB peaked in 2002 with 142.2 cases per 100,000 declining to 72.9 cases per 100,000 in 2013. The absolute number of all cases registered in 2013 totaled 15,530 new and relapse TB cases (see Table 3). Over two-thirds (79.1%) of these cases presented with pulmonary TB, 14.6% had only extra-pulmonary TB (EPT) and 6.3% were diagnosed with both pulmonary and EPT.

Table 3 Incidence (New and Relapses), Prevalence and Mortality Rates 2011-2013.

Year	Incidence (New and Relapses)		Prevalence		Mortality	
	Abs.	Per.	Abs.	Per.	Abs.	Per.
2011 (21,354,396 population)	17,672	82.8	30,769	143.6	1,283	6.0
2012 (21,316,420 population)	16,766	78.7	28,454	133.5	1,249	5.9
2013 (21,316,420 population)	15,530	72.9	26,584	124.7	1136	5.3

Source: Data for TME 2014

The majority of cases (77%) were classified as new, while 15.9% were relapse cases and 7.1% were defaulters or failures. In 2013, 59.1% of new pulmonary cases were smear-positive, 39.7% were smear-negative and 17.9% were extra-pulmonary TB. For retreatment cases, 69.2% were relapses⁷, 7.5% were on treatment after failure, and 15.6% after default (see Table 4). Culture confirmation was available in 73.4% of cases, but drug sensitivity test (DST) results for Isoniazid and Rifampicin were available only for 49.8% of culture confirmed cases (5,966/11,974) in 2012. 8.9% of the cases with available DST results presented with MDR-TB.

Table 4 TB Case Notification 2011-2013, Civilian Sector

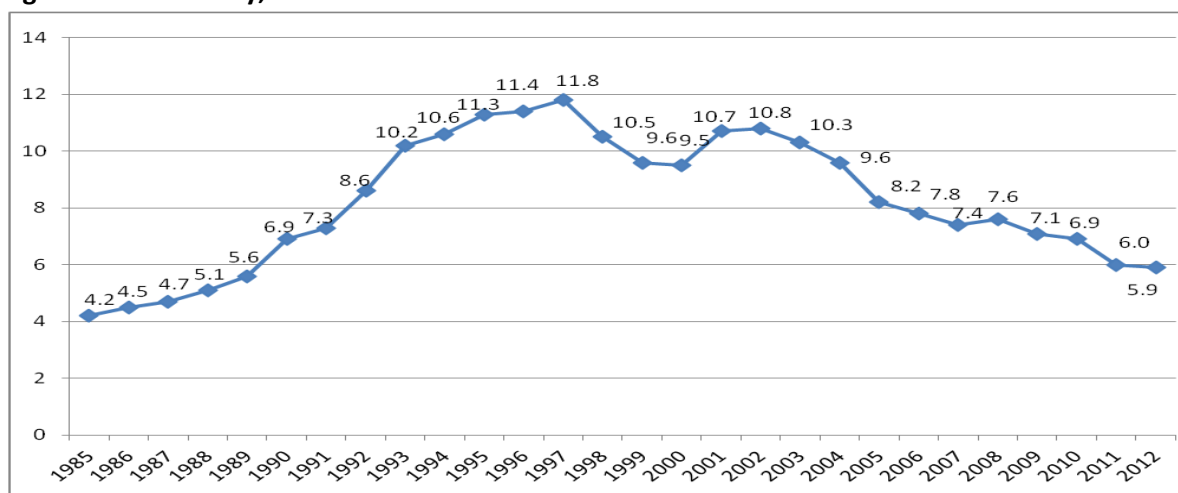
Case Notifications	2011		2012		2013	
	Abs.	Per.	Abs.	Per.	Abs.	Per.
New cases						
Smear-positive	7,396	62.1	7,103	62.2	6,202	59.1
Smear-negative	4,399	36.9	4,168	36.5	4,207	39.7
Smear unknown	116	1.0	145	1.3	196	1.8
Extra-pulmonary TB	2,627	18.1	2,472	17.8	2,336	17.9
Other	-	-	-	-	-	-
Total new	14,538	100.0	13,888	100.0	12,941	100.0
Retreatment cases						
Relapse	3,137	67.2	2,880	66.8	2,685	69.2
Treatment after failure	401	8.6	349	8.1	291	7.5
Treatment after default	729	15.6	688	16.0	605	15.6
Other	400	8.6	392	9.1	295	7.6
Total retreatment	4,667	100.0	4,309	100.0	3,876	100.0

Source GLC/Europe monitoring mission to Romania, March 10-15, 2014; Data were updated for TME 2014

Adjusted TB mortality rates from vital registration systems reflect an overall downward trend from 10.2 in 2003 to 5.3% in 2012 (figure 1).

⁷ Relapse patients were treated, declared cured, but have a new episode of TB confirmed by laboratory and radiograph results.

Figure 1 TB Mortality, 1985-2012



1. Demographics

TB adversely affects more men than women in Romania with rates in males accounting of 69% of all cases in 2012. The highest rates of TB were reported for adults ages 45-64 years old and in young adults (15-44 years) with, respectively, 76.2 and 73.3 cases per 100,000. The median age at diagnosis was 44 years (range 0-95 years).

a. Pediatric TB

Pediatric cases fell from 48.2 cases per 100,000 in 2002 to 21.8 cases per 100,000 in 2013. There were a total of 698 cases of which 248 cases were 0-4 years of age and 450 were 5-14 years. This comprised 4.2% of total TB cases⁸. Two of these cases were diagnosed with MDR-TB. The decrease in TB in pediatric populations indicates a real decline in TB incidence. The 2014 Program Review, however, expressed concern that pediatric cases may be under-diagnosed. The diagnosis of TB in children is more difficult than in adults because young children cannot easily produce a sputa sample.

b. Geographical Distribution

Regional differences exist with TB rates with notifications ranging from 26 cases per 100,000 population (2013) in the least effected district to 114 cases per 100,000 in the highest impacted area. Variations are related to the socio-economic status of the Romanian regions with higher case rates reported in the Eastern, Western and Southern parts and lower rates in the Central and North-western parts. The highest TB notification rates were reported in southern districts.

2. Vulnerable Populations

TB also adversely affects the most vulnerable segments of Romania often at greater risk of exposure due to their living situation and at greater risk to progressing to active TB disease due to poorer health status and

⁸ National Database Data sent for TME 2014

weaker use and access to health care services (refer to Table 5). While the capital city of Bucharest and many other large urban areas may be comparable to other major European capitals, Romania has a sizeable population of underserved and vulnerable populations. The country's rural population, which comprises 45% of the population, suffers from high rates of poverty and low socio-economic development. Only about 50% of rural residents have access to improved sanitation facilities and 40% have difficulty with access to primary healthcare services compared to only 15% in urban areas. Rural populations, in general, are disproportionately affected by TB as well as likely to experience higher treatment failure and default.

Table 5 Risk Factors Associated with TB

	2012		2013	
	Number	Percentage	Number	Percentage
Total Patients	18,192	100%	16,718	100%
Unemployment	124	0.68%	113	0.68%
Smoking Tobacco	613	3.37%	567	3.39%
Alcohol Use	596	3.28%	497	2.97%
Drug Use	24	0.13%	42	0.25%
Mental health*	267	1.47%	303	1.81%
Homelessness	127	0.70%	135	0.81%
TB Healthcare Worker	9	0.05%	9	0.05%
Other medical personnel	120	0.66%	91	0.54%

a. Roma

The minority Roma population are disproportionately poorer than the majority Romanians, with as many as 75 percent of Roma living in poverty compared to 32.2 percent overall of Romanians (*source: Amnesty International*). The Roma community encounters greater obstacles and difficulties in accessing health care and paying for treatment. As a result, Roma often do not access or receive care in a timely manner compared with the general population⁹. The Roma also suffer higher rates of TB.

While the NTP does not collect specific ethnic data on patients, TB rates among Roma have been report to be double that of the general population and up to four times higher in adults ages 55-64¹⁰. According to a recent prevalence study¹¹ performed in two rural Roma communities, the prevalence of TB infection was 27,000 per 100,000 persons.

b. TB among Homeless Population

There are an estimated 11,000 homeless in Romania with 5000-6000 living in Bucharest. A 2011 study estimated that the TB prevalence in the Bucharest homeless population at 6,700 cases per 100,000 or 50

⁹ Roma face greater obstacles and difficulties in accessing healthcare and paying for medication. 11% of Roma respondents reported that in the last year they had needed healthcare but did not get it, in comparison with 5% of the general population (source).

¹⁰ European Roma Rights Centre, October 2013

¹¹ Operational research (conducted under the Global Fund Round 6 TB Grant): "TB prevalence in Roma communities in Bihor and Arad counties", Dr. Nini Gheorghe & all.

times higher than the general population's TB prevalence. According to data from the NTP, homelessness was associated with 135 TB cases in 2013 up from 127 in 2012.

c. TB in Prisons

The problem of TB in prisons has received significant attention in the media and from international organizations. TB can spread rapidly due to poor infection control and crowding in congregate settings. There are 38 penitentiary centers and six prison hospitals in Romania. Each prison has a medical cabinet and a small medical staff. An initial medical screening occurs at intake. Romania implemented several projects to combat TB in prisons using Global Fund support. As a result, the TB incidence dropped from its zenith of 2967 cases per 100,000 in 2002 to 465 cases per 100,000 (2013). The absolute of notified cases was 148 in 2013, but the rate remains 6.5 times higher than in the general population (see Table 6).

Table 6 TB Case Notification 2011-2013, Prison sector (NTP)

Case Notifications	2011		2012		2013	
	Abs.	Per.	Abs.	Per.	Abs.	Per.
<i>New cases</i>						
Smear-positive	43	44.3	46	47.4	40	39.6
Smear-negative	54	55.7	51	52.6	60	59.4
Smear unknown	0	0	0	0	1	1
Extra-pulmonary TB	14	12.6	16	14.2	21	17.2
Other	-	-	-	-	-	-
Total new	111	100.0	113	100.0	122	100.0
<i>Retreatment cases</i>						
Relapse	31	83.8	15	75.0	19	73.1
Treatment after failure	1	2.7	0	0	2	7.7
Treatment after default	4	10.8	0	0	5	19.2
Other	1	2.7	5	25.0	0	0
Total retreatment	37	100.0	20	100.0	26	100.0

Source GLC/Europe monitoring mission to Romania, March 10-15, 2014

The main TB control activities and interventions in the penitentiary system are now institutionalised and sustainable, but some challenges remain. Prison health officials conduct an initial TB screen using clinical history and symptom reviews during intake processing and during an annual health check-up. Inmates suspected of having TB during the clinical exam receive a chest radiograph or are referred to the local prison hospital or local TB dispensary for further evaluation. Sputa can also be collected within the prison and the samples transported to the TB dispensary/ laboratory for investigation. Nonetheless, data shows that some TB cases are missed during initial intake screenings. For instance, during the 2014 World Health Organization Regional Office for Europe program review, 3 out of 9 TB cases at the Poarta Alba prison were not identified during intake subsequently developed TB during their prison stay.

There is also concern regarding continuation of treatment after discharge. Not all prisoners return to their home districts after release and some TB patients are lost to follow-up. This issue could be addressed through

better discharge planning and the creation of incentives to encourage former prisoners to finish their treatment¹².

D. Diagnosis of TB

The diagnosis of TB in Romania primarily occurs through passive case detection. This means a case of TB is only identified when a person with symptoms seeks assistance from the health care system. Primary Health doctors, called Family Doctors, usually provide the initial screening and refer TB suspects to an out-patient department dispensary for further evaluation and diagnosis¹³. The TB dispensary will collect a biological sputa sample for testing and send these to the nearest hospital TB laboratory. Romanians, regardless of insurance status, can also self-refer to a hospital emergency department or go directly to a TB dispensary for diagnosis. The initial laboratory diagnosis is based on smear microscopy which involves staining for acid-fast bacillus (AFB) to look for bacteria. A sputa sample is collected from a TB suspect, processed and spread onto a glass slide, then treated with a special stain. The laboratory technician trained for this activity¹⁴ examines the specimen under a microscope. Using this method, the specialist can determine the presence of acid-fast bacilli, the most common of which is *M. tuberculosis*. Under guidelines approved in 2014, two sputum samples are collected from TB suspects for initial diagnosis¹⁵. The initial microscopy provides a presumptive diagnosis of TB, but a culture is required to confirm TB.

Cultures are also used to monitor the effectiveness of treatment and to determine when a patient is no longer infectious. The time to process of a culture varies depending on what technologies are used. Romania uses both solid and liquid media methods. Solid media takes around three weeks, while a liquid culture can be processed in 10-14 days. The primary reason for using solid versus liquid methods involves resource limitations. Nonetheless, almost 10% of smear-positive cases were culture negative because of low quality of either culture examination or problems with sputum collection and transportation of specimens.

1. Active Case Finding among Vulnerable Populations

Several projects were funded by previous Global Fund grants to identify TB among high-risk populations such as homeless adults and street children. One project, led by the non-governmental organization, Save-the-Children in Romania conducted a case finding program targeting homeless population. The project found 799 TB suspects amongst the homeless and actually confirmed 228 cases with 80% successfully treated. The program was extended under the Global Fund Transition Funding Mechanism (through March 2015). As of December 2013 it identified a total of 280 TB suspects with 70 TB patients diagnosed. Romania also implemented a limited number of outreach activities to improve case finding such as improving health communication, minimizing access barriers, and engaging providers focused on Roma and urban poor. These activities focused on awareness building about TB symptoms, diagnosis, and treatment services. Case finding programs and outreach projects were not been adopted into a sustain program by the Government. The NTP

¹² Stillo, 2013

¹³ Clinicians from any hospital can send specimens (sputa) to the closest TB laboratory for diagnosis.

¹⁴ Tests may be processed by a laboratory technician, physician or biologist depending on their availability.

¹⁵ Two more sputa specimen will be collected for monitoring infectiousness after a patient is diagnosed

does not consider active case finding programs as cost effective and did not develop a dedicated strategy for outreach to vulnerable groups or education of patients and communities about TB, but these activities were not rigorously evaluated and the vulnerable populations targeted through these interventions continue to be disproportionately affected by TB and lack of access to care.

2. Drug-Resistant TB

Drug resistance results from the improper use of antibiotics in drug-susceptible TB patients, from administration of improper treatment regimens, and failure to ensure that patients complete the whole course of treatment. MDR-TB is diagnosed through drug susceptibility tests (DST) that identify sensitivity, or the resistance of *M. tuberculosis* bacteria, to one or more drugs commonly used to treat TB. If the bacteria are resistant to more than one of the primary drugs used for therapy - Rifampicin (RMP) and Isoniazid (INH) - the organisms are called multidrug-resistant TB (MDR-TB). If the bacteria are resistant to multiple first-line and second-lines of therapy this constitutes an extensively drug-resistant tuberculosis (XDR-TB) case.

According to the Global Tuberculosis Report 2012, the estimated MDR-TB burden in the country in 2011 was 2.8% among new (1.8-4.2) and 11% (8-15) among retreatment cases. In 2012, there 530 MDR-TB cases compared to 547 and 30 XDR-TB in 2011 (see Table 7). 301 cases were reported for the initial nine months of 2013. The prevalence of MDR-TB reported was 4.18% out of all registered TB cases indicating a reservoir of MDR-TB. The overall number remains about 10% out of all MDR-TB cases, but this may be under-diagnosed as not every cases with resistance to Rifampicin is tested for second-line DST.

The percentage of XDR-TB among registered MDR-TB cases was 11.37% according to the National study on SLD resistance (2010) with the rate among new cases of 9.9% and 11.6% among retreatment cases. Out of 1,264 MDR-TB patients this amounts to 148 patients with XDR-TB, whose treatment is almost impossible due to poor access to later generation fluoroquinolones, Capreomycin and Group 5 drugs.

Table 7 Registered MDR-TB Cases in Civilian and Prison Sectors, 2011-2013

Type	2011	2012	2013 (9 months data)
New	124	114	70
Re-Treatment	423	416	231
Total	547	530	301

Source GLC/Europe monitoring mission to Romania, March 10-15, 2014

The number of cases reported under represents the total case burden due to the low DST coverage of all culture positive cases¹⁶. In 2012, out of 5,966 cases tested for MDR-TB (3,944 new and 2,022 retreatment), a total of 530 cases were diagnosed (see Table 8) which amounts to less than 50% of culture positive pulmonary TB new and retreatment cases tested for drug-susceptibility. Nearly 25% of cases did not receive a culture exam.

¹⁶ In 2009, 35.6% of all culture positive new cases were covered with DST, 53.2% of CC+ among relapses, and 59.3% among other retreatment cases. The situation has not been improved over the past two years mostly because of the decreased financing and poor referral for DST by doctors (not every SS+ and CC+ covered with DST). DST to SLD is also not yet performed to all MDR-TB patients by the time of diagnosis HR resistance, which makes impossible to estimate the actual number of XDR-TB. Additional drug resistance to second-line drugs in MDR-TB cases was evaluated by the prospective study, performed during a period of four months (October 2009 and January 2010): out of a total of 756 MDR-TB cases whose strains were collected, XDR-TB was found in 9.9% of new MDR-TB cases and 11.6% in retreated MDR-TB cases.

Table 8 Cases Tested for MDR-TB, 2012

	New	Retreatment	Total
Cases Tested for MDR-TB	3944 (46.1%)	2022 (57.6%)	5966
Laboratory Confirmed Cases	117	413	530
Patients started on MDR-TB treatment			736

Source GLC/Europe monitoring mission to Romania, March 10-15, 2014

MDR and XDR-TB can be identified by conducting drug susceptibility tests (DST) using solid, Lowenstein Jensen (LJ) medium or by using liquid media techniques such as BACTEC MGIT 960. The first-line DST tests for RMP and INH resistance, while the second-line DST tests resistance to the following anti-tuberculosis drugs (streptomycin, ethambutol, kanamycin, amikacin, capreomycin, ofloxacin, and ethionamide).

To diagnose MDR and XDR-TB with solid media requires about 7-10 weeks on solid media for the first-line drugs (INH, RMP in absolute concentration method in LJ medium) and an additional 4-6 weeks for the second-line drugs (proportion method in LJ medium) after the initial 3 weeks for culture. If liquid media methods are used then this time frame is reduced to 10 to 14 days for first-line DST (if culture is obtained in liquid medium from specimens with positive microscopy) and an additional 7-14 days for second-line DST in the same MGIT system).

During this processing period for cultures and DST, physicians and patients must wait to determine how to best treat a patient's TB. These delays provide an opportunity for the disease to spread. While Romania has achieved high levels of drug susceptible TB (DS-TB) case detection, over 70% since 2005, the ratio of cases that do not receive a culture or a DST remain amongst the lowest levels in the World Health Organization (WHO) European Region. The number of culture confirmed cases in Romania slightly decreased between 2008 and 2013, while the percent of DST results increased from 30% (2008) to 49.3% for new cases in 2013.

The NTP recommends providing a DST to all culture positive new TB cases, but the tests are not routinely used, or understood by the county level physicians. As a result, many patients who remain smear positive at the end of intensive phase do not always receive a DST for first-line drugs. This situation extends to MDR-TB patients with resistance to INH and RMP not receiving a DST for second-line drugs. This indicates insufficient supervision and monitoring of patient treatment as well as a need for clear guidelines regarding DST in TB patients.

An additional challenge for timely diagnosis of MDR-TB is the lack of reliable transportation of specimens. While some districts have vehicles that can be used to transport laboratory specimens, current restrictions on fuel consumption can hinder their use. In regions that lack transportation, other solutions such as the use of courier services will have to be investigated.

3. TB/HIV Co-Infection

Globally, TB is the leading cause of death among adults living with HIV/AIDS. Late diagnosis of TB is a major contributor. However, the diagnosis of TB within HIV-positive patients is more difficult because HIV-positive patients tend to have extra-pulmonary TB or smear-negative pulmonary TB which makes it harder to diagnosis

TB with the initial diagnostic tool, sputum smear microscopy. Microscopy has lower sensitivity to detect AFB, especially among people living with HIV, than culture.

The rate of TB/HIV co-infection remains relatively low in Romania. In 2008/2009 the percentage of HIV positive cases among TB cases was 3.3%, declining to 2.7% in 2013. The total number of cases was 265 (2013) which was a slight increase over the prior year (see Table 9). However, while both the number and percentage of TB patients tested for HIV for increased since 2008, in 2013, only 59.5% of TB patients knew their HIV status. The peak in testing occurred in 2005.

Table 9 Screening for HIV among TB patients, 2005-2013

Year	No of notified TB cases	No of TB cases HIV tested	% TB cases HIV tested	No of HIV+ cases among TB cases	% of HIV+ cases among TB cases
2005	29,347	10,860	37.0	160	1.5
2008	24,786	6,123	24.7	202	3.3
2009	23,267	6,443	27.7	214	3.3
2010	21,078	7,121	33.8	229	3.2
2011	19,205	9,623	50.1	244	2.5
2012	18,197	9,922	54.5	232	2.3
2013	16,718	9,953	59.5	265	2.7

Source. Data for TME 2014

Processing cultures to diagnosis TB can provide a substantially more sensitive test, but the traditional methods of TB culture are very slow, and results too delayed to be clinically useful. The use of new molecular diagnostics can assist to more accurately and rapidly diagnose TB.

The testing for HIV among TB patients is regulated by a 1993 MoH order and updated in 1999. In 2011, the MoH, NTP and National Commission to Fight AIDS developed a TB/HIV collaborative protocol to strengthen HIV/TB activities including testing and reporting of TB and HIV. As part of this protocol, all TB cases (bacteriological confirmed or non-confirmed) should be tested for HIV and, conversely, all persons infected with HIV should be screened for TB at infectious disease hospitals. Any case suspected of TB is referred for further investigation. The current target for testing of HIV status in TB patients is 90%. However, this target has not been met. In 2012, out of 18,197 registered TB patients, a little more of one-half (54.5%) had a known HIV status reported and 232 (2.3%) were identified as HIV infected.

a. IDU Population

While the number of co-infected TB and HIV cases remains low, there is growing concern about an emerging population at risk of both HIV and TB, namely injecting drug users (IDU). Within Romania, the number of intravenous drug use, and other drug use, has increased during the past few years. In 2011, an estimated 20,000 drug users were estimated to live in Bucharest. This population has experienced an increase in multiple health problems including a rise in HIV. The portion of IDUs among new HIV annual cases rose as a

risk factor in 3% of all new HIV-positive cases in 2010 to 29% in 2012¹⁷. Routine monitoring performed at registration for drug treatment services indicates an increase in HIV-positive cases among IDUs tested rising from 1.1% (2/182) in 2008, 3.3% (11/329) to 11.6% (25/216) in 2011.

There has also been a rise in the percentage of PLHIV co-infected with TB among the IDU population since 2011. One study (Oprea, Cristiana) in 2012 reported that among 159 IDUs with HIV, 49 (30.8%) were co-infected with both HCV and TB. Among the IDUs, use of the new substances with psychoactive properties or amphetamine type stimulants are a risk factor in increasing HIV spread, but IDU's are also at increased risk of TB because of malnutrition.

Summary - TB Diagnosis

While Romania has an effective system to diagnose drug-susceptible TB, There are several challenges for improving TB diagnosis summarized in Table 10. These include improving the timeliness of detection by modernizing the TB laboratories and reducing inefficient labs and ensuring rapid and safe transport of specimens (sputum, cultures) from periphery to center. There is also a need to train providers and technician on collecting, preserving and transporting specimens to the laboratories to meet processing standards.

Table 1 Challenges for Accurate and Timely Diagnosis of TB

Diagnosis of HIV/TB Co-infection
<i>TB infection in HIV-patients results in rapid progression of disease, but only slightly over half of TB patients currently determine their HIV status.</i>
<i>Detecting TB in Persons Living With HIV/AIDS is more complicated than diagnosis in HIV negative patients; however, use of new molecular diagnostics can assist to more accurately and rapidly diagnose TB.</i>
<i>There is a growing concern about injection drug users (IDU) in Romania at risk of both HIV and TB. More dedicated outreach and assessment of this population is needed to prevent TB outbreaks.</i>
MDR- TB Diagnosis
<i>A significant number of multiple drug resistant-TB (MDR-TB) cases go undetected due to inadequate culture and drug susceptibility testing resulting in improper treatment of TB patients.</i>
<i>Diagnosis of MDR-TB using conventional culture and drug susceptibility testing can take several months resulting in inappropriate treatment and ongoing transmission.</i>
<i>Rapid methods (molecular diagnostic technologies, automatic liquid cultures facilities, and rapid phenotypic DST methods) are needed to expedite diagnosis.</i>
<i>The lack of a reliable supply of consumables and transportation system for specimens also delays diagnosis</i>
<i>Laboratory staff and clinician skills have not been trained how to use the algorithm for the diagnosis of DR -TB in practice or how to understand and use lab results.</i>

¹⁷ National Commission for fighting against AIDS – CNLAS -, the Focal Point in Romania for ECDC Stockholm.

E. Treatment Practices

When a patient is diagnosed with TB in Romania treatment is initiated by doctors specialized in lung health (called pneumologists). The length of treatment and the regimen of medications depends on the type, or classification, of diagnosis. Most TB patients in Romania have drug susceptible tuberculosis (DS-TB), meaning the bacteria responds to the standard regimen of anti-tuberculin medications. Patients are classified with either new smear positive, smear negative or extra-pulmonary disease or as a retreatment case¹⁸.

If detected in a timely manner, TB is a treatable and curable disease. Indeed, the majority of cases successfully complete treatment for TB. Romania has successfully treated over 82% of new smear positive cases since 2002 reaching 86% in 2012 (for 2011 cohort) and 86% for smear-negative and extra-pulmonary cases, but remains low among retreatment cases (59.3%).

1. Duration and Setting for Treatment

While TB is treatable and curable for most cases, the overall treatment period remains quite long with the currently available medications. New drug susceptible TB requires six months for treatment, which increases eight additional months for retreatment cases, and even longer for MDR-TB patients. The intensive phase lasts two months with isoniazid (H), rifampicin (R), pyrazinamide (Z) and ethambutol (E) followed by a continuation phase of four months with HR. For retreatment patients, the treatment regimen begins with two months of HRZE and streptomycin (S), followed by one month of HRZE, then five months with HRE.

During the initial phases of treatment, patients are not typically cared for at home or in the community, rather, the common practice is to hospitalize patients for an extended period. Diagnosed patients are initially treated in a hospital for up to nine (9) weeks for drug-susceptible TB (DS-TB) or longer if the case is confirmed as MDR-TB. Following discharge, TB dispensaries manage treatment for the continuation phase of treatment for DS-TB patients. Hospitalization reflects treatment practices ingrained in how TB has been managed for decades and how treatment resources are funded. Lengthy hospitalization does not model WHO-recommendations for treating TB in outpatient settings as early as suitable. Several prior review missions evaluating the standards of practice for TB in Romania have strongly recommended reducing lengthy, costly and unnecessary hospitalization practices and to strengthen outpatient care.

Treatment within the hospital is provided 7 days a week, BID, or at a single dose. Within ambulatory settings, patients take the drugs 5 days a week with Saturday dose taken under self-administration. Some facilities at the PHC level provide patients with 1-2 week supply of drugs for self-administration which is not recommended as it can result in unfavorable outcomes and continued infectiousness.

¹⁸ A retreatment case means that the patient was previously begun on a course of TB treatment, but returned to treatment after default, after treatment failure, or having a case of relapse TB.

2. Cure or Successful Treatment

A patient is deemed cured when they complete treatment and the laboratory tests come back negative. Treatment completion means that the treatment was completed, but there is no laboratory confirmed. Either category is reported as a successful treatment. A sizeable number of patients have difficulty adhering to the lengthy treatment period and may start and stop treatment or completely default. As a result, Romania produces a significant pool of retreatment cases from treatment failure and non-adherence.

In 2012, Romania reported 4,309 retreatment cases (15% involved patients whose treatment had already failed, but were given an extended phase of first-line drugs). The majority of treatment failures may be due to drug-resistant TB, but accurate information is not available as testing for drug resistance remains unacceptably low. The lack of timely DST testing with this group indicates a failed opportunity to identify the role of drug resistance in their unfavourable treatment outcomes. The large pool of MDR-TB represents another challenge due the slow, or delayed, diagnosis as previously presented in an earlier section. The lack of availability for effective treatment and comprehensive care for all MDR-TB is another barrier contributing to unacceptable treatment outcomes.

3. Case Holding

The problem with non-adherence constitutes a need for case holding and adherence strategies. One of the core strategies to support completion of therapy involves Directly Observed Therapy (DOT). DOT involves assigning a healthcare provider, or another designated person, to regularly observe that patients take their medications and identify and resolve barriers to treatment such as adverse reactions or other factors that impede making clinical appointments. The provision of DOT varies upon local circumstances such as the availability of staff to do DOT, residence of the patient in rural area or urban area and where the TB dispensaries are located.

Within urban settings, DOT is typically offered at the PHD clinic and TB dispensary with self-administered treatment taken on Saturdays. However, DOT has been inconsistently provided and, beyond this, there has been only limited social support provided to TB patients. In rural settings, the option for DOT is even more restricted due to the distance between patient homes and clinics. In some areas a community nurse provides an option, but these nurses are not always available, and those working for the public health services are not motivated to perform daily DOT to lack of financial incentives or transportation (or reimbursement for out of pocket expenses). Family doctors as well lack interest to provide strict DOT for TB or DR-TB patients during the continuation phase due to lack of financial incentives. Family doctors and nurses were previously providing a token financial compensation for DOT, but this funding was suspended.

Patients with TB who work in the formal sector are entitled to 100% of their salary for one year. This support does not extend to the unemployed, self-employed, laborers in agriculture or subsistence farming, and persons in the informal cash economy which comprise the majority of Romania's TB patients¹⁹. The benefits for salaried employees also last only one year and is not extended if a patient has M/XDR-TB treatment or

¹⁹ Stillo, 2013

treatment is extended beyond one year. The loss of income and lack of social support have been reported as a contributing factor for non-adherence.²⁰

Through the Global Fund programs, Romania has used a variety of incentive and adherence strategies with some positive effects. Some interventions involved offering an incentive reward, like the Red Cross and former Doctors of the World projects, to encourage taking medications and attending medical appointments, while other projects used peer support interventions, telephone reminders or psychological support and counseling to improve adherence. The Global Fund Transitional Funding Mechanism (TFM) grant did provide a small amount of social support totaling \$1440 to MDR and XDR patients who enrolled in the Global Fund cohort implemented by UNOPA.

There has been some limited evaluation of the incentive projects. For instance, there is a study for the project implemented by Red Cross showed some increased treatment completion within eligible populations in two countries compared to the previous year. However, there was no comparison of different strategies; all patients in high incidence districts were eligible for the incentives. For the interventions implemented by UNOPA under TFM there will be an assessment on treatment success and adherence which will be available in 2015. In general, the interventions have not been rigorously design to test which individual strategies, or combination of strategies, could be most effective.

4. Treatment of Drug Resistant TB

The treatment and management of patients with MDR-TB requires a much longer treatment period than DS-TB, at minimum two years, with more complicated second-line drugs (SLDs) that can cause serious adverse reactions. The system to treat MDR-TB was based on National Guidelines on Programme Management for Drug-resistance Treatment (PMDT) set in 2005 which do not reflect recent WHO guidelines. Guidelines are being updated to reflect new treatment guidelines including diagnostic algorithms, management of side effects, and registration of patient, but these guidelines have yet to be approved by the MoH.

Due to the lack of resources for SLDs, the treatment of MDR-TB has been divided into two treatment cohorts: one group of patients has been provided treatment funded through the GFATM/GLC and the remaining MDR-TB population. The GLC project ensures that treatment and medications are continuously available to patients. The remaining MDR-TB patient populations receive drugs that are available through Romania's current drug procurement processes which are often inadequate, unavailable, or ineffective.

Between 2004 and 2011, a total of 884 patients were enrolled in the GLC program with Round 2 and 6 GFATM funding (see Table 11). Patients in the GLC group are selected/excluded using the following criteria: existence of treatment resources, identification of elements that suggest the reversibility of the disease, limited lesions, limited DST to provide treatment coverage with at least 4 active drugs, possibility for surgery, the continuity of treatment is assured, written consent, and physician available in the territory to assure the continuity of the treatment.

²⁰ Stillo, 2013

Table 2 Treatment Outcomes for GLC MDR-TB Patients, 2004-2011

Cohort	# Enrolled	Still on treatment	Success	Default	Failure	Lost to follow-up/ excluded*	Died
Cohort 1 (2004-2005)	200	0	118 (59%)	22 (11%)	31 (15.5%)	4 (2%)	25 (12.5%)
Cohort 2 (2006-2007)	200	0	150 (75%)	16 (8%)	20 (10%)	1 (0.5%)	13 (6.5%)
Cohort 3 (2009)	145	0	96 (66.2%)	10 (6.9%)	17 (11.7%)	1 (0.7%)	21 (14.5%)
Cohort 4 (2010-2011)*	339	205	46	23	28	3*	27
TOTAL	884	217	406	71	95	9	86

Source GLC/Europe Monitoring Mission to Romania, 2014

There is concern that not all patients are reviewed for eligibility by the MDR-TB commissions or that exclusion criteria may be too subjective, in particular, the judgment about whether a patient will or will not adhere to treatment. One solution would be to use more objective tools to assess the likelihood of adherence. A more reasonable solution would be for Romania to expand to universal treatment of MDR-TB²¹.

Treatment outcomes for patients in the GLC cohorts have ranged from 59% treatment success for the first cohort (2004-05) to 75% in cohort 2 (2006-07) and 66.2% in cohort 3 (2009). 150 additional patients were approved for the program (131 MDR-TB and 19 XDR-TB patients) starting in October 2013²². The treatment outcomes for the non-GLC cohorts are extremely less favorable with the 2010 treatment cohort achieving only 20.0% treatment success, 17.1% dying, 40.2% reported as failure, 18.5% defaulting and 4.2% not evaluated (refer to Table 12).

Table 3 Treatment Outcomes for Non-GLC MDR-TB Cohort, 2010, Civilian and Prison sectors

Registration group	Cured	Treatment completed	Died	Failed	Defaulted	Not evaluated ²³	Total
New	30	4	15	46	16	5	116
Relapse	32	3	24	50	24	7	140
After default	6	2	14	26	32	3	83
After failure of Category I and II treatment	18	2	17	29	17	3	86
Other retreatment, or unknown retreatment	17	1	28	80	17	6	149
Total	103	12	98	231	106	24	574
Percentage	17.9%	2.1%	17.1%	40.2%	18.5%	4.2%	100%

Source GLC/Europe Monitoring Mission to Romania, 2014

²¹ NTP Review, 2014

²² A total of 400 MDR-TB patients were enrolled under the GFATM Round Two grant and 523 under Round 6 (the difference of 43 MDR TB patients were enrolled with the approval of the GFATM based on the available stocks of drugs in 2012). An additional 300 patients were registered under TFM (out of these 300, 19 will be XDR TB). The enrolment of the MDR TB patients in TFM began in August 2013

²³ Not evaluated' includes 'transferred out', 'still on treatment' and any other registered case where the treatment outcome has not been evaluated.

The primary factor for the poor outcomes for non-GLC cohorts has been the lack of appropriate medications and support. In 2008, the country decentralized the system of drug procurement which contributed to the unavailability of the full range of second-line anti-TB medications recommended by the WHO treatment of MDR-TB and XDR-TB. This policy was reversed in 2013, but current procurement laws still do not cover all the recommended drugs. As a result, MDR-TB patients in the non-GLC cohorts cannot obtain aminoglycosides (kanamycin and amikacin) and capreomycin as well as fluoroquinolones (ofloxacin and levofloxacin) leaving patients with only weak ciprofloxacin as their option.

The majority of MDR-TB patients are treated in district or regional hospitals using drugs procured by individual hospitals. These patients face shortages and stock outs of required drugs and lack the comprehensive care provided to the GLC cohorts. There was a recent nationwide tender for second-line injectable drugs, but no supplier was secured. As a result of these problems, treatment success for non-GLC MDR-TB patients is around 20% which is comparable to expected outcomes if the patients refused any treatment.

For the GLC-treated cohort, MDR-TB patients begin treatment in one of the two centers, and then are referred to their home counties for continuation phase. One MDR-TB center is based at Marius Nasta Pneumology Institute (MNI) and the other at Bisericani TB hospital in Piatra Neamț. The GLC treatment regimens for MDR-TB are designed by two DR-TB committees. Patients receiving the GLC treatment may have to travel long distances away from their homes and remain hospitalized for six months or longer. However, these patients receive quality-assured medications, including PAS and capreomycin which non-GLC patients cannot receive. Further, they are provided with psychological and social support.

Patients in the GLC MDR-TB cohort are provided pyrazinamide and ethambutol from NTP, while the Global Fund Primary Recipient, the Romanian Angel Appeal (RAA) procures Kanamycin, Capreomycin, Levofloxacin, Cycloserine, Protionamide, and PAS. Under TFM there is no Ofloxacin. RAA procures only Levofloxacin, but there is also Moxifloxacin, together with group 5 of drugs for 19 XDR patients (the drugs will be available by the end of the year 2014). Non-GLC patients are limited to an average of six (6) months of injectable medications. Their regimens lack Capreomycin due to drug registration issues as well as PAS, and contain Amikacin. The current treatment regimen for XDR patients not part of the GLC cohort is also inadequate. In January 2012 Romania received an approval from GFATM to enroll 300 MDR-TB patients with quality-assured second-line anti-TB drugs (SLD) and support treatment continuation of 200 MDR-TB patients from previous cohorts, including XDR patients, but Global Fund resources only cover approximately 20% of the estimated number of patients infected with MDR/XDR today. There is a desperate need to increase access to quality-assured SLD from the government sources and improve other important aspects of PMDT; otherwise, the country will continue facing the increasing threat of M/XDR-TB in the future.” (*Source: WHO/GLC Mission Report, March 2013*).

Patients on therapy for DR-TB are monitored with sputum smear microscopy and culture at the start of treatment, and repeated on a monthly basis during the intensive and continuation phases. Clinical examinations include blood and urine test, and biochemical analysis. Chest radiography is available at the MDR-TB Centres and TB hospitals. SLDST have to be performed in a MDR case initially and, if culture remain or become positive, after four months of treatment. Additional services are provided for patients when hospitalized, but this ranges from setting to setting, however, palliative care services are limited.

An estimated 50% of patients have adverse reactions such hearing loss and pain at the site of injection. The most common clinical response is to reduce the dosage in about half of these cases. Many of the adverse reactions can be managed or are resolved spontaneously but discontinuation of treatment has been a

reported as a problem. Non-adherence can contribute to further drug resistance. Management of adverse reactions requires improvement through both training of doctors and nurses and adequate supply of ancillary medications. The recording of adverse reasons is performed only upon temporary/permanent withdrawal of medicine from a regimen.

Low adherence to treatment in MDR-TB patients is enhanced by the heavy burden of pills, frequent adverse effects of drugs, lengthy treatment, extended hospitalization, social isolation and stigma associated with the disease. There is a general lack of mechanisms targeting patients' adherence to treatment, such as lack of social support, and psychological care, except within the GLC cohorts. In addition, there is low motivation of personnel to work with MDR-TB patients and weak defaulter tracing. As a result, some patients interrupt treatment without doctor's approval. Non-adherence contributes to a high rate of therapeutic failure, abandonment of treatment and spread of M/XDR-TB.

5. Treatment of XDR-TB

For patients diagnosed with XDR-TB, the situation is even direr. The success rate for XDR-TB patients is only 3.3%. These patients receive the same treatment as MDR-TB with the addition of Moxifloxacin if it is locally available. Of the group five drugs, only Clarithromycin is widely used to treat TB. Patients with XDR, and with fluoroquinolone resistance, are unable to access the drug Linezolid because it is not on the list of approved drugs to treat TB. Some patients, with the necessary financial resources, have attempted to purchase the medications via the internet or from other countries.

6. Treatment of HIV and TB

Overall, Romania reports relatively few cases of co-infected TB-HIV patients. There were 232 cases reported in 2012 which is about 2.3% (TB Surveillance Report, 2014) of total cases or 0.6 cases²⁴. If a patient with HIV has TB diagnosed, that patient is started on anti-TB treatment, which has priority over anti-retroviral treatment (ART). The treatment of patients with HIV infection and smear positive TB is done in pulmonary departments. Treatment should occur within the TB hospital to prevent the exposure and transmission of infectious TB to other patients, but this does not always occur and sometimes patients are housed on the same wards. The majority of the HIV-positive TB patients are placed on co-trimoxazole preventive therapy (CPT) (174 or 76%) and 205 patients (90%) were provided antiretroviral therapy (ART). Unfortunately, co-infected patients continue to experience worse treatment outcomes than HIV-negative patients: 69.3% success rate for pulmonary new cases CC+, and HIV+, compared to 86.1% success rate for pulmonary new cases CC+, HIV-neg for 2011 cohort. Non-adherence is very frequent among IDUs, even in those in substitution therapy, due to many factors including methadone interactions with TB medication.

7. Compassionate Use and Palliative Care

Palliative care is specialized medical care for people with serious illnesses. It focuses on providing patients with relief from the symptoms, pain, and stresses of a serious illness—whatever the diagnosis. The goal is to

²⁴ WHO, 2014 Data: www.who.int/tb/data

improve quality of life for both the patient and the family. Romania currently lacks a strategy for palliative care for TB patients. Patients without therapeutic options may be sent home, discharged themselves, or they may be hospitalized in a TB ward. The majority of hospitals, however, do not have a section for these patients. Patients without treatment options are left to suffer and often shuttle between home and hospital suffering from hemoptysis, and possibly remaining smear positive and infectious. This situation endangers their families, healthcare providers and other patients.

Summary – TB Treatment

Overall, treatment outcomes for TB cases reflect the ability of Romania to successfully manage and treat most TB cases. Nonetheless, there is a significant percentage of patients who are not cured and do not complete therapy. Several factors contribute to this situation (see Table 13) including improper diagnosis related to the lack of timely DST testing. As a result, MDR-TB goes undiagnosed and patients are given months of ineffective treatment. Even if patients are properly diagnosed, current drug procurement restrictions do not ensure they would be provided with effective treatment regimens unless the patient was fortunate to be enrolment in the GLC treatment group. The lack of availability for recommended drugs and comprehensive care for all MDR-TB results in unacceptable treatment outcomes and needs urgent resolution.

Regardless of whether a patient is drug susceptible or has drug resistance, the treatment is often lengthy and difficult to adhere to. There is little ongoing or institutional social support provided to TB patients with a few exceptions. The loss of income and lack of social support have been reported as a contributing factor for non-adherence. Patients are often unnecessarily hospitalized for excessive periods, rather than being provided effective community-based treatment, further contributing to isolation and frustration. Hospitalization may be warranted in cases of serious illness or other health factors, but it should not be the sole option for care. The problem with non-adherence, in particular with retreatment cases, constitutes the need for more patient centered strategies.

Table 4. Summary of TB Treatment Challenges

<i>The reliance on hospitalization for treatment results in lengthy and expensive hospital stays and undermines development of more patient-centered ambulatory treatment options.</i>
<i>There is a lack of strategies to support adherence, including Directly Observed Treatment (DOT) and appropriate incentives and enablers.</i>
<i>Financial and other resources are required to improve community-based DOT and contact holding efforts have been limited to externally funded projects.</i>
<i>The high number of retreatment cases indicates problems with appropriate treatment and case holding strategies.</i>
<i>Contact Investigations are not systemically conducted and routinely documented.</i>
TB/HIV Treatment
<i>Treatment of HIV-TB patients should occur in TB hospitals, however, a number of co-infected patients remain hospitalized in the infectious diseases wards.</i>
<i>IPT is not sufficiently documented.</i>
MDR-TB Treatment

• <i>MDR-TB treatment and management guidelines need to be completed, approved by the MoH and disseminated to practitioners.</i>
• <i>The number of MDR-TB patients under appropriate treatment regimens is insufficient resulting in adverse health outcomes.</i>
• <i>Critical medications are not available due to lack of MoH approval resulting in procurement of more costly and less adequate alternatives.</i>
• <i>There is a lack capacity for specialized MDR-TB care in terms of trained providers and facilities distributed.</i>

F. Prevention and Infection Control of TB

The primary effort to prevent the transmission of TB in Romania involves providing bacille Calmette-Guerin, or BCG, vaccination to children, and early detection of contacts of case. There is not a comprehensive program for infection control measures and treatment of latent TB infection is limited.

BGC vaccination provides some protection to prevent childhood TB-meningitis and miliary disease, but does not prevent primary infection or reactivation of latent pulmonary infection, the principal source of bacillary spread in the community. The impact of BCG vaccination on transmission of *M tuberculosis* is therefore limited.

1. Contact Investigations

Upon diagnosis of a TB case, the diagnosing hospital informs the local TB dispensary to conduct an epidemiological investigation under national protocol (order 8/2000) referred to as a contact investigation²⁵. This requires collaboration between a family doctor, dispensary doctor and an epidemiologist. The family doctor and workplace occupational health are requested to provide a list of contacts. The TB dispensary sends a letter to those contacts that should be evaluated. There is no registration system for the contacts, and therefore, often no follow-up. Some contacts may go to a TB dispensary, while other may present to a private clinic, or simply refuse any evaluation.

2. Infection Control

In terms of preventing transmission of infectious TB, exposure to *Mycobacterium tuberculosis* poses a risk to medical and laboratory staff as well as other patients and family members. In areas of high tuberculosis (TB) incidence such as Romania the risk for hospital workers may be greater than that for the general population, therefore, controlling exposure to TB and resistant TB in healthcare settings to prevent nosocomial transmission is an essential part of the health care system. At the health facility level, TB infection control involves a set of administrative, environmental, and respiratory measures. The NTP developed a comprehensive plan regarding TB infection control, but due to financial limitations these measures were not yet implemented. Among the measures described in the plan, all TB units should be equipped with UV

²⁵ Contract tracing is an important practice to find and treatment additional household and close contacts.

Germicide Irradiation equipment (UV lamps) and all TB staff (including those working in laboratories) should be trained in TB infection control.

Administrative infection control protection in Romania is needed to reduce the opportunities for exposure and transmission through infectious patients and housing infectious patients apart from other patients, in particular immuno-compromised patients. Unfortunately, co-infected HIV-TB patients continue to be in infectious disease wards, rather than dedicated TB wards placing other patients at-risk of exposure. There are also serious infection control shortcomings in the TB laboratories. Although Ministerial order 1202/2007 requires laboratories to work with TB in a Class II biosafety cabinet, many laboratories continue to operate without this safety equipment. Currently, only 2 out of 14 Level 1 labs, 33 out of 48 Level II have biosafety cabinets. All of the Level III labs have this equipment.

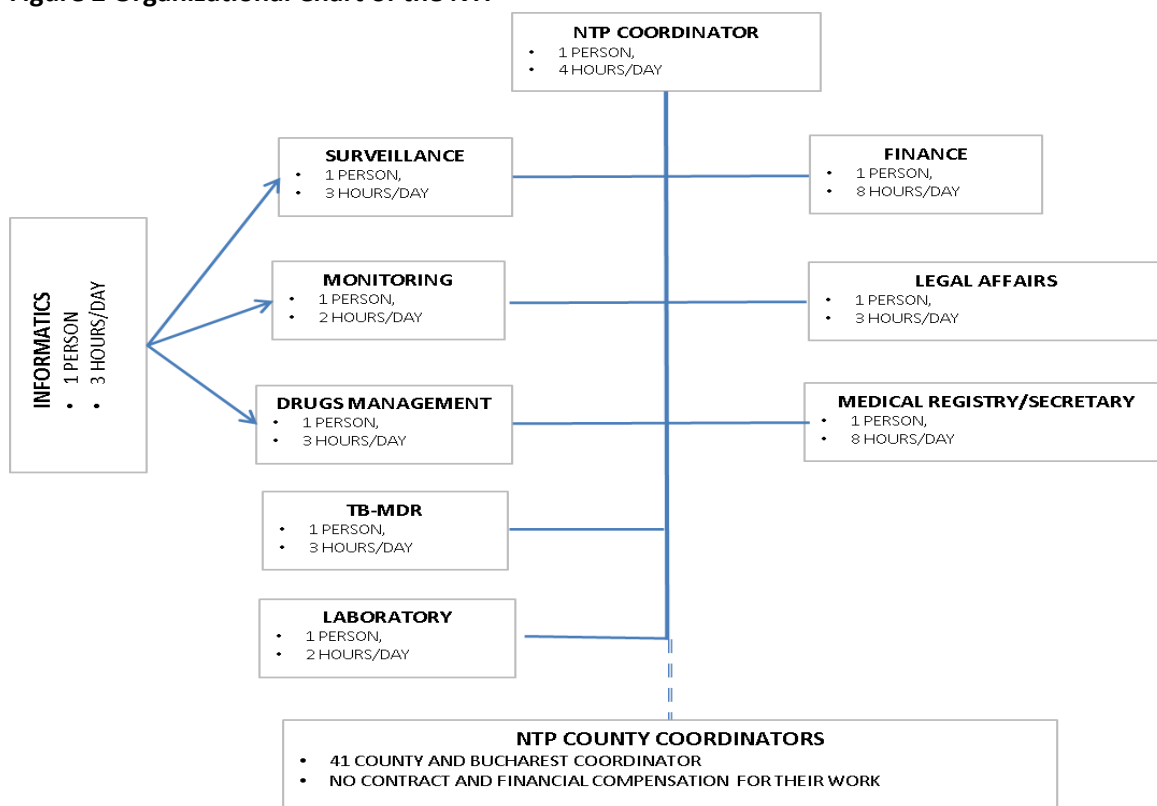
Summary - Prevention of TB

Within Romania, prevention of TB is primarily based on passive case detection to identify and treat infectious TB cases, providing BCG vaccinations to children, and carrying out contact investigations for close contacts of TB cases. Infection control within healthcare settings has been historically weak. The measures that do exist are not routinely enforced and little technical assistance is provided to facilities interested or requiring stricter infection control

G. Program Oversight & Management

The National Program on Tuberculosis (NTP), located in the Marius Nasta Institute in Bucharest, maintains responsibility for setting diagnostic and treatment standards, conducting surveillance, and developing technical capacity. The MoH, through Marius Nasta, allocates resources for TB care, drugs and consumables to peripheral hospitals and dispensaries. An NTP coordinator manages the program through a Central Coordination Unit (CCU) which includes the following departments: Surveillance, Monitoring Drug Management, Laboratories, and MDR-TB (see Figure 2). The NTP was established by Order 422/2013 of the Ministry of Health Order as a technical assistance and management in Marius Nasta Institute. The NTP currently consists of 10 employees (8 are part-time and 2 full-time employees).

Figure 2 Organizational Chart of the NTP



Source. 2014 National Program Review.

In addition to the NTP, the Public Health Directorate of MoH, and the National Commission of Pulmonology, Alergology and Clinical Immunology (constituted by members who are nominated by the MoH and meet at least twice a year) play a role in program oversight.

4. TB Network and Human Resources for TB Control

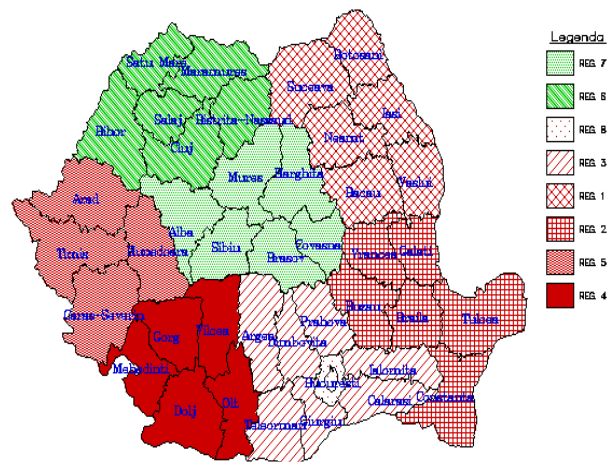
Diagnostic and treatment services for TB are provided through a network of facilities referred to as the *Romanian Pneumology Network*. The Network includes more than 700 doctors and over 2,000 nurses across the country (see Table 14). Diagnosis and ambulatory care are provided by 174 TB dispensaries supported by a series of laboratories, while in-patient treatment services are provided through 93 hospitals (municipal, district, and regional tertiary centres) with a total of 5625 beds. Forty-one (41) district hospitals are organized into eight (8) regions which offer a range of clinical services and beds dedicated to TB patients²⁶ (see Figure 3).

Table 5 TB Personnel (2012)

	Hospitals	TB Dispensaries	Laboratories	Total
Medical Doctors	402	323	60	785
Nurses	1504	587	294	2385
Auxiliary Personnel	1078	210	73 biologists/ 19 chemists	1380

²⁶ Brasov, Bucharest, Călărași, Cluj, Constanta, Craiova, Iasi, and Timisoara

Figure 3 Health Planning Regions



The dispensaries, hospitals and workforce in the network are funded partially by the MoH and the National Health Insurance Agency, but are not managed by the Central government. Rather, they operate under local districts (Judets) and municipalities through district public health departments. The TB dispensaries are typically located in a clinic away from the hospital and The TB dispensaries and report to a district TB coordinator.

While these facilities are essentially autonomous through Romania's decentralization of healthcare reforms they are required to follow guidelines developed by the NTP and set by the MoH which funds prevention and disease control activities. While the NTP has created a number of guidelines, many of these have

not been formally approved by the MoH which limits their effectiveness with the districts.

5. Training and Recruitment

Ensuring sufficiently trained workforce for TB control is a challenge for the future TB control efforts. Many of the personnel working on TB are aging and are not being replaced as low salaries and the inability to compete with private sector or opportunities outside of Romania hinder the new recruitment. For example the average age for personnel working in the laboratories is 44 years for the biologists/bio-chemists (range 29-65), 47 years for technicians (range 26-64) and 49 years for doctors (range 30-65).

Moreover, there is not a systematic method to develop personnel skills and capacities. This issue, in particular, affects the frontline workforce. For example, within the laboratories, the last training for frontline staff received was in 2006. Since then, only the National Reference Laboratory (NRL) staff received any individualized training. Most training occurs on-the-job or by attending pneumonology congress which do not generally address laboratory issues. Doctors and nurses have to pay these fees out of their own pockets which can amount to two months of salary. If there is a training, it is often episodic and not followed up by mentoring or supportive supervision. The trainings provided rarely provide progressive skills development. There is an urgent need to develop the skills for Romania's pneumologists, laboratory doctors and technicians to address the rise in MDR-TB cases and recent revisions to treatment guidelines.

6. Role of Family Doctors

Within Romania, family doctors provide the majority of primary care services. Family doctors work independently from the public health system, but receive contracts and payments through the National Health Insurance Agency (NHIA) to care for a specific list on insured population. As of 2013, there were around 10,000 doctors with an average list of 2,000 patients.

While family doctors are not part of the formal TB network, the doctors – along with their nursing staff - have played an important role in TB referrals, contact tracing and continuation of care. This role has been adversely affected by changes in how family doctors are compensated for TB services. In the past, family doctors were paid for diagnosing and supervising TB patients, but the government ceased these payments in 2010 in exchange for a fee per-service structure with very limited reimbursement for TB care. As a result fewer and fewer family doctors are interested to take on TB patients or assist with public health activities.

Summary - TB Network and Personnel

While Romania has an extensive network of personnel working on TB issues, many of these healthcare workers are aging and not being replaced. The staff that does exist does not receive routine or target skills development reflecting an overall lack of a human resource plan for TB control. Family doctors can serve as an important gateway provider for TB control. However, changes in how they are funded and reimbursed have adversely affected their interest in TB control.

Table 6 Summary TB Network and Personnel Challenges

• <i>Important control guidelines for the TB have not been approved.</i>
• <i>Routine supervision and monitoring visits are limited due to lack of funding and resources.</i>
• <i>The TB workforce is aging, there are important gaps in skills, and barriers to hire prevent filling critical positions.</i>
• <i>The NTP lacks some critical expertise or dedicated staff.</i>
• <i>Private providers (family doctors and nurses) lack incentives to collaborate on TB control.</i>

H. Surveillance

Surveillance is a basic component of TB programs required to monitor disease trends and track impacts on population. Programs use surveillance information to evaluate treatment outcomes and to detect emerging threats such as MDR-TB and co-infections. Within Romania, the NTP is responsible for the surveillance of TB. Three persons work part-time for the Central Unit of the TB Register although there not have a specially-trained epidemiologist capable of conducting or directing routine and important research on disease trends and demographic or other risk factors or leading outbreak investigations.

The NTP relies upon epidemiological reports submitted by District staff using an electronic national TB database designed in 2006. This data covers program needs and is used for reporting TB statistics to the ECDC and the WHO. The legal basis for the current reporting system is covered under the Technical Norms of the National Public Health Programs for 2013-2014, Order no. 422/2013. There have been no upgrades to the database software since 2006, nor have computer terminals been replaced.

Most data is electronically collected, reported and recorded. Local entities (dispensaries, most laboratories, and some hospitals) can directly access the surveillance system via a web-based portal. Hospitals that cannot access the system send paper-based notifications to local TB dispensaries. The Ministry of Justice and Defence can also use the system to report cases. Paper-based registers are still used to register patients in the TB dispensaries. The registers are used for checking completeness and quality of electronic data. Much of the current reporting and data collection forms need to be revised and aligned with new laboratory tests and

linked to the HIV registry, vital and population registries to enhance completeness and improve case management.

The TB County Managers (50 in total including the Ministries of Defence and Justice) are responsible for data validation, verification and assessment of completeness. In 2013, the HIV and TB registers were linked, but without legal basis. There is no linkage of TB data with other vital registries (population, mortality).

Summary – Surveillance System

The overall surveillance system for TB is adequate, albeit, somewhat outdated. The data collected is used primarily for reporting TB statistics to the ECDC and the WHO and not for planning or investigation purposes. There have been no upgrades to the database software since 2006, nor have computer terminals been replaced. To improve the TB surveillance system will require an update in technology, software and in human resources to more effectively and dynamically use surveillance data.

Table 7 TB Surveillance Challenges

• <i>The TB surveillance database is out of date and software and hardware upgrades are needed.</i>
• <i>The overall surveillance and epidemiological capacity within the NTP is limited to data collection and processing; there are no routine epidemiological investigations or technical support to identify, investigate and manage outbreaks or to prioritize resources for TB hotspots.</i>

I. Program Supervision and Monitoring

The NTP is responsible to conduct program monitoring and supervision. This is done by conducting one supervisory visit to each county per year. There are 20 supervisors who participate in program visits. Each supervisor makes two visits per year using a series of standardized checklists. Following these visits, the monitoring team prepares a program visit report which is shared with the local site with a copy kept in the Central Unit.

A similar review occurs within the laboratories. A laboratory working group consisting of nine members was created in 2006 and recognized in 2010 by the MoH. This group has responsibility to develop the country’s laboratory plan, standard operating procedures (SOPs) and laboratory manuals. The group also develops and provides some training, but the staff and resources to carry this out are limited. The laboratory group conducts supervisory visits using a standardized check-list and prepare recommendations based on these visits to improve local activities. Routine supervision should be done at least once a year, but is not consistently funded.

Beyond these periodic monitoring visits, the overall use of TB epidemiological data at the local and regional level appears limited. Routine analysis of epidemiological and program data for policy making and program decisions does not take place. Part of the reason is lack of access to the data, but more importantly district staff are not trained to use the data for planning and decision-making. MDR-TB registers are integrated into the general database, but local and district staff have limited access to data. Districts could conduct TB cohort analyses to study and respond to treatment outcomes after 12 months for DS-TB, or 24 months for MDR-TB.

The National Institute of Public Health is mandated to annually and quarterly review TB epidemiological data for statistical analysis and publication²⁷.

Summary - Program Monitoring

Romania has a monitoring system in place for TB services, clinical, programmatic and laboratory, but this system is constrained by lack of resources for follow-up. Routine data analysis and assessment must take place to review factors that both contributed or detract from important program outcomes.

Table 17 Program Supervision and Monitoring Challenges

Monitoring is provided through a team of program and laboratory supervisors who conduct annual visits to district offices.
The frequency of program visits is limited due to lack of resources.
Districts and NTP do not routinely use data for planning and decision-making.

J. Laboratory Services

A fundamental requirement for effective TB control is the presence of a laboratory system capable of producing accurate and timely results in a safe manner. Within Romania, there are currently three levels of laboratories that have a role in diagnosis and evaluation of TB referred to as level I, II and III laboratories. As of 2013, TB diagnosis was realized in fourteen (14) level 1 laboratories which perform only microscopy, while the 47 level II laboratories conducted smear microscopy and cultures, and 44 level III laboratories processed smears, cultures, and drug sensitivity testing for isoniazid (INH) and rifampicin (RMP). Two of the level III labs have an additional role as a national reference laboratory (NRL) for the country. One NRL is located at the Marius Nasta Institute and the other is in the Leon Danielo Hospital in Cluj. The NRLs also conduct second-line drug susceptibility (SLDST) testing and genetic tests.

The geographic distribution of laboratory services varies with 13 counties having one TB laboratory, 19 counties having 2-3 laboratories, and 8 counties with 4-5 facilities. There are also seven laboratories in Bucharest. The workloads vary tremendously among the laboratories. For instance, microscopy analysis in level 1 facilities range from 39 to 2707 specimens a year. In level III laboratories, the number of smears analyzed ranged from 1689-20,442 while the number of cultures processed on solid media ranged from 248 to 20,442.

The work load in some laboratories is below levels needed to maintain capacity and ensure quality of diagnosis. As an example, the positivity rates vary in facilities from 0% to 21% for microscopy and from 3.3% to 18.3% for culture. Low rates can reflect problems with quality, problems with the sputa sampling, or issues with inefficient isolation procedures. Concurrently, the high positive rates can reflect population levels of TB,

²⁷ The National Institute of Public Health, through the National Centre for Communicable Diseases Surveillance and Control (NCCDSC), monitors TB trends on a national level based on aggregate data received from “Marius Nasta” Institute. A descriptive analysis based on this data is sent to all the Public Health Authorities (PHA), to all the Public Health Regional Centers (PHRC) of NIPH and to MoH. The case-based TB data reported in TESSy by “Marius Nasta” Institute are also analyzed on a yearly basis with a report published on NCCDSC’s website. The NCCDSC also receives information from PHA about the TB clusters/outbreaks in collectivity settings and make a yearly analysis which is then sent to all the PHA, PHRC, “Marius Nasta” Institute and MoH.

particular settings (sanatoriums) or reflect cross-contamination. The work levels in some facilities indicate a need to rationalize and consolidate laboratory services.

Laboratory operations have also been adversely affected by the lack of equipment and resources to process specimens in an accurate and safe manner. For example, eight laboratories which use Mycobacterial Growth Indicator Tube (MGIT) for culture cannot routinely use operated due to the lack of reagent materials. This hinders testing for FLD DST and rapid identification of TB²⁸. Some laboratories lack recommended fluorescent Light Emitting Diode (LED) microscopes which could improve also initial diagnosis²⁹. Only one lab, the Bisericani has a LED microscope, while nine other laboratories are equipped with UV bulb fluorescent microscopes. There is also concern about the lack of biosafety cabinets and infection control practices to reduce exposure to TB.

Laboratory results are also affected due laboratories not following guidelines or standard operating procedures (SOPs) for processing and managing specimens. For instance, some laboratories do not collect the recommended number of specimens, properly stain slides and deviate for number of tubes for cultures inoculated for a specimen, or incorrect operating speeds with the centrifuge equipment. Finally, the transportation of specimens functions well in the south-west of Romania, but does not function adequately in other regions.

While the NRLs have existed since 1997 and have specific terms of references, they lack official status and resources for coordination and oversight responsibilities. The overall EQA process for microscopy is insufficient and does not adhere to WHO Regional Office for Europe recommendations. In terms of quality of cultures, there is concern about contamination of cultures. Contamination rate of cultures ranges from 0.0% to 25%, with an average of 2.8% at country level. EQA for cultures is provided by a distributor of specimens obtained from LabQuality-Finland, but not all laboratories level doing cultures participate.

The initial laboratory diagnosis is based on smear microscopy which involves staining for acid-fast bacillus (AFB) to look for bacteria. The initial microscopy provides a presumptive diagnosis of TB, but a culture is required to confirm TB. Cultures are also used to monitor the effectiveness of treatment and to determine when a patient is no longer infectious. The time to process of a culture varies depending on what technologies are used. Romania uses both solid and liquid media methods. Solid media takes around three weeks, while a liquid culture can be processed in 10-14 days. The primary decision for using solid versus liquid methods within Romania involves resource constraints.

Drug resistance can also be identified by using solid, Lowenstein Jensen (LJ) medium or by using liquid media techniques such as BACTEC MGIT 960. Both solid and liquid media methods provide comparable sensitivity and specificity. However, the liquid media methods significantly reduce processing time for results. To diagnose MDR and XDR-TB with solid media requires about 7-10 weeks on solid media for the first-line drugs (INH, RMP in absolute concentration method in LJ medium) and an additional 4-6 weeks for the second-line drugs (proportion method in LJ medium) after the initial 3 weeks for culture. If liquid media methods are used then this time frame is reduced to 10 to 14 days for first-line DST (if culture is obtained in liquid medium from

²⁸ According to the WHO, SLD DST should only be performed in laboratories that can process a minimum of 200 tests/year in order to remain proficient. Only the two NRLs and the Bisericani MDR center perform SLD DST on solid LJ medium using Proportion method.

²⁹ According to the WHO, LED microscopy was equivalent to that of international reference standards, it was more sensitive than conventional Ziehl-Neelsen microscopy and it had qualitative, operational and cost advantages over both conventional fluorescence and Ziehl-Neelsen microscopy.

specimens with positive microscopy) and an additional 7-14 days for second-line DST in the same MGIT system. Romania currently uses the proportion method in LJ medium (RMP, INH, SM, EMB, ETM, OFL, K, Ak) in the NRL Bucharest, the NRL in Cluj Napoca, and at the Bisericani MDR treatment center.

Summary - Laboratory Issues

A cornerstone of effective TB control is the ability of the health system to ensure timely and accurate diagnosis and test results. While laboratory services in Romania have performed exceptionally well a number of challenges and gaps need attention (see Table 18) to ensure that patients are placed on the most effective treatment regimens. This will require modernizing diagnostic facilities with more rapid technologies, reducing facilities that do not meet performance standards, and ensuring sufficient, trained laboratory staff to carry out important laboratory functions.

Table 8 Laboratory Network Challenges

<i>A number of laboratories do not meet minimum processing thresholds or standard, and the overall system EQA is weak</i>
<i>Laboratories lack new diagnostic technology, reliable supply of consumables, and adequate infection control measures.</i>
<i>Staff are not appropriately trained and supervised.</i>
<i>New diagnostic technologies will require addressing EQA gaps</i>

K. Drug Procurement

Providing effective anti-TB medications in an assured manner is another core function of an effective TB control program. While first-line medications are readily available in Romania to treat drug-susceptible TB in adults, the current situation for formularies for pediatric TB treatment, some first-line injectables not on the approved lists of medications, and second-line medications to treat multi-drug resistant TB are not available in Romania.

From 2002 – 2006, Romania utilized a centralized procurement system for anti-tuberculosis medicines based on a drug management guideline established in 2005. Beginning in 2007, there was a shift to decentralized procurement for TB medicines whereby funds were distributed to the TB units and each facility procured its own medicines. The decentralization of procurement had negative implications for TB treatment creating stock outs of important SLDs.

Romania agreed to centralize the procurement of medications through a 2013 -2014 national tender for first-line and most of the second-line drugs. The process began in February 2014 (and covered a limited number of SLDs)³⁰. While some drug prices have decreased through competition, there are still important short-comings with the current tender process. For instance, several second-line drugs (SLDs) recommended by the World Health Organization Regional Office for Europe for MDR-TB treatment cannot be procured because they are not registered on the national essential drugs list or not available with national suppliers. Districts confront

³⁰ Cycloserine, ofloxacin, clarithromycin, Moxifloxacin, and protionamida were covered in the tender, but the tender was canceled for kanamycin and amikacin due to procedure issues.

stockouts for SLD injectables and fluroquinolones with some unable to secure medications for up to four months.

In general, the overall management of existing medication is weak and districts and NTP often have difficulty to quantify and project anti-TB medicines requirements. There is no administrative support for the procurement and drug management system and each facility remains responsible for procuring and managing its own drug supply with outcomes often dependent on local managerial skills and historical budget trends. Part of the problem relates to how drugs are quantified in terms of their cost or “value” and not in absolute terms. There is no specialized program for inventory control, management and tracking consumption. In terms of actual patient consumption, there is limited evidence of direct observed treatment and no real evidence of patient consumption. As a result of improper planning, or the lack of a budget, districts can experience stockouts and shortages of important medications including SLDs and ancillary drugs to manage adverse reactions to treatment.

In terms of SLD procurement, Romania is eligible to purchase recommended second-line drugs at a significant price discount through the Global Drug Facility (GDF), but Romanian law requires that drugs are purchased through a tender and the GDF does not do this. The GDF also requires payment in advance, while the Government of Romania only pays 60-90 days after delivery. As a result critical drugs are unavailable in Romania. Given the large number of MDR-TB patients, these barriers need to be urgently resolved.

As a response to inconsistent, and often ineffective, treatment regimens for MDR-TB, the NTP established an MDR-TB commission to make recommendations regarding the preferred treatment regimens. Unfortunately, the recommendations are not always followed due to the lack of availability of recommended medications and the limited authority of this commission.

Summary – Drug Procurement

While first-line medications are readily available in Romania to treat drug-susceptible TB in adults, there is an urgent need to address the procurement of second-line medications to treat multi-drug resistant TB as well as formulas to treat pediatric TB. To improve the drug procurement situation, Romania needs to take steps to develop a more effective system for planning and managing anti-tuberculosis medications. This system needs to be capable to monitor at national level the orders, consumption and stocks, with sufficient resources, and allocating for procurement.

Table 19 Drug Procurement Challenges

<i>The drug management system for TB is inadequate resulting in stock outs or unavailability of critical second-line anti-tuberculosis medicine.</i>
<i>Romania legislation does not allow procurement of critical, “emergency” SLD medications and pediatric TB formulas which contributes to poor treatment outcomes.</i>
<i>The NTP’s recommendations to determine and select anti-tuberculosis drug procurement needs to be strengthened</i>

L. Community and Patient Awareness and Practices

Ensuring high awareness in communities about health in general and of TB and TB services -can help to at-risk communities and patients to recognize TB symptoms and take timely action to seek care. Vulnerable populations need to understand that the available health services offer a solution to healthcare problems at an affordable cost and be assured that such services do not come at a social cost caused by stigma associated with the disease or the services being offered. More information about the perceptions and knowledge of TB and TB services is, therefore, required. This information is needed to both improve the quality of health services and to develop communication and outreach strategies that support improved knowledge and behaviours.

Romania has some limited experience developing patient and provider education materials and activities. These activities have been referred to as Information, Education and Communication campaigns as well as Advocacy, Communication and Social Mobilization (ACSM). The majority of these efforts have been led by non-governmental organizations and not the NTP. Past interventions include media outreach, training of providers, conducting caravans and outreach presentations, and creation of IEC materials. Under the Global Fund, a national TB-IEC strategy was created but not approved by the MoH. Reliable access to prevention, diagnosis and treatment is needed. Special materials on adherence, infection control and MDR-TB, XDR and HIV-TB co-infection can reinforce messages provided by clinicians. The NTP previously created a website, but that site is not currently active. When it operated, there was limited information and content available on the site and little to no promotion. A new site should be created to provide information to the general public, patients and providers about TB, diagnostic and treatment guidelines along with statistical and program data.

Summary – Education and Outreach

Health education and outreach can provide support TB control program objectives for early detection and treatment adherence by developing awareness and knowledge among patients, families and providers about various issues. To be effective, these activities must be test, targeted and supported over a sustained period. Too often, education occurs in a shot-gun and episodic manner provided as a once and done approach. This type of strategy has limited effectiveness. Information needs to be tailored to specific audiences and made available through multiple channels. As it currently stand, the NTP lacks a comprehensive strategy for education and lacks personnel and resources to carry out effective education and outreach (see Table 20).

Table 20 Community and Patient Education

• <i>No national TB-IEC strategy exists to guide education activities and set overall strategy.</i>
• <i>There is no sustainable process to create and distribute IEC materials for providers and patients.</i>
• <i>The NTP website is non-functional and needs to be more consistently maintained.</i>

M. Engagement of Civil Society

The role of civil society and non-governmental organizations (NGOs) to support TB control activities has been limited in Romania, but several NGOs, academic institutions and civil society organizations (CSOs) have play a supportive, and even leadership role. More recently, several patient associations have started to emerge to advocate on behalf of TB patient groups. While the actions of these groups have been laudable and innovative for Romania, they are commonly challenged by the lack of sustainable funding. Once external funding stops, many of the projects also ended. As a result, there is very limited sustained outreach, education or patient support activities in Romania.

The majority of NGOs with activities in TB are based in Bucharest, with the exception of the Romanian Children’s Humanitarian Foundation. Some of these organizations (like Center for Health Policies and Services, Save the Children and the Red Cross) have conducted activities outside of the capital, but these all relied upon funding from the Global Fund. One organization, Romania Angel Appeal, has played a vital role in providing technical assistance to the NTP through its role as the Principal Recipient of Global Fund grants.

Save-the-Children has conducted a project to locate TB among the homeless and accompany and suport patients to access and receive services. Their interventions among the homeless and poor have referred 799 homeless people for TB diagnosis between 2008 and 2010 yielding 228 cases of TB. During a subsequent phase funded through the TFM in 2013, an additional 130 people were referred and 36 cases of TB identified. In addition to referring people for services, TB education also took place in this project reaching 1779 homeless people 2008-10 and 587 in 2013.

In 2011, the Association for MDR-TB Patients Support (AMRTPS) was established to advocate for TB patient needs. AMRTPS provides in partnership with UNOPA (national federation of organizations of persons affected by HIV/AIDS) peer support and incentives for TB patients at-risk of non-adherence. Its members, along with psychologists, serve as volunteers. There was another patient association, the Romanian TB Patients Association (ART-TB) which reported to have 400 members, 50% which are current or former TB patients.

Summary – Engagement of Civil Society

The overall role of civil society for TB control has been limited. In the past, there have been initiatives led by NGOs, but these activities are dependent on external funding and not sustainable or supported through domestic resources. In addition, patient led initiatives have only recently begun in Romania, but these activities show potential for expansion.

Table 21 Engagement of Civil Society Challenges

<i>The role of civil society and non-governmental organizations to address and support TB control is limited in Romania.</i>
<i>The emergence of a patient led organization is a positive recent step which needs to be supported to fulfill potential.</i>

N. Costs and Funding for TB Services

Within Romania, the diagnosis and treatment of TB is free of charge. TB activities and services are funded through several different sources including domestic and external sources. Treatment costs are paid for by National Health Insurance program regardless of the insurance status of a patient. However, ancillary drugs and auxiliary diagnostic tests can only be purchased through a co-payment system.³¹ The existence of co-payments in the health care system can deter and delay people seeking care who cannot know whether there condition is TB. In addition, other associated costs for patients including transportation and the potential lost wages may impact health behaviours to seek and adhere to treatment.

Virtually all TB patients are hospitalized at the beginning of treatment. The cost of hospitalization is reimbursed by the National Insurance House (NIH) to the hospital at a rate of \$40 per day.³² During hospitalization, all other treatment costs, such as medications to manage adverse reactions, are covered, but these become the patient's responsibility during the outpatient phase of treatment. This is a challenge for M/XDR-TB patients as the side-effects are serious and even life-threatening³³ for the second-line drugs and the treatment duration is up to two years for MDR-TB and even longer for XDR-TB³⁴.

For MDR-TB patients not enrolled in the GLC program, an additional cost may involve the purchase of some medications from other countries since not all recommendation medications are available or covered by the national health insurance. The ability to receive this care is, of course, dependent on the resources of the patient and their families. The result is inequality in the system.

While these issues have not been formally studied, anecdotal information indicates that charges for basic TB tests within some local facilities act as a barrier to care. One sign that this may be a problem is the extensive pulmonary damage that is often reported when cases are finally diagnosed. It is difficult to state if delays are due to any single factor or this represent a combination of system, community and individual barriers. System factors involve barriers to access care or problem with providers suspecting or recognizing TB in a timely manner, while community or patient factor which delays seeking care may be due to inadequate knowledge about TB symptoms or services, stigma, financial barriers or perceptions the affect healthcare utilization.

There is a range of cost estimates to treat an individual case of TB. As reported by Stillo (2013), medications to treat drug susceptible TB cost around US\$100 per case. The main initial costs involve hospitalization during the intensive phase followed by the costs for supervising patients during the continuation phase. Nearly all TB patients are hospitalized at the beginning of treatment with the average duration lasting 37 days. The National Insurance House pays hospital at a rate of \$40 per day which covers the "hotel" aspect of hospitalization and no other costs such as staffing, testing, building maintenance, and other related costs³⁵. While the individual cost for TB has not been calculated, the cost for just the anti-TB amounted to \$5,151,515 in 2013³⁶.

The cost for hospitalizing an MDR-TB patient for 90 days, without other complications, amounts to around \$12,000 - \$18,000 for the Global Fund cohort. This includes cost for treatment with capreomycin, PAS,

³¹ NTP Programme Review, 2014

³² This hospitalization cost only covers the "hotel" aspect of hospitalization, not the total costs such as staffing, testing, building maintenance, and other related costs.

³³ Side-effects for second line drugs include: nausea, headaches, photosensitivity, indigestion, peripheral neuropathy, ototoxicity, depression, paranoia, liver and kidney failure, and many others.

³⁴ Stillo, 2013

³⁵ Stillo, 2013

³⁶ Stillo, 2013

levofloxacin, kanamycin and cicloserine, and protionamide as well as social support payments of \$1400 over two years. The costs for MDR-TB medications depend on how the second-line drugs are procured with estimates ranging from €1800 to €13,600^{37, 38}. As Romania's capacity to diagnose more M/XDR-TB cases, the overall cost of treatment will certainly rise³⁹.

Romania was the recipient of the €10 million of funding between 2007 and 2014. Global Fund resources have been used to scale up MDR-TB control enabling second-line drug (SLD) treatment for 523 MDR-TB patients in Round 6 and 300 patients under the TFM. Romania was eligible for a TFM grant (October 2012 – September 2014) which provided treatment for an additional MDR-TB cohort. Additional external support for development of 4 multidisciplinary services and patients' professional integration comes from the European Social Fund – POSDRU Programme and Romanian Angel Appeal Foundation - €1.4 million⁴⁰ and from the Swiss-Romanian Cooperation Program (73,920 CHF). Romania is also negotiating for an additional €5.3 million grant (with co-financing from Romania) from the Norwegian funds. The country recently received approval for €5.4⁴¹ million of funding (2014-2016) to expand MDR-TB treatment and improve laboratory diagnostics. This grant will enable treatment for 500 MDR-TB patients per year, procurement of rapid diagnostic tests and update to the TB surveillance database.

The general financial system for health care in Romania has created unfortunate barriers for improving clinical practices and, conversely, promotes some suboptimal practice. For example, within the hospital setting patients are tied to specified beds and administrators and doctors are not allowed to move these patients into alternative settings, such as a dedicated TB ward by infectious stage, which would help to reduce the transmission and exposure of infectious TB. Moreover, the current payment system creates incentives to hospitalize patients for extended periods (37 days in the case of non-resistant TB), rather than holding patients based on clinical factors or using these funds to strength ambulatory treatment of TB. Hospitals cannot increase, or reduce, the number of hospital beds dedicated to TB, adjust staff ratios based on clinical and epidemiological need, or adopt alternative case management practices unless prescribed by a specific regulation.

Unfortunately, there was no a corresponding changes in the allocation of payment to family physicians to provide ambulatory care and this will create new challenges for continuity of care and positive treatment outcomes.

Summary – Financing TB

Within Romania, the diagnosis and treatment of TB are free of charge. TB services are supported with domestic and international funds with treatment paid for by National Health Insurance program. The general financial system for health care in Romania, however, promotes some suboptimal practices including the extensive use of expensive inpatient instead strengthening ambulatory treatment of TB.

³⁷ Stillo, 2013

³⁸ RAA, 2014

³⁹ Stillo, 2013

⁴⁰ This project ended in 2014. RAA is partner and the project addressed the problem of TB among IDUs. The budget for RAA was 150,000 euro (including 20% RAA co-finance

⁴¹ Romania is required to provide 15% in co-funding.

IV. Operational Plan

This section describes in details the specific steps Romania will take to improve TB outcomes. By carrying out the proposed initiatives, Romania will achieve the following goals and objectives for TB control:

Goal: *To achieved dramatic reductions in TB incidence and mortality by 2020.*

*By 2020, Romania will achieve the following **Strategic Objectives**:*

- *Objective 1 - Ensure universal access to rapid diagnosis methods for DS-TB and M/XDR-TB by 2020*
- *Objective 2 - Diagnose at least 85% of all estimated DS-TB and MDR-TB cases*
- *Objective 3 - Successfully treat at least 90% of new culture positive TB cases and 85% of all retreatment cases by 2020.*
- *Objective 4 - Successfully treat 75% of MDR-TB cases by 2020.*
- *Objective 5 - Reduce overall TB mortality rate to 4.3 per 100 000 population by 2020.*
- *Objective 6 - No affected families facing catastrophic costs due to tuberculosis⁴².*
- *Objective 7 - Case notification rate of all forms of TB per 100,000 population - bacteriologically confirmed plus clinically diagnosed, new and previously treated cases will decrease from 73 in 2013 to 46.59 cases per 100 000 population by 2020.*
- *Objective 8 - Improve health system capacity to control TB.*

To ensure the achievement of the strategic objectives, Romania pursues a series of key intervention areas based upon the following three pillars:

Pillar 1: Integrated Patient-Centered Care and Prevention

Pillar 2: Bold Policies and Supportive Systems

Pillar 3: Innovative Research and Evidence-Based Strategies

⁴² Out-of-pocket expenditure on health care exceeding 40% of discretionary household expenditure has been defined by WHO as a catastrophic level. The threshold for catastrophic total cost (including indirect costs) has not yet been established.

The following key interventions will be implemented under the 3 pillars of the NSP 2015-2020:

Pillar 1: Integrated Patient-Centered Care and Prevention

Interventions:

- 1.1. Develop universal access to rapid diagnostic methods and universal drug-susceptibility testing
- 1.2. Improve the timeliness and accuracy of diagnosis of TB
- 1.3. Effectively treat TB patients by following WHO-treatment recommendations
- 1.4. Improve treatment outcomes for MDR-TB and XDR-TB patients by following WHO-treatment recommendation
- 1.5. Improve patient support and case holding systems
- 1.6. Prevent transmission of TB through vaccinations, targeted screenings, and infection control
- 1.7. Ensure collaborative tuberculosis/HIV activities

Pillar 2: Bold Policies and Supportive Systems

Interventions:

- 2.1. Ensure adequate resources for tuberculosis care and prevention
- 2.2. Strengthen the capacity of the National TB Program for TB control
- 2.3. Develop human resource capacity for TB care and prevention
- 2.4. Establish centralized procurement and distribution of first, second and third-line anti-TB medications
- 2.5. Establish infection control standards and requirements for healthcare facilities
- 2.6. Engage and facilitate involvement of impacted communities and civil society organizations in TB control
- 2.7. Support the involvement of public section and family doctors and community workers to provide ambulatory and community-based TB care and services

Pillar 3: Innovative Research and Evidence-Based Strategies

Interventions:

- 3.1. Ensure a dynamic and effective TB surveillance system
- 3.2. Develop epidemiological and research capacity for TB control
- 3.3. Conduct operational and epidemiological research to improve TB control

The links between pillars, interventions and strategic objectives are presented in table 22 Pillars, interventions and associated strategic objectives.

Table 22 Pillars, interventions and associated strategic objectives

Pillars	Interventions	Strategic objectives							
		O1	O2	O3	O4	O5	O6	O7	O8
1. Integrated Patient-Centered Care and Prevention	1.1. Develop universal access to rapid diagnostic methods and universal drug-susceptibility testing.	X				X	X		X
	1.2. Improve the timeliness and accuracy of diagnosis of TB.		X			X	X		X
	1.3. Effectively treat TB patients by following WHO-treatment recommendations.			X		X	X		X
	1.4. Improve treatment outcomes for MDR-TB and XDR-TB patients by following WHO-treatment recommendations.				X	X	X		X
	1.5. Improve patient support and case holding systems.			X	X	X	X		X
	1.6. Prevent transmission of TB through vaccinations, targeted screenings, and infection control.							X	X
	1.7. Ensure collaborative tuberculosis/HIV activities.	X	X	X	X	X	X		X
2. Bold Policies and Supportive Systems	2.1. Ensure adequate resources for tuberculosis care and prevention.	X	X	X	X	X	X	X	X
	2.2. Strengthen the capacity of the National TB Program for TB control.	X	X	X	X	X	X	X	X
	2.3. Develop human resource capacity for tuberculosis care and prevention.	X	X	X	X			X	X
	2.4. Establish centralized procurement for anti-TB medications.			X	X	X	X		X
	2.5. Establish infection control standards and requirements for healthcare facilities.					X	X	X	X
	2.6. Engage and facilitate involvement of impacted communities and civil society organizations in TB control.		X	X	X		X	X	X
	2.7. Support the involvement of public section and family doctors and nurses to provide ambulatory and community-based TB care and services.		X	X	X		X	X	X
3. Innovative Research and Evidence-Based Strategies	3.1. Ensure a dynamic and effective TB surveillance system.								X
	3.2. Develop epidemiological and research capacity for TB control.								X
	3.3. Conduct operational and epidemiological research to improve TB control.								X

Table 23 outlines impact and outcome indicators, baseline data and milestones for the above objectives. The objectives will be achieved by implementing an integrated and comprehensive set of strategies and program interventions. Some of the proposed activities sustain current best practices, while other initiatives are new and needed in response to existing program gaps and weaknesses previously explained.

Table 9 Impact and outcome indicators

Interventions	Indicators	Baseline	Year of baseline	2015	2016	2017	2018	2019	2020
Impact Indictors	TB mortality rate	5.3	2013	5.52	5.49	5.20	4.91	4.65	4.30
Outcome indicators	Case notification rate of all forms of TB per 100,000 population - bacteriologically confirmed plus clinically diagnosed, new and previously treated cases	72.99	2013	82.12	82.12	73.91	65.04	57.23	49.79
	Case notification rate per 100,000 population - bacteriologically confirmed, new and relapse cases	45.11	2013	49.70	49.71	44.74	41.73	36.73	31.95
	Treatment success rate - bacteriologically confirmed new TB cases	86%	2012	86%	87%	87%	88%	88%	90%
	Treatment success rate bacteriologically confirmed relapses	57%	2012	60%	65%	70%	75%	80%	85%
	Treatment success rate of MDR-TB: Percentage of bacteriologically confirmed drug resistant TB cases (RR-TB and/or MDR-TB) successfully treated	20%	2010	50%	55%	60%	65%	70%	75%

PILLAR 1: Integrated Patient Centered Care and Prevention

Intervention 1.1 Develop universal access to rapid diagnostic methods and universal drug-susceptibility testing

The first intervention established for the 2015-2020 National Strategic Plan is to ensure universal access to rapid diagnosis of drug susceptible and M/XDR-TB through strengthening the TB laboratory network by the following activities:

1.1.1 Development of the operational framework for the TB laboratories which involves the following:

- Analysis of the current status of TB laboratory network
- Development of **standards for TB laboratories** including basic requirements for the safe and effective operation of laboratories
- Development of the **National laboratory guideline for TB laboratory network** (addressing the organization of laboratories, infection control, diagnostic algorithms, new diagnostic methods, SOPs, reagents storage, daily maintenance of equipment, troubleshooting, recording and reporting of results)
- Development of a centralized **plan for procurement of equipment and necessary supplies**
- Development of a **review process** to ensure that laboratories follow standards and meet performance criteria. If warranted, the MoH will consolidate or close laboratories that cannot meet performance standards. It is expected that 100% of TB laboratories will meet standards by 2020.

1.1.2 Ensuring the necessary equipment and consumables for TB diagnosis which involves the following:

- 50 TB laboratories will be renovated in order to respect IC TB
- Upgrade laboratory **biosafety equipment**: by 2020, 50 TB labs will have new biosafety equipment
- Replace outdated microscopes with more sensitive light emitting diode (**LED**) **microscopes**: by 2020, 50 TB labs will have LED microscopes
- Procure **centrifuges** for the isolation of TB: by 2020, 50 TB labs will have new centrifuges
- Scale-up the use of **rapid molecular method (LPA, GenoType-Hain)** started in 2012 to 9 regional reference laboratories to routinely identify *Mycobacterium tuberculosis* and resistance to INH and RMP. The NRLs will use genotyping to detect resistance to second-line drugs
- Scale-up the use of **MGIT method** in nine regional laboratories
- Scale-up the use of **GeneXpert** method (Nucleic Acid Amplification/NAA) to identify *M. tuberculosis* and RMP resistance in the risk groups (HIV infected, drug resistant contacts, prisons, children, and immigrants) in 42 laboratories. NAA technology will be placed in areas with high TB incidence and population with drug resistant TB. This equipment could be relocated after one year of use and assessment of efficacy
- Ensure all the **necessary reagents and consumables** for diagnostic and monitoring of the treatment

1.1.3 Development of a safe and reliable transportation system

In order to ensure the rapid diagnostic, a safe transport system of specimens (sputum, cultures) from periphery to center will be developed either by using the NTP vehicles or identification of courier services.

1.1.4. Quality assurance, monitoring and evaluation

In order to ensure the monitoring and evaluation of the use of new technologies, quality of diagnosis and reporting and recording of the data by the TB laboratories, the NTP will:

- conduct **training session** for laboratory staff (including elaboration of the curriculum based on the National Guidelines for TB laboratories): 5 training sessions/yearX20 personsX2 days (included under intervention 2.3 Develop human resource capacity for tuberculosis care and prevention)
- conduct **routine supervision** from NRLs to the level of RRLs and from RRLs to county laboratories: 50 supervisory visits/year
- ensure the **accreditation process** through RENAR (the local body responsible with the accreditation for microbiology laboratories)
- conduct **External Quality Assessment (EQA)** for the laboratory network as follows:
 - the SNRL will coordinate, plan and provide the EQA for the 2 NRLs
 - The two NRLs will coordinate, plan and provide EQA for the rest of TB laboratory network

Table 24 Intervention 1.1 Output indicators

Intervention 1.1. - Develop universal access to rapid diagnostic methods and universal drug-susceptibility testing								
Indicator	Baseline	Year of baseline	2015	2016	2017	2018	2019	2020
Number of notified cases of all forms of TB - bacteriologically confirmed plus clinically diagnosed, new and relapses	15523	2013	15322	15292	13735	12063	10594	9198
Number of TB bacteriologically confirmed, new and relapse cases	9593	2013	9912	9893	8886	8273	7266	6308
% of TB bacteriologically confirmed new and relapse cases	62%	2013	65%	65%	65%	69%	69%	69%
Number of regional laboratories implementing genetic and liquid methods	5	2013	3	1	0	0	0	0
Number of laboratories using cartridge-based Nucleic Acid Amplification (NAA)Techniques	2	2014	14	26	0	0	0	0
Number of strategic documents developed for standardization of TB laboratory network (national TB laboratory guidelines, reorganization concept, etc.)	N/A		0	1	0	0	0	0
% of specimens delivered per processing standards	N/A		30%	70%	80%	90%	100%	100%

Intervention 1.2 Improve the timeliness and accuracy of diagnosis of TB.

Overall, Romania does a good job to identify new pulmonary TB cases and therefore, the GoR will sustain existing TB referral and diagnosis system to identify and refer TB suspects.

However, not all care providers (family doctors, community workers, NGOs/CBOs, etc) are involved in identification and referral of suspects and therefore the GoR will sustain more involvement from the other care providers and more attention will be given to key affected population.

During the next six years, Romania will diagnose at least 85% of all estimated DS-TB and 100% of M/XDR-TB cases, through the implementation of the following activities:

1.2.1. Sustain existing TB referral and diagnosis system

Over the next six years, Romania expects to refer over 800,000 TB suspects and over 300,000 TB contacts for evaluation out of which over 80,000 TB cases (new and previously treated cases) will be detected.

Romania will provide support for the referral of TB suspects by ensuring maintaining and supporting referral, clinical and diagnostic skills of healthcare providers and supporting the availability of clinical, X-ray, PPD and IGRA tests as well as the smear microscopy and culture examinations as per diagnostic guidelines.

1.2.2. Improve diagnosis of TB in children (age 0-15 yrs.)

To improve the diagnosis of TB in children, Romania will:

- update the national guidelines regarding management of TB in children in order to evaluate children for TB using appropriate methods (including development of the referral process for examining TB in children ages 0-4)
- identify the necessary equipment needed and the facilities capable to examining pediatric TB
- provide training sessions for medical staff working in pediatric facilities (included under intervention 2.3 Develop human resource capacity for tuberculosis care and prevention)

It is expected that over 97,000 children ages 0-15 will be screened for TB by 2020.

1.2.3. Engagement of all care providers in TB service delivery

Since not all care providers (family doctors, community workers, NGOs/CBOs, etc.) are currently involved in identification and referral of suspects, the GoR will sustain more involvement from the other care providers by implementation of the following activities:

- Conduct an assessment of the current situation of engagement of all care providers in TB service delivery in Romania (including implementation of PAL strategy)
- Elaborate the national guidelines re. detection and referral system for TB patients for all care providers (including active case detection in key affected populations)

- Revise the PAL strategy
- Elaborate of a training curriculum for community workers and CBOs/NGOs (included under intervention 2.3 Develop human resource capacity for tuberculosis care and prevention)
- Elaborate a training curriculum for primary care doctors (included under intervention 2.3)
- Provision of training sessions (included under intervention 2.3)

These activities are only part of the answer to the need for engagement of all the providers in service delivery. There are a number of other activities interrelated and complementary to those mentioned above (such as: Elaboration of training curriculum; Provision of training sessions for the providers; Elaboration of the financial mechanism for reimbursement of services; National and regional meetings of national stakeholders and service providers) placed under the Pillar 2 - Bold Detailed Policies and Support Systems (see Interventions: 2.3, 2.6 and 2.7).

1.2.4. Improve the timeliness of TB detection in high-risk populations through active case finding with high risk population

To stop the spread of TB, it is critical to detect and treat TB in high-risk populations. One strategy to accomplish this is through active case finding. Romania has previously used active case finding strategies, but never developed a comprehensive strategy or criteria for conducting active case finding/case detection among vulnerable populations including prison inmates, homeless and IDU users.

To ensure that future interventions are effective, the NTP will perform a need assessment evaluation for high risk groups and will implement the guidelines for active case finding (described above) and ensure that these interventions are adequately evaluated to efficacy.

Interventions will be designed to address the following high-risk populations: prisoners, homeless, injecting drug users and rural/urban poor.

a. Prisoners

To ensure that TB in prisons remains controlled, the Ministry of Health in collaboration with the Ministry of Justice (MoJ), will:

- Revise the methodological norms of implementation of the National TB Control Programme in Penitentiaries (NTPP)
- Provide training sessions for the NTPP staff on revised methodological norms of implementation of the NTPP (included under intervention 2.3 Develop human resource capacity for tuberculosis care and prevention)
- Conduct biannual working meetings for improvement of the coordination between civilian and penitentiaries network
- Implement routine supervision at the level of penitentiaries
- Development and printing of IEC materials for prisoners
- Conduct IEC TB sessions for prisoners
- Implement systematic screenings to diagnose TB through provision of GeneXpert equipment and the necessary consumables

- Develop a specimen transportation system from penitentiaries to designated TB laboratories.

Under this system, the MoH/MOJ will screen all prisoners for TB symptoms upon intake and refer TB suspects for examination using rapid diagnosis methods. When cases are found, patients will be provided supervised TB treatment during incarcerations with assured continuity of care in the public sector when released if still under treatment.

b. Homeless

There are an estimated 11,000 homeless in Romania with 5,000-6,000 living in Bucharest. A 2011 study estimated that the TB prevalence in the Bucharest homeless population at 6,700 cases per 100,000 or 50 times higher than the general population's TB prevalence.

The main activities to be implemented for active case finding among homeless population are the following:

- Identification of CBOs/NGOs working with homeless population and mapping the geographic areas of intervention
- Provision of training sessions for the NGOs/CBOs working with homeless population (included under intervention 2.3 Develop human resource capacity for tuberculosis care and prevention)
- Contracting the identified CBOs/NGOs and provision of necessary funds for TB service delivery among homeless
- Provision of TB services by CBOs/NGOs through a mix of interventions (peer education, IEC, identification and referral of suspects, etc.)

c. IDUs

There is growing concern about an emerging population at risk of both HIV and TB, namely injecting drug users (IDUs). Within Romania, the number of intravenous drug use, and other drug use, has increased during the past few years. In 2011, an estimated 20,000 drug users were estimated to live in Bucharest. This population has experienced an increase in multiple health problems including a rise in HIV. There has also been a rise in the percentage of PLHIV co-infected with TB among the IDU population since 2011.

The main activities to be implemented for active case finding among IDUs are the following:

- Identification of CBOs/NGOs working with IDUs and mapping the geographic areas of intervention
- Provision of training sessions for the NGOs/CBOs working with IDUs
- Contracting the identified CBOs/NGOs and provision of necessary funds for TB service delivery among IDUs
- Provision of TB services by CBOs/NGOs through a mix of interventions (peer education, IEC, identification and referral of suspects, outreach harm reduction services, tests for HIV, Hep B and C, etc)

d. Poor population with limited access to health services (including Roma population)

TB disproportionately affects poor and unemployed Romanians. One group, the ethnic minority Roma population is disproportionately poorer than the majority Romanians, with as many as 75 percent of Roma living in poverty compared to 32.2 percent overall of Romanians. The Roma also suffer higher rates of TB

than the general population up to four times higher in adults ages 55-64⁴³. Poor Romanians encounters greater obstacles and difficulties in accessing health care and paying for treatment. As a result, diagnosis can be delayed allowing TB to progress into serious disease.

The main activities to be implemented for active case finding among poor population with limited access to health services are the following:

- Mapping of geographic areas of intervention with high TB burden and identification of community workers and/or family doctors able to work with poor population with limited access to health services
- Provision of necessary funds for TB service delivery among poor population with limited access to health services
- Provision of TB services by community workers and/or family doctors through a mix of interventions (IEC, identification and referral of suspects, etc.)

The activities related to active case detection among key affected populations (homeless, IDUs, poor population with limited access to health services) are interrelated and complementary to those described under:

- Pillar 1, activity 1.2.3 - Engagement of all care providers
- Pillar 2, intervention 2.3- Develop human resource capacity for tuberculosis care and prevention, 2.6 - Engage and facilitate involvement of impacted communities and civil society organizations in TB control and 2.7 - Support the involvement of public section and family doctors and nurses to provide ambulatory and community-based TB care and services

By 2020, 5,200 homeless persons, 20,000 IDUs and over 77,000 poor persons will receive information about TB symptoms, services and treatment.

1.2.5. Improve diagnosis of MDR-TB and XDR-TB

To improve the detection of MDR-TB and XDR-TB, the National TB Programme will:

- increase the use of first-line drug susceptibility tests (genetic, liquid and solid media) for all new and retreated cases
- provide second-line drug susceptibility tests (genetic, liquid and solid media) to all patients with H and/or R resistance

As a result, it is expected that 100% of new and retreated cases will be provided FLDST by 2020. In addition, 100% of patients with H and/or R resistance will receive SLDST by 2020. Improved diagnosis is expected to result in diagnosing over 3,400 patients with MDR-TB and 390 cases of XDR-TB by 2020.

⁴³ European Roma Rights Centre, October 2013

Table 25 Intervention 1.2 Output indicators

Intervention 1.2. Improve the timeliness and accuracy of diagnosis of TB								
Indicator	Baseline	Year	2015	2016	2017	2018	2019	2020
Number of suspects and contacts to be evaluated for TB diagnosis	218,722	2013	229,278	228,816	205,520	180,502	158,522	137,634
Number of persons from high risk groups evaluated for TB diagnosis	N/A		17,850	22,060	22,690	31,060	33,590	35,700
Number of TB cases (all forms) notified among key affected populations/high risk groups	N/A		985	1,406	1,469	2,306	2,559	2,770
Number of TB cases (all forms) notified among homeless	N/A		25	100	100	100	100	100
Number of TB cases (all forms) notified among IDUs	N/A		60	400	400	400	400	400
Number of TB cases (all forms) notified among poor population with limited access to health care services (including roma)	N/A		700	686	769	1,606	1,859	2,070
Number of TB cases (all forms) notified among prisoners	160	2013	200	200	200	200	200	200
Number of notified TB cases, all forms, contributed by non-NTP providers - private/non-governmental facilities	N/A		85	500	500	500	500	500
Percentage of notified TB cases, all forms, contributed by non-NTP providers - private/non-governmental facilities	N/A		0.52%	3.06%	3.41%	3.88%	4.42%	5.09%
Number of notified TB cases, all forms, contributed by non-NTP providers - community referrals	N/A		700	706	769	1,606	1,859	2,070
Percentage of notified TB cases, all forms, contributed by non-NTP providers - community referrals	N/A		4.27%	4.32%	5.24%	12.46%	16.42%	21.06%
Number of notified TB cases, all forms, contributed by non-NTP providers - family doctors	N/A		3,275	4,903	4,404	4,196	4,369	4,320
Percentage of notified TB cases, all forms, contributed by non-NTP providers - family doctors	N/A		20%	30%	30%	33%	39%	44%
Number of notified TB cases, all forms, contributed by NTP (including self-referral)	N/A		12,317	10,235	9,007	6,591	4,595	2,941
Percentage of notified TB cases, all forms, contributed by NTP (including self-referral)	N/A		75.21%	62.62%	61.36%	51.12%	40.58%	29.92%
Number of children evaluated for TB using appropriate methods	2500	2013	19,652	19,613	17,616	15,472	13,588	11,797
Percentage of new TB patients receiving DST	58.30%	2012	60%	80%	90%	100%	100%	100%

Percentage of previously treated TB patients receiving DST	68.80%	2012	70%	80%	90%	100%	100%	100%
Percentage of patients with H and/or R resistance provided second-line drug susceptibility tests	N/A		80%	100%	100%	100%	100%	100%
Number of notified MDR TB cases new and retreatment	547	2013	517	632	639	624	548	476
Number of notified XDR-TB patients	44	2013	67	82	75	66	57	49
% detection MDR TB total	66.00%	2013	65.28%	79.90%	90.00%	100.00%	100.00%	100.00%
% detection XDR TB total	69.00%	2013	80.72%	100.00%	100.00%	100.00%	100.00%	100.00%

Intervention 1.3 Effectively treat TB patients by following WHO-treatment recommendations

The Government of Romania will successfully treat 90% of new TB patients and 85% of retreatment cases by 2020. To accomplish this, the MoH will:

- ensure that all confirmed cases of DS-TB initiate treatment with WHO-recommended first-line treatment regimens
- secure treatment formulations for pediatric TB cases
- secure Rifabutin for the TB IDUs patients on substitution treatment with methadone
- ensure ancillary drugs for all TB cases
- conduct monitoring examinations (clinic, Xray and laboratory)
- conduct activities in order to increase the treatment adherence (detailed under Intervention 1.5. Improve patient support and case holding systems)

Table 26 Intervention 1.3 Output indicators

1.3. Effectively treat TB patients by following WHO-treatment recommendations								
Indicator	Baseline	Year	2015	2016	2017	2018	2019	2020
Percentage of all new TB cases, bacteriologically confirmed plus clinically diagnosed, successfully treated (cured plus treatment completed) among all new TB cases registered	86%	2012	86%	87%	87%	88%	88%	90%
Percentage of all relapses, bacteriologically confirmed, successfully treated (cured plus treatment completed) among all relapses registered	57%	2012	60%	65%	70%	75%	80%	85%
Percentage of reporting units reporting no stock-out of first-line anti-TB drugs on the last day of the quarter	N/A		na	na	Na	85%	90%	100%

Intervention 1.4 Improve treatment outcomes for MDR-TB and XDR-TB patients by following WHO-treatment recommendations

Romania will improve M/XDR TB treatment outcomes using a multi-faceted approach as follows:

- Establish legal framework that enable access to WHO-recommended treatment regimens (detailed under intervention 2.4 Establish centralized procurement and distribution of first, second and third-line anti-TB medications)
- Provision of an uninterrupted, centrally procured supply of quality second and third-line anti-TB drugs and ancillary medications for all MDR-TB and XDR-TB patients.
- Conduct monitoring examinations (clinic, X-ray and laboratory)
- Conduct activities in order to increase the treatment adherence (detailed under Intervention 1.5. Improve patient support and case holding systems)

Through implementation of these activities, Romania will treat over 3,400 patients, through 2020 with the minimal objective to successfully treat 75%.

Table 27 Intervention 1.4 Output indicators

1.4. Improve treatment outcomes for MDR-TB and XDR-TB patients by following WHO-treatment recommendations								
Indicators	Baseline	Year	2015	2016	2017	2018	2019	2020
Number of MDR TB patients receiving WHO recommended treatment regimens	135	2013	517	632	639	624	548	476
% of MDR-TB patients receiving WHO recommended treatment regimens	40%	2013	100%	100%	100%	100%	100%	100%
Number of XDR TB patients receiving WHO recommended treatment regimens	N/A		67	82	75	66	57	49
Treatment success rate MDR TB	20%	2012	50%	55%	60%	65%	70%	75%
Number of cases with drug resistant TB (RR-TB and/or MDR-TB) started on treatment for MDR-TB who were lost to follow up at six months	N/A		52	63	32	31	27	24
Percentage of cases with drug resistant TB (RR-TB and/or MDR-TB) started on treatment for MDR-TB who were lost to follow up at six months	N/A		10%	10%	5%	5%	5%	5%

Intervention 1.5 Improve patient support and case holding systems

The effective treatment of TB requires more than medical interventions. Ensuring successful treatment outcomes requires implementing patient-centered strategies, such as using outreach workers to deliver home-based DOT, conducting peer education or offering incentives and enablers. Through the Global Fund programs, Romania has used a variety of incentive and adherence strategies with some positive effects. More patient-centered strategies will be required to reduce default, prevent development of drug resistance, and to achieve more positive treatment outcomes.

On the other hand, as part of the process to reduce unnecessary hospitalization and to implement an ambulatory based treatment of TB cases, Romania will implement a major reform (detailed under Pillar 2, intervention 2.1.2 Implementation of the reform of ambulatory and patient-centered care). Some of the activities included under the reform are aimed on improving the patient support and case holding system as follows:

1.5.1 Implementation of the comprehensive ambulatory care

The implementation will start in 2015 in 6 high TB burden counties and will be fully implemented by 2020 in all Romanian counties through:

- Establishment of multidisciplinary teams to provide medical, social and psychological services to all cases diagnosed with TB. These teams will evaluate patients for non-adherence and will establish individualized plans to address social and psychological support needs.
- Provision of patient education on treatment and treatment adherence through:
 - Performing a needs assessment study of TB patients and providers
 - Development of an education strategy and plan
 - Development of IEC materials for patients
 - Provision of information through multidisciplinary teams, peer supporters, community workers, NGOs/CBOs
- Provision of directly observed treatment to new and retreatment DS-TB patients through TB units, but also through a range of DOT supporters for TB including community health workers, family doctors, social assistants, NGOs/CBOs representatives. The GoR proposed to improve the coverage of DOT from the current baseline of 40% to 100% by 2020.
- Provision of social support in the form of incentives and enablers (food and transport) for all patients in treatment ambulatory phase. In recognition of the need for critical enablers such as food and transport required to continue treatment, the GOR will establish a process to provide social support for patients at risk of default.
- Provision of psychological and peer support for the patients at high-risk of default based on assessment provided by the multidisciplinary teams through specialized psychologist and peers

1.5.2 Provision of housing support for homeless and vulnerable patients

It is expected that over 100,000 days of housing support will be provided to homeless and vulnerable populations by the end of 2020 through:

- Identification of the facilities for homeless housing,
- Establishment of an eligibility and referral process
- Identification of related support services.

1.5.3 Ensure compassionate and palliative care

It is expected that over 500 patients who treatment fails, or those at the end of life through provision of resources through established hospices, sanatoria or via home-based strategies (target at vulnerable populations) will benefit from some form of palliative care by the end of 2020.

Table 28 Intervention 1.5 Output indicators

Intervention 1.5. Improve patient support and case holding systems								
Indicators	Baseline	Year	2015	2016	2017	2018	2019	2020
Number of counties implementing ambulatory care model	0	2012	6	12	18	24	32	42
Number of multidisciplinary teams in place	4 teams	2014	6	12	18	24	32	42
% of TB patients receiving DOT	40%	2013	50%	60%	70%	80%	90%	100%
Number of TB patients receiving DOT	6209	2013	8189	9806	10276	10314	10191	9831
% of TB patients receiving social support	N/A		25%	35%	47%	50%	60%	70%
Number of TB patients receiving social support	N/A		4094	5720	6900	6447	6794	6882
Number of renovated/reorganised in-patient treatment facility for patients who are at highest risk of non-adherence, default and death due to poor economic status and precarious living conditions	N/A		0	1	1	0	0	0

Intervention 1.6 Prevent transmission of TB through vaccinations, targeted screenings, and infection control

Greater actions are required to prevent the transmission of TB in Romania. The primary actions taken have included provision of BCG vaccinations for children. During the next six years, vaccinations will continue, but prevention control activities will expand, in particular, these efforts will focus on preventing TB from spreading in healthcare and other congregate care facilities.

1.6.1. Vaccinate children with BCG

The MoH will continue to provide BCG to eligible children per vaccination guideline and annually monitor and report on vaccinations. It is expected that by 2020, Romania will administer over 1,100,000 BCG vaccinations.

1.6.2 Provide preventive therapy (IPT) to vulnerable populations

The GOR will work to integrate diagnosis of active and latent TB in high risk groups (including PLHIV and children). As part of this effort, the MoH will monitor IPT and report on services and outcomes. It is expected that over 100,000 patients will receive IPT by 2020.

1.6.3 Improve infection control practices to reduce transmission and exposure of TB

It is recognized that current healthcare and laboratory facilities lack comprehensive or active infection control practice. In response to this, the MoH will work with facilities to strengthen infection control practices. To accomplish this, the NTP will:

- survey facilities on infection control practices and needs
- finalize the infection control guidelines and disseminate this to healthcare and TB laboratories facilities.
- provision of financial and material support for implementation of infection control measures (administrative, environmental, and personal respiratory protection)
- routine monitoring and evaluation of the infection control plan in all facilities during the routine supervision visits.

It is expected that 100% of health care facilities will implement infection control practices for TB.

Table 29 Intervention 1.6 Output indicators

1.6. Prevent transmission of TB through vaccinations, targeted screenings, and infection control								
Indicators	Baseline	Year	2015	2016	2017	2018	2019	2020
Number of children vaccinated with BCG	198,216	2013	194,163	190,280	186,475	182,745	179,090	175,508
Number of patients provided IPT	17,765	2013	15,001	16,669	16,122	18,613	18,871	18,999
Number of facilities implementing infection control practices	0%		20%	40%	60%	80%	100%	100%

Intervention 1.7 Ensure collaborative tuberculosis/HIV activities, and management of co-morbidities

Improvements are needed to both improve the timeliness and accuracy of TB tests in HIV positive patients, to increase the number of TB patients who know their HIV status, and to reduce risk of exposure and transmission of TB with infectious disease wards. These steps are required to ensure that the problem of TB-HIV co-infection remains under control.

To accomplish this, the Romania will:

- Ensure greater coordination and policy setting between the main governmental agencies responsible for TB and HIV through:
 - elaboration of National TB/HIV clinical guidelines
 - organization of meetings between the NTP and HIV/AIDS National Committee to address policy and practice concerns including screening and treatment
- Improve the screening of HIV among TB patients through:
 - Development of education materials on TB-HIV co-infection
 - Enabling HIV screening in TB patients by ensuring testing kits
 - Ensuring counseling and referrals for HIV testing to all TB patients
- Improve the screening of TB among HIV patients through provision of TB tests for all persons admitted into hospitals for HIV treatment
- Ensure the ART treatment for all TB patients diagnosed as HIV positive

Table 30 Intervention 1.7 Output indicators

1.7. Ensure collaborative tuberculosis/HIV activities, and management of co-morbidities								
Indicators	Baseline	Year	2015	2016	2017	2018	2019	2020
Number of coordination meetings between NTP and National HIV/AIDS programme	N/A		2	2	2	2	2	2
Percentage of TB patients who know their HIV status	59.5%	2013	65%	70%	75%	80%	90%	95%
Number of HIV patients screened for TB	N/A		4000	3900	3800	3700	3600	3500

Pillar 2: Bold Policies and Supportive Systems

Intervention 2.1 Ensure adequate resources for tuberculosis care and prevention

Romania has made progress to improve the funding and resource situation for TB control through domestic and external funds. However, these activities need to be sustained and expanded to meet recent and emerging TB control challenges.

2.1.1. Ensure that TB gains high-level attention from policy-makers and public health leaders

One strategy to improve awareness and commitment for TB at the policy, legislative and fiscal level is to create a high-level advisory body. The MoH will lead efforts to establish an advisory body to facilitate inter-governmental coordination of TB issues and advise the Government on TB control policies and needs. This group will develop a meeting schedule to monitor progress, barriers, and achievements with the National Tuberculosis Strategic plan and set annual recommendations based on program and epidemiological status.

2.1.2 Implementation of the reform of ambulatory and patient-centered care

During 2015-2020, Romania will develop and implement a major reform aimed on changing the current system of care for TB cases from in-patient to out-patient care, which will result in reduction of hospitalization cost while redirecting more resources to ambulatory and patient-centered care.

The main steps of this reform are described as follows:

- Development of the reform plan with objectives, targets and responsible parties
- Development of the comprehensive national guidelines for the diagnosis, treatment and case management of TB that reflect updated policies and recommendations, including the criteria selection of TB patients for hospitalization or for ambulatory care
- Conduct a national assessment regarding the situation of ambulatory and hospitalized treatment in Romania and development of the ambulatory model of care
- Conduct an assessment of the current situation of engagement of all care providers in TB service delivery in Romania and the implementation of PAL strategy (described under activity 1.2.3. Engagement of all care providers in TB service delivery)
- Assessment of the financial mechanism regarding the reimbursement of TB services to all care providers involved in TB control: TB staff, family doctors⁴⁴, community workers⁴⁵, NGOs/CBOs⁴⁶, etc.
- Revision of financial mechanism of reimbursement to all care providers involved in TB control: TB staff, family doctors⁴⁷, community workers⁴⁸, NGOs/CBOs⁴⁹, etc. (including unit cost per service provided and framework of payments for each staff category)

⁴⁴ Described under intervention 2.7 Support the involvement of public section and family doctors and nurses to provide ambulatory and community-based TB care and services

⁴⁵ Described under intervention 2.6 Engage and facilitate involvement of impacted communities and civil society organisations in TB control

⁴⁶ Described under intervention 2.6 Engage and facilitate involvement of impacted communities and civil society organisations in TB control

⁴⁷ Described under intervention 2.7 Support the involvement of public section and family doctors and nurses to provide ambulatory and community-based TB care and services

⁴⁸ Described under intervention 2.6 Engage and facilitate involvement of impacted communities and civil society organisations in TB control

⁴⁹ Described under intervention 2.6 Engage and facilitate involvement of impacted communities and civil society organisations in TB control

- Re-organisation of 2 medical centers to assist TB/X/MDR-TB socially deprived cases during the treatment
- Provision of TB training sessions for TB staff, family doctors, community workers and NGOs/CBOs (described under intervention 2.3 develop human resource capacity for tuberculosis care and prevention)
- Starting the implementation of the reform in 6 TB counties with high TB burden through provision of adapted services for the ambulatory patients (described under activity 1.5.1 Implementation of the comprehensive ambulatory care)
 - o Establish multidisciplinary teams to provide medical, social and psychological services to all cases diagnosed with TB
 - o Provision of patient education on treatment and treatment adherence
 - o Provision of directly observed treatment to new and retreatment DS-TB patients
 - o Provision of patient centered support (social, psychological and peer)
- Approval of the legislative framework (reform plan, comprehensive national guidelines, financial mechanism regarding the reimbursement of TB services to all care providers involved in TB control) by all the stakeholders involved.
- Scale up the reform including each year additional counties.
- Secure the funds saved from hospitalization for TB related activities through yearly budget requests from NTP and MoH to the Ministry of Finance.
- Monitoring and evaluation of the ambulatory model of care, including a cost-analysis study.

Through the implementation of this reform, it is expected that the cost for hospitalization for TB will decrease from 23 million EURO per year in 2015 to less than 6 million per year in 2020, through:

- Progressive decrease in the number of hospitalization days from 561,000 days in 2015 to 132,720 days in 2020 by:
 - o Progressive decrease in the percentage of TB patients hospitalized, from 92% in 2015 to 50% in 2020 and the period of hospitalization from 33 days/patient in 2015 to 20 days/patient in 2020.
 - o Progressive decrease in the percentage of MDR-TB patients hospitalized from 95% in 2015 to 60% in 2020 and the period of hospitalization from 93 days/patient in 2015 to 50 days/patient in 2020.

Table 31 Intervention 2.1 Output indicators

Intervention 2.1. Ensure adequate resources for tuberculosis care and prevention								
Indicators	Baseline	Year	2015	2016	2017	2018	2019	2020
Establishment of high-level TB advisory body	0		1	1	1	1	1	1
Percentage of TB patients who will start the treatment in ambulatory phase	0%	2013	8%	12%	15%	20%	30%	50%
Percentage of MDR TB patients who will start the treatment in ambulatory phase	0%	2013	5%	7%	11%	15%	25%	40%
Number of TB patients who will start the treatment in ambulatory phase	0	2013	1226	1835	2060	2413	3178	4599
Number of MDR TB patients who will start the treatment in ambulatory phase	0	2013	26	44	70	94	137	190
Average hospitalisation period for TB cases	33	2014	33	33	33	25	20	20
Average hospitalisation period for MDR TB cases	99	2014	93	93	93	80	65	50
Number of renovated/reorganised in-patient treatment facility for patients who are at highest risk of non-adherence, default and death due to poor economic status and precarious living conditions	N/A		0	0	2	0	0	0

Intervention 2.2 Strengthen the capacity of the National TB Program for TB control

To ensure that best practices are followed for TB control, specific actions will be taken to build the capacity of the NTP to perform core functions through:

- Revision of NTP operational needs and gaps
- Development of written standards of operations with formalization of job duties and roles.
- Strengthening the role of the MDR-TB commission as the primary body responsible to set MDR-TB recommendations through formal recognition.
- Ensure the key personnel required for TB Control, including a full-time epidemiologist and health educator
- Organization of the TB Network at least two times per year (one for TB clinic staff and for TB laboratory staff). As part of their key role to coordinate TB at the district level, TB network members will receive copies of all TB control guidelines in Romanian and review national priorities, surveillance data and present challenges/best practices during semi-annual meetings.
- Implementation of routine supervision and monitoring

Table 32 Intervention 2.2 Output indicators

2.2. Strengthen the capacity of the National TB Program for TB control								
Indicators	Baseline	Year	2015	2016	2017	2018	2019	2020
Develop core competencies of the NTP to carry out TB control	N/A		30%	50%	75%	100%	100%	100%
Number of TB Network meetings	1	2013	2	2	2	2	2	2
Number of routine supervision and monitoring visits performed	42	2013	42	42	42	42	42	42

Intervention 2.3 Develop human resource capacity for tuberculosis care and prevention

While there is currently a broad network of facilities and personnel involved with TB control, there are several important challenges that must be considered to maintain vibrant workforce for TB control. A more systematic approach for capacity building and the recruitment of new healthcare workers will be applied through:

- elaboration of an Human Resource Development Strategic Framework in the area of TB which will identify personnel needs, skills and the necessary resources,
- elaboration of Human Resource Plans including training plans and curriculum for each staff category involved in TB control⁵⁰
- provision of training sessions to all staff categories involved in TB control (staff working in TB dispensaries, hospitals and laboratories, family doctors, community workers, representatives of NGOs/CBOs, etc.)
- mid-term evaluation of the implementation of the human resource plan

Based on current projections, it is anticipated that more than 12,000 persons from all staff categories involved in TB control will be trained by 2020.

Table 33 Intervention 2.3 Output indicators

2.3. Develop human resource capacity for tuberculosis care and prevention								
Indicators	Baseline	Year	2015	2016	2017	2018	2019	2020
Development of Human Resource Development Strategic Framework	0		0	1	0	0	0	0
Development of Human Resource Plans (including training plans and curriculum for each staff category involved in TB control)	0		0	1	0	1	0	0
Number of persons from TB network trained	250	2014	750	750	750	750	750	750
Number of family doctors trained	N/A		0	200	1200	1200	1200	1200
Number of community workers trained	N/A		240	600	600	600	600	600
Number of training sessions for NGOs/CBOs working with IDUs and homeless	N/A		2	4	4	4	4	4

⁵⁰ Training topics will be elaborated based on the needs of each category of staff involved in TB control.

Intervention 2.4 Establish centralized procurement and distribution of first, second and third-line anti-TB medications.

To improve the drug procurement situation, Romania needs to take steps to develop a more effective and rationale system for planning and managing anti-tuberculosis medications. This system needs to be capable to monitor at national level the orders, consumption and stocks, with sufficient resources and strategies for procurement. Most importantly Romania requires policies and regulations that will urgently resolve the lack of a reliable centralized, supply of second-line treatment regimens for MDR-TB. These policies should allow for emergency public health exceptions for tenders in order to purchase critical medications for the treatment of MDR-TB. This would allow procurement of medications through mechanisms such as the GDF.

2.4.1. Conduct review of current procurement processes to determine effectiveness and required modifications

To improve the procurement, storage and distribution of anti-TB medications, the MoH will review of current procurement processes to determine effectiveness and required modifications. As part of this process, the MoH will organize workshops with decision makers to review current tender process, assess legal and regulatory framework for procurement of critical anti TB SLDs and Group 5, and identify impact and barriers of the current procurement.

2.4.2. Establish centralized drug management for procurement, storage and distribution process for medications and quality control

Based on these previous activities, the MoH will develop recommendations and strategies to ensure procurement of critical medications, how to review and incorporate new medications for TB control, and determine best practices for the storage and distribution of medications including planning for establishment/strengthening of active pharmacovigilance. Once established, trainings on drug management: quantification, ordering, stores management will be needed to build capacity.

2.4.3. Secure recommended medications for MDR-TB

Romania is eligible to procure low cost medications for the treatment of MDR-TB through the Global Drug Facility (GDF) but is restricted by current tender requirements. The MoH will determine medication requirements for MDR/XDR-TB patients and work with legislative counterparts to determine national and international sources of all needed TB medications and take steps to update law 95/2006 and order of MoH 85/2013 to enable emergency procurement of medications outside of normal tender process.

Table 34 Intervention 2.4 Output indicators

2.4 Establish centralized procurement of first, second and third-line anti-TB medications.								
Indicators	Baseline	Year	2015	2016	2017	2018	2019	2020
National review of anti-TB drug procurement	0		0	1	0	0	0	0
Creation of centralized drug procurement process			0	0	1	0	0	0
Percentage of health facilities reporting no stock-outs of essential drugs	N/A		N/A	N/A	N/A	80%	90%	100%

Intervention 2.5 Establish infection control standards and requirements for healthcare facilities

The NTP will develop infection control standards for laboratories and health care facilities by revising the Ministry of Health's Order N°916 (26 July 2006) to address infection control measures for TB transmission and securing MoH endorsement and support to implement the National Infection Control Plan for 2013-2017. These standards will serve as the basis for hospitals and laboratories to create institutional infection control plans.

Table 35 Intervention 2.5 Output indicators

2.5. Establish infection control standards and requirements for healthcare facilities								
Indicators	Baseline	Year of baseline	2015	2016	2017	2018	2019	2020
Establishment of infection control standards	N/A		1	0	0	0	0	0
% of facilities with IC plan	60%	2013	80%	90%	100%	100%	100%	100%

Intervention 2.6 Engage and facilitate involvement of impacted communities and civil society organizations in TB control

Civil society organizations and other partners have been important to address the non-medical needs of patients and impacted communities. These organizations provide training, outreach and advocate for patients. In addition, these groups have developed public health capacity and filled important technical and administrative gaps. Most recently, several NGOs including patient organisations started to emerge to directly voice the concerns of those directly affected by TB. Many of these groups, however, have depended on the financial commitment of external resources as domestic resources have been restricted. Once these funds ceased, many innovative and important activities simply stop.

To address the issue, the Romania will perform the following activities:

- Assessment of the financial mechanism regarding the reimbursement of TB services to NGOs/CBOs
- Revision of financial mechanism of reimbursement to NGOs/CBOs
- Approval of the revised financial mechanism of reimbursement to NGOs/CBOs
- Organisation of working meetings for improving the coordination of services between the TB network and the CBOs/NGOs working in TB field.

Table 36 Intervention 2.6 Output indicators

2.6. Engage and facilitate involvement of impacted communities and civil society organizations in TB control								
Indicators	Baseline	Year of baseline	2015	2016	2017	2018	2019	2020
Number of revised financial mechanism of reimbursement to NGOs/CBOs developed	N/A		0	1	0	0	0	0
Number of revised financial mechanism of reimbursement to NGOs/CBOs endorsed	N/A		0	1	0	0	0	0
Number of working meetings for improving the coordination of services between TB network and the CBOs/NGOs working in TB field	N/A		2	2	2	2	2	2

Intervention 2.7 Support the involvement of public section and family doctors and community workers to provide ambulatory and community-based TB care and services

The NTP recognizes that the family doctors can play a critical role for TB. To improve participation level, the NTP plans to review the role and function of family doctors and community workers in case finding, completion of treatment and contact tracing and to work with the MoH to review and modify the compensation process for family doctors and community workers. By changing the financial mechanisms for TB services the NTP anticipates increased participation in TB activities from family doctors and community workers.

To address the issue, the Romania will perform the following activities:

- Assessment of the financial mechanism regarding the reimbursement for TB services to family doctors and community workers
- Revision of financial mechanism of reimbursement for TB services to family doctors and community workers
- Approval of the revised financial mechanism of reimbursement to family doctors and community workers
- Organisation of working meetings for improving the coordination of health services between TB network and representatives of family doctors and community workers

Table 37 Intervention 2.7 Output indicators

2.7. Support the involvement of public section and family doctors and community workers to provide ambulatory and community-based TB care and								
Indicators	Baseline	Year	2015	2016	2017	2018	2019	2020
Number of revised financial mechanisms of reimbursement to family doctors and community workers developed	N/A		0	1	0	0	0	0
Number of revised financial mechanisms of reimbursement to family doctors and community workers endorsed	N/A		0	1	0	0	0	0
Number of working meetings for improving the coordination of health services between TB network and representatives of family doctors and community workers	N/A		2	2	2	2	2	2

Pillar 3: Innovative Research and Evidence-Based Strategies

Intervention 3.1 Ensure a dynamic and effective TB surveillance system

Accurate and accessible surveillance data is critical to understand disease trends and for determining and allocating healthcare resources. Romania's TB surveillance system has been generally effective for reporting epidemiological data, but the system is out of date and not responsive for current needs. Much of the surveillance equipment and forms are also out-of-date and require upgrading. To provide critical analysis for planning and decision-making, Romania's NTP not only must develop hardware and software capacities, but also the analytical capacity for investigating and researching epidemiological issues. In response to this need, the NTP will upgrade the electronic national data collection system by 2020. The initial step will require a review of recording and reporting needs and ascertain requirements for data collection on referrals, evaluation of suspects, and contact investigation. Based on this review, the NTP will initiate revisions of necessary reporting and data collection forms and determine and design software upgrades for the surveillance system.

One of the current short-coming for planning is the limited utilization of TB data for decision-making. To remedy this situation, the NTP will improve access and utilization of its data. In particular, district TB coordinators will be trained on planning, conducting cohort review and participate in routine review process.

Intervention 3.2 Develop epidemiological and research capacity for TB control

There is no overall research strategy for TB control in Romania. In response to this situation, the NTP will establish a standing research committee to set research guidelines and priorities and review proposals. This committee will develop research goals, objectives and deliverables.

Intervention 3.3 Conduct operational and epidemiological research to improve TB control

To improve the understanding of important programmatic and epidemiological concerns about TB in Romania, the NTP will conduct at minimum one operational research or epidemiological study per year through 2020. Research may investigate factors related to:

- Requesting and using DST
- Implementation of new laboratory diagnostic methods
- Effectiveness of active case finding strategies
- Drug procurement and stock-outs
- Pediatric case detection
- Timeliness and quality of biological specimens, or
- Policy and financial implications related to hospitalization of TB patients.

Table 38 Interventions 3.1-3.3 Output indicators

Pillar 3: Innovative Research and Evidence-Based Strategies								
Indicators	Baseline	Year	2015	2016	2017	2018	2019	2020
Status of surveillance system	not-updated	2014	updated					
Number of cohort reviews	N/A		1	4	4	4	4	4
Number of OR/epidemiological studies	N/A		1	1	1	1	1	1

V. Technical Assistance

Issue: Develop sufficient capacity and action plan for using new diagnostics for routine TB detection.

Strategy: Use WHO/ECDC resources to review implementation plan for use of rapid diagnostics and support methods harmonisation within the EU/EEA, develop External Quality Assurance (EQA) schemes and identify resource requirements, and provide training activities to ensure capacity building

Issue: Develop surveillance and epidemiological capacity

Strategy: Consult with WHO/ECDC to review potential structure and determine resource requirements; recruit and hire epidemiologist, and support capacity with placement of Sr. Epidemiologist.

Issue: Develop comprehensive clinical and case management guidelines for TB control.

Strategy: Consult with WHO to draft a comprehensive guideline for TB control

Issue: Develop infection control guidelines and facility assessment tools

Strategy: Use WHO/ECDC resources to develop IC guidelines and facility assessment tool

Issue: Develop HRD assessment and training and education strategy

Strategy: Consult with WHO/ECDC to design and conduct HRD assessment and to design and develop training and education strategy

VI. Monitoring & Evaluation

To ensure implementation of the National TB Control Strategy 2015-2020, the proposed strategy was reviewed by key governmental partners and stakeholder and supported through governmental approval. The NTP will hold a series of inter-departmental and intra-sectorial meetings to generate all required cooperation or MOUs. The Government of Romania, through the Office of the Prime Minister and the Ministry of Health was provided an opportunity to review and comment on the draft proposal and their comments resulted in revisions to the final plan.

To monitor and evaluate the implementation and outcomes of the national strategic plan, the NTP will coordinate and supervise implementation of the strategy and annually report on progress and barriers to both the CCM and the TB Network. Progress reports will be made available to the MoH and government representatives as well as to the public.

Monitoring and evaluation shall measure the success of activities from the perspective of process and impact results. Monitoring is the process applied permanently to estimate the measure of effective running of strategy actions and activities, in order to identify the weaknesses and to decide the necessary measure. Monitoring shall provide information regarding the success level of the activities by comparison with the defined standards and shall allow the process follow-up by comparison with the expected one. Monitoring shall be oriented especially toward the process, the specific activities (e.g. adequate training courses, suppliers' performance etc.) and less toward the results (information and behavior changes etc.) or impact (morbidity and mortality decrease, improvement of population health status etc.). Supervision and monitoring are activities that can be run simultaneously.

Evaluation is the process of systematic examination of the effects and impact of the Strategy's activities and interventions, aiming to estimate the degree of objectives' meeting. Monitoring and evaluation of TB control degree offers essential information about the subsequent improvement of interventions and activities.

The application of the Strategy shall be monitored and evaluated by one body; this shall have a global perspective of all departmental interventions. This way, the coherence of all interventions shall be insured and the ultimate goal shall be fully met. TAMU-NTP shall be responsible of this process. TAMU shall have the following main roles:

1. Monitoring and evaluation of the National Strategy for TB Control implementation;
2. Establishing the expert committees in charge with the elaboration and implementation of interventions;
3. Evaluation and review of the current interventions, the level of localization and integration in the National Strategy for TB Control;
4. Development of new interventions, adequate to the strategic action plans;
5. Strengthening of interventions development and resource identification;
6. Constant monitoring, evaluation and adjustment of each intervention;
7. Integration of the international programs with the necessary interventions in order to meet the objectives of the National Strategy for TB Control, insuring interventions coordination and avoiding these to be doubled;
8. Insuring communication among the involved partners;
9. Mobilization of partners in order to insure the necessary resources;

The intermediate evaluation of National Strategy for TB Control implementation shall be done to provide output, effect and impact indicators. Evaluation indicators shall be determined individually for each program, by the commissions coordinated by the TAMU-NTP.

Periodic evaluation of the National Strategy for TB Control implementation shall be done at every 2-3 years, by the international bodies with expertise in the area of TB (WHO, ECDC, IUATLD), in collaboration with local experts.

VII. Budget Plan

The global budget for TB control activities between 2015 and 2020 is projected to total € 279,029,903 (see Table 39). The costs include the total project cost for diagnosis, treatment and upgrades to laboratories, surveillance, epidemiological and human resources. The budget will be funded through a range of domestic and external funding sources.

Table 39 Budget by years and funding sources (EURO)

Sources of funding	2015	2016	2017	2018	2019	2020	TOTAL
GoR	42,103,357	42,969,340	43,174,679	36,718,915	30,879,785	26,942,072	222,788,150
Norway	6,894,922	3,624,690	0	0	0	0	10,519,612
GFATM	2,639,824	4,027,894	1,656,498	83,964	0	0	8,408,180
ESF	0	4,197,660	7,254,470	7,295,091	7,221,580	7,119,660	33,088,461
World Bank	0	2,741,500	1,066,500	66,500	66,500	66,500	4,007,500
Other	110,000	108,000	0	0	0	0	218,000
TOTAL	51,748,103	57,669,084	53,152,147	44,164,470	38,167,865	34,128,232	279,029,903

Figure 4 Distribution of budget by funding sources

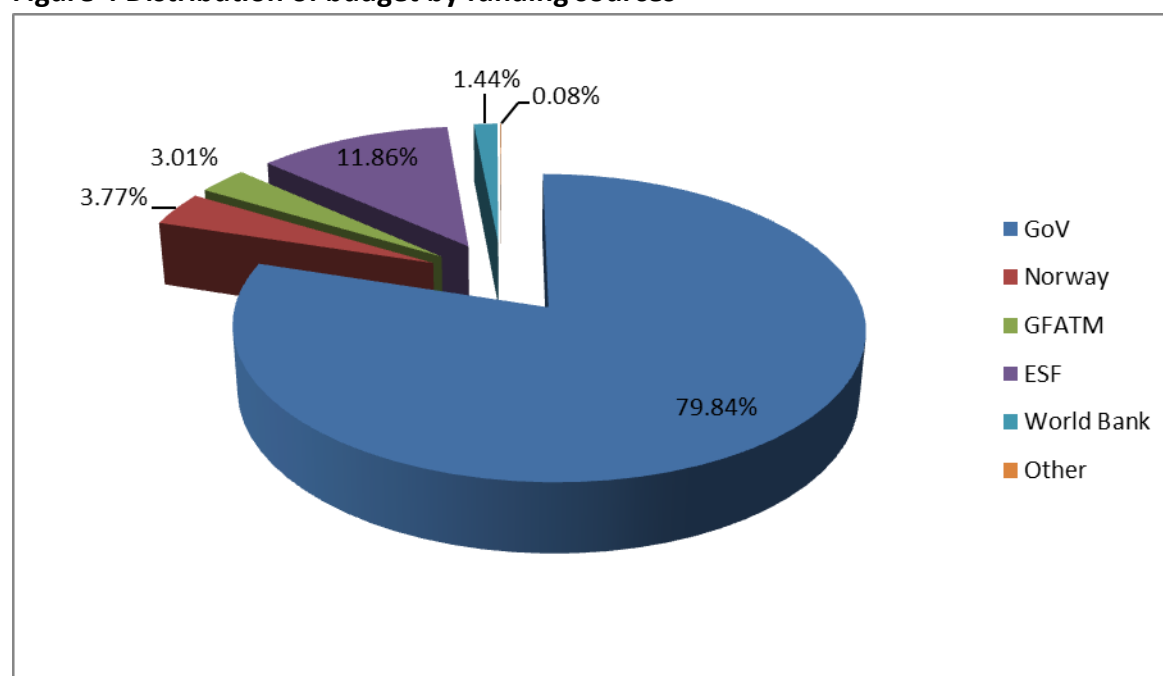


Table 40 Budget by year and interventions (EURO)

No	Name of intervention	2015	2016	2017	2018	2019	2020	Total
1.1	Develop universal access to rapid diagnostic methods and universal drug-susceptibility testing	6,743,711	9,052,282	6,144,595	5,121,032	4,695,718	4,243,245	36,000,581.00
1.2	Improve the timeliness and accuracy of diagnosis of TB	2,413,884	4,486,434	5,030,309	4,881,266	4,762,363	4,580,665	26,154,920.23
1.3	Effectively treat TB patients by following WHO-treatment recommendations	3,335,914	3,627,814	3,258,480	2,861,708	2,513,398	2,182,404	17,779,718.00
1.4	Improve treatment outcomes for MDR-TB and XDR-TB patients by following WHO-treatment recommendation	3,167,920	2,804,680	3,725,680	3,990,120	3,505,780	3,378,300	20,572,480.00
1.5	Development and implementation of a comprehensive ambulatory care and support system	23,699,630	23,805,570	24,458,460	14,947,130	10,405,120	7,622,050	104,937,960.00
1.6	Prevent transmission of TB through vaccinations, targeted screenings, and infection control	998,898	733,011	422,704	432,269	469,911	522,711	3,579,503.45
1.7	Ensure collaborative tuberculosis/HIV activities, and management of co-morbidities	160,582	172,188	157,716	140,622	127,152	114,348	872,608.00
2.1	Ensure adequate resources for tuberculosis care and prevention	1,000	1,000	1,000	1,000	1,000	1,000	6,000.00
2.2	Strengthen the capacity of the National TB Program for TB control	666,800	630,600	630,600	740,600	630,600	633,800	3,933,000.00
2.3	Develop human resource capacity for tuberculosis care and prevention	10,335,200	10,573,200	10,323,200	10,341,300	10,323,200	10,323,200	62,219,300.00
2.4	Develop regulatory and policy framework for effective TB control practices	-	18,100	37,500	-	-	-	55,600.00
2.5	Establish centralized procurement and distribution of first, second and third-line anti-TB medications	120,100	78,000	78,000	78,000	78,000	78,000	510,100.00
2.6	Establish infection control standards and requirements for healthcare facilities	-	24,100	-	-	-	-	24,100.00
2.7	Develop policies and practices that will strengthen outpatient treatment for TB and reduce unnecessary hospitalization of TB patients	-	15,100	-	-	-	-	15,100.00
2.8	Engage and facilitate involvement of impacted communities and civil society	-	6,000	-	-	-	-	6,000.00

	organizations in TB control							
2.9	Support the involvement of public section and family doctors and nurses to provide ambulatory	-	18,100	-	-	-	-	18,100.00
3.1	Ensure a dynamic and effective TB surveillance system	411,842	5,000	5,000	5,000	5,000	5,000	436,842.00
3.3	Conduct operational and epidemiological research to improve TB control	530,000	730,000	200,000	200,000	200,000	200,000	2,060,000.00
TOTAL		52,585,480	56,781,179	54,473,244	43,740,047	37,717,241	33,884,723	279,181,912.68

Table 41 Interventions and sources of funding (EURO)

No	Intervention	GoR	NORWAY GRANTS	GFATM	ESF	WORLD BANK	OTHER	TOTAL
1.1	Develop universal access to rapid diagnostic methods and universal drug-susceptibility testing	16,800,509	4,223,320	1,277,200	9,138,665	2,357,000	108,000	33,904,694
1.2	Improve the timeliness and accuracy of diagnosis of TB	9,147,154	11,750	1,487,075	9,038,775	50,000	-	19,734,754
1.3	Effectively treat TB patients by following WHO-treatment recommendations	17,041,776	-	54,000	-	-	60,000	17,155,776
1.4	Improve treatment outcomes for MDR-TB and XDR-TB patients by following WHO-treatment recommendation	18,687,142	4,245,000	3,490,691	60,000	-	-	26,482,833
1.5	Development and implementation of a comprehensive ambulatory care and support system	7,621,956	280,300	1,029,314	4,985,555	1,000,000	-	14,917,125
1.6	Prevent transmission of TB through vaccinations, targeted screenings, and infection control	2,035,403	600,000	-	4,500	600,500	50,000	3,290,403
1.7	Ensure collaborative tuberculosis/HIV activities, and management of co-morbidities	314,700	-	8,850	150,000	-	-	473,550
2.1	Ensure adequate resources for tuberculosis care and prevention	89,135,110	24,200	738,900	1,037,500	-	-	90,935,710
2.2	Strengthen the capacity of the National TB Program for TB control	61,750,400	213,200	13,500	233,500	-	-	62,210,600
2.3	Develop human resource capacity for tuberculosis care and prevention	-	362,600	138,000	7,415,966	-	-	7,916,566
2.4	Establish centralized procurement and distribution of first, second and third-line anti-TB medications	234,000	125,800	131,550	-	-	-	491,350
2.5	Establish infection control standards and requirements for healthcare facilities	-	16,600	4,500	-	-	-	21,100

2.6	Engage and facilitate involvement of impacted communities and civil society organizations in TB control	-	-	13,500	9,000	-	-	22,500
2.7	Support the involvement of public section and family doctors and community workers to provide ambulatory and community-based TB care and services	-	-	21,100	15,000	-	-	36,100
3.1	Ensure a dynamic and effective TB surveillance system	20,000	416,842	-	-	-	-	436,842
3.3	Conduct operational and epidemiological research to improve TB control	-	-	-	1,000,000	-	-	1,000,000
TOTAL		222,788,150	10,519,612	8,408,180	33,088,461	4,007,500	158,000	279,029,903

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