19.11.2015, revised 17.04.2017

Monitoring and Evaluation Plan for the National Tuberculosis Control Programme of Romania (2015-2020)

Abbreviations

AFB - Acid Fast Bacilli
ART – Antiretroviral treatment
C (+/-) - Culture (positive/negative)
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
GFATM – Global Fund to Fight AIDS, Tuberculosis and Malaria
GLC – Green Light Committee
HIV – Human immune deficiency
HRD Human Resource Development
IC – Infection control
INH - Isoniazid
LPA - Line Probe Assay
M&E - Monitoring and Evaluation
MDR-TB – Multi drug-resistant tuberculosis
MoH – Ministry of Health
MOJ – Ministry of Justice
NHIH – National Health Insurance House
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
SLD – Second-line anti-tuberculosis drugs
SLDST – Second-line drug susceptibility test
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

Background

The National Strategic Plan (NSP) for TB control 2015-2020 was based on the WHO ‑ ECDC NTP review in March 2014 and was officially approved, including its budget, by the Government in February 2015. External funding includes the Global Fund (April 2015-March 2018) with the Romanian Angel Appeal (RAA) Foundation as principal recipient and the Norway Funding Arrangement (August 2014-April 2016, with a possible extension of 12 additional months). National funding is expected to be gradually increased as the external funding will be reduced.

The Monitoring and Evaluation (M&E) Plan for the NTP is a mandatory part of the Global Fund collaboration. It is based on the NSP, and includes not only GF activities but also activities carried out by all partners. It is urgent to strengthen monitoring and evaluation to speed up the implementation of the NSP while external funding is available.

Objectives of the TB M&E Plan:

- Elaboration of a list of key basic indicators, that will allow monitoring of the implementation of the NSP, based on the indicators in the NSP and with clear definitions in line with WHO/ECDC recommendations and agreed with all partners, reducing separate reporting by different partners
- Contribution to better quality and timeliness of the M&E system for TB
- Description of sources to be used for necessary M&E data collection;
- Description of how the collected information will be disseminated.
- Promotion of the use of routine TB data for management at local and central levels.

The M&E plan follows the standard GF format. A M&E performance framework had recently been developed for the GF projects, with baseline and targets, in the document “Romania TB_PF_NFM_TB_M&E sign-off.xls”. The current plan includes a revised table with indicators, baseline and targets 2015-2020.

The legal basis for TB monitoring and evaluation

- Government Decision No. 589 of 13 June 2007 establishing the methodology for data recording and reporting for surveillance of infectious diseases
- Ministry of Health Order No. 1171/2015 on Methodological Norms for TB Control Programme Implementation.

Indicator definitions and measurement

The indicators in this plan are basically used by all partners to measure progress of the implementation of the NSP. The NTP will also assess other variables and indicators such as defined in the Methodological guide, in its routine (often quarterly) assessment of the TB programme, both at national and local (county, dispensary) levels. The funders may have additional indicators related to use of funds which are not included in this document. Methodological guide is the core document for implanting the National TB Program and is officially approved by the Order of the Ministry of Health.

At the moment the M&E part and indicators of the global and regional End TB Strategy is still under development. The indicators in the current plan have therefore been selected taking into consideration the following:

- Indicators included in the NSP, following the same structure but lowering considerably the total number (87) to reduce workload and to keep focus. Some have been omitted because they are duplications or already part of another indicator, for example both number of cases and rates per 100 000 population.
- The note "M&E framework WHO European Region TB Action plan 2016-2020", with a draft excel sheet listing 26 indicators, harmonized with the top 10 global indicators in the End TB Strategy.
- Some indicators of special importance in Romania were added.
- Priority was given to indicators collected from the routine R&R system
- Indicators are of different types:
  (1) Impact indicators that measure the progress towards the three End TB Strategy and the WHO European Region targets;
  (2) Outcome indicators that monitor the broader changes in TB control enhanced as a result of a set of interventions;
  (3) Process indicators that monitor progress of specific intervention and
  (4) Input indicators that measure policy environment, commitment and capacity in the country.

At the end of the document there are two tables:
Table 1: Short list of the 26 key indicators under subheadings in the NSP
Table 2: List with more detailed description of each indicator.

Routine data collection, data management, and data quality assurance.

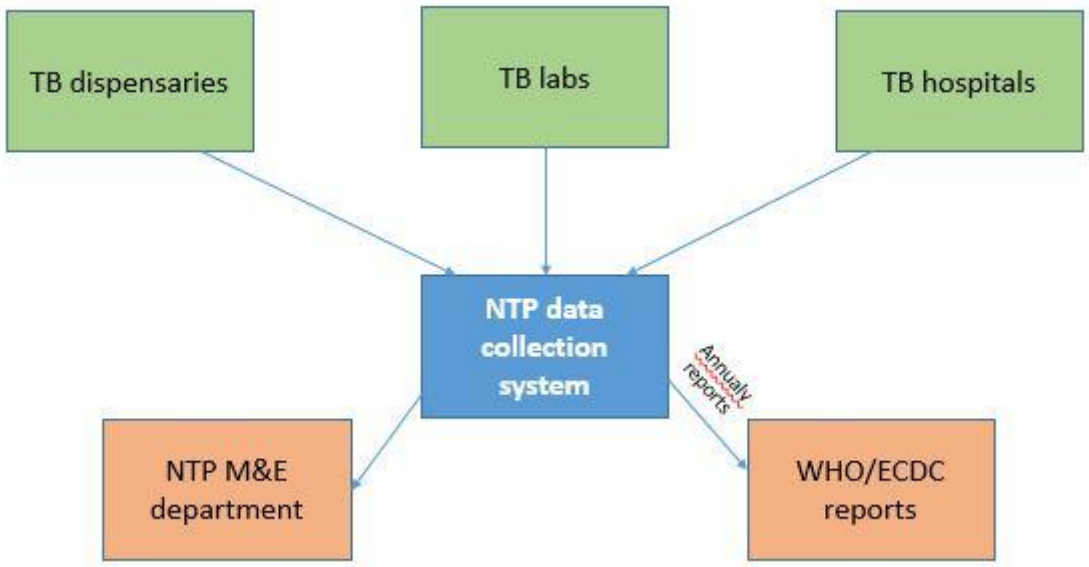
The text is partly based on the NTP review 2014 and the GLC report 2015.

Data collection
TB Surveillance is mandatory for all institutions involved in TB program. There is both a paper based and electronic system for TB recording and reporting. The forms of the paper based system are described in the Methodological guide for implementing the national program for TB prevention, supervision and control 2015.

The process of information flow includes following steps:

1. Patient data are entered into the national electronic data base. Data is entered by the TB laboratories and TB dispensaries, for every patient.
2. Data base includes all treatment schemes of the patient, lab results, personal data and the treatment outcome.
3. Data is stored on a hardware in the Marius Nasta Institute.
4. Data is reported based on the database interrogation, done by a specialist from Marius Nasta institute.

Fig. 1 The National Tuberculosis Surveillance System Data Flow



Clinicians diagnose TB and start treatment in hospitals or dispensaries. Clinicians from hospitals should fill in a paper-based TB announcement form, from which the TB dispensary enters the notification data into the web-based TB surveillance system (SOFT) which contains the National TB register. If the dispensary put the diagnostic, the announcement form is not necessary. Once the notification data are introduced in SOFT, the notification form can be printed automatically.
Data are entered by all pulmonology dispensaries, (in 41 counties and six sectors of Bucharest) and different ministries (two facilities under the Ministry of Justice, one under the Ministry of Defense and one under the Police). Hospitals do not enter patients in the web-based system but send the announcement forms (by fax or email) to the dispensary where the patient lives and where the notification is entered in the web system. The dispensary should send all the notification forms printed and signed to the TB county coordinator; the TB county coordinator sends them every month to the County Public Health Authority which forwards reports every month to the NTP. The patient is also entered in a paper-based TB dispensary register and in a county TB register.

Every doctor sign electronically the notification form, which is sent electronically to the County Public Health Authority; it is not necessary that the County Public Health Authority sends any form to the NTP: the NTP can see all signed forms directly in SOFT.

The National TB Registry is kept at the NTP Central Unit in the Marius Nasta Institute. The register consists of five modules: (i) patient' data; (ii) diagnostic characteristics; (iii) treatment data (including laboratory and treatment regimen); (iv) automatically generated quarterly and annual reports; and (v) administrator's module. The integration with the national system of vital registrations is not possible yet due to the costs.
The clinician sends documents for MDR-TB cases to the local MDR TB Center of Excellence and to the local MDR-TB coordinator. There is a separate electronic MDR-TB registry within

the National Registry on patients diagnosed with MDR-TB. Access to MDR-TB registry is available at central level (MDR-TB coordinator), at each TB MDR clinic, and at each TB Dispensary. The registry contains information on patient's unique number, diagnosis, bacteriology results (smear, culture, DST), treatment regimen and clinical testing.

There are paper based laboratory registers in hospitals and dispensaries. The unified laboratory module for the National register, was finished by 2016. The module includes only data about patients' tests (including monitoring tests) not suspects, so it does not reflect the volume of work for TB labs.

The management of drugs has a dedicated component (not visible from the main page) were information related to drug management can be collected. The component is used for M/XDR TB drugs (not for all drugs).

Data management

The electronic database is kept in Microsoft SQL Server, version 2000. From this data base the reports are predefined and can be exported in excel.

Since TB-related activities have to be reported monthly, quarterly and yearly to local and national authorities (epidemiological, programmatic and administrative data), creating a complex reporting system which is unclear for local and county policy-makers to use. The National TB Registry is not linked to other existing national databases (such as for population or mortality). The updated system is more user-friendly, contain all needed variables, generate the necessary reports, strengthen link with the laboratory register and integrate MDR-TB patients more easily, and not only MDR-TB patients started on treatment.

Program review, evaluations and surveys

WHO-ECDC review of the NTP was carried out in March 2014. GLC visits once per year, last February-March 2015, and will continue. The drug resistance survey is being finalized and is not yet published. NTP review and operational research will be included in the next EEA grant – POCU.

Data quality assurance, data safety and related supportive supervision

The first data validation is carried out at county level, with a further daily check at central level. Crosschecking with the National TB Laboratory Register (70% of all TB laboratories entering the positive laboratory results) is also possible. The National TB Register has had an operational link with the National HIV Register since 2013, although it is not legally official, and TB and HIV data are crosschecked every year. There is no link to the population registry nor to vital statistics.

The application software includes some enhanced protection mechanisms against undesirable access or loss of data (user' rights defined for each level, firewall, antivirus, register's application and program in separate servers). Weaknesses can, however, be found, such as servers not being secure locations, backups archived in the same room as the server codes for case registration only partially documented and no confidentiality declaration requested. The user manual was updated with funds from the Norwegian grants.

Supervision of the facilities with TB services at county level is carried out once per year during summer months by the Supervisory Commission of the NTP from the Marius Nasta Institute in Bucharest while TB county coordinators supervises TB clinics every month. The supervision of laboratories should be ensured by the Laboratory Working Group and by the county TB laboratory coordinators.

Since 2010 regular supervision visits are performed. At least once per year for each TB dispensary and hospital (including laboratories) with funds ensured through MoH. The supervision visits are performed by specialised staff and based on checklists developed for TB dispensaries, hospitals, pharmacies, laboratories, etc. Terms of reference for the TB coordinators in counties are found in the Guidelines, Annex 6, page 61-62).
The Central Coordination Unit perform quarterly snapshots over quality of data recording into National Registry in each county and define the range of missing data. There is no distinct overall snapshot for every quarter, but correspondence with counties is available.

M&E coordination

The main external funding partners in TB control include The Global Fund, The Norway Financial Mechanism, The European Social Fund (ESF, via the Ministry of Health) and the World Bank.

The partners participated in the development of the NSP where the objectives and indicators were agreed. The partners base their reporting requirements on the indicators agreed upon. The indicators are compatible with WHO 2013 new TB definitions and ECDC definitions and with the End TB Strategy indicators being developed.
The partners meet regularly to assess the progress of the implementation of the NSP.

There are two collaborating management structures involved in the M&E of the grant: The **NTP Central Coordination Unit** and the Principal Recipient. For the diagnosis and treatment related interventions, the M&E coordination is provided by the central coordination unit of the NTP, which represents the national management structure in charge with TB monitoring and evaluation. The NTP is directly coordinating the country units (MDR-TB centers, TB Hospitals, TB Laboratories and TB Dispensaries).

The Principal Recipient is directly coordinating all the SRs involved in the implementation of the GFATM TB grant. The NTP, as well as the SRs are regularly providing data to the PR for the purpose of progress reporting to GFATM. The two entities – NTP Central Coordination Unit and the PR are closely collaborating in order to ensure alignment and harmonization of country indicators and to report to GFATM and WHO (i.e. national TB data and yearly cohort results are sent by NTP to WHO for regular monitoring at regional and global level).

Information products, dissemination and use

NTP provides quarterly and annually routine data (regarding the Global Incidence (GI) of TB among general population and children) to The Ministry of Health, The National Center for the Contagious Disease Control (from the National Institute of Public Health) and the National Center of Statistics and Informatics in Public Health who uses it for its epidemiological analysis and publications. The NTP reports regularly every year to the Joint ECDC-WHO Reporting Platform.

Twice per year at the NTP meeting with TB county managers, the quarterly reports regarding the Global Incidence (GI) of TB among general population and children and larger set of

indicators are analysed: GI, TB Mortality, TB BK confirmation, proportion of DST-s among culture pos. cases, HIV-TB association, MDR-TB, Success rates.

Work plan – and next steps

See table 1 with a list of indicators and targets. Key issues to implement the M&E plan include:

- NTP to discuss and agree with partners on the M&E plan and use it to monitor the implementation of the NSP.
- NTP to ensure finalization of the update of the electronic system (NTP expects it to be ready by April 2016). It is important that the recording and reporting system (notification forms, local registers) and electronic system include variables and tables/reports to monitor all the indicators.
- Ensure procurement and distribution of all necessary TB drugs (ongoing process).
- Establish rapid tests for diagnosis of TB and drug resistant TB (in process)
- Capacity building: Central level supervisors and county TB coordinators need to be trained when the M&E plan has been agreed on and the content of supervision updated correspondingly. The training should include both the content of the M&E plan, definitions, etc., and also how to use routine data for decision-making, as recommended in NSP (intervention 3.1, p.75). Such training should take place before next year's round of supervision of central level supervisors and when the electronic system has been updated (estimated to April 2016), but could be done earlier with county TB coordinators who are doing supervision more frequently.

Reference documents:

- National Strategic Plan for TB control (2015-2020),
- WHO/ECDC joint TB Programme review report 2014;
- GLC mission reports May 2015;
- The Global Fund: Standard Concept Note March 2014
- NTP Methodological guide for the TB programme, developed in May 2015 (parts translated into English)
- EEA/Norwegian Financial mechanisms 2009-2014, Project application and Project Extension July 2014
- WHO European TB Action Plan 2016-2020
- Global Fund: Monitoring and Evaluation Plan. Guidance for submission of an M&E plan for Global und Grants. (http://www.theglobalfund.org/en/me/documents/plan/)
- Definitions and reporting framework for tuberculosis - 2013 revision. WHO
- Questions and answers to the 2013 revision of the WHO definitions and reporting framework for tuberculosis (http://www.who.int/tb/publications/definitions_faq/en/)

Table 1: The recommended indicators in the M&E plan, listed according to interventions in the National Strategic Plan. Indicators not included in the NSP are written in *italics*. Baseline values and targets are presented for each year 2015-2020 from the NSP, but updated with targets until 2018 in the Global Fund M&E plan.

Indicator	**Source**	**Frequency**	**M&E plan indicator #**	**NSP indicator #**	**Baseline**	**Year**	**Target 2015**	**Target 2016**	**Target 2017**	**Target 2018**	**Target 2019**	**Target 2020**
Impact and outcome indicators:												
TB mortality rate	National Institute of Statistics	A	1	1	5.3	2013	5.52	5.49	5.20	4.91	4.65	4.30
Case notification rate of all forms of TB per 100,000 population - bacteriologically confirmed plus clinically diagnosed, new and previously treated cases	National Tuberculosis Registry	A	2	2	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	National Tuberculosis Registry	A	3	3	48.43	2013	49.70	49.71	44.74	41.73	36.73	31.95

Indicator	Source	Frequency	M&E plan indicator #	NSP indicator #	Baseline	Year	Target 2015	Target 2016	Target 2017	Target 2018	Target 2019	Target 2020
Treatment success rate - bacteriologically confirmed new TB cases	National Tuberculosis Registry	A	4	4	85.5%	2012	86%	87%	87%	88%	88%	90%
Treatment success rate bacteriologically confirmed previously treated patients	National Tuberculosis Registry	A	5	5	57%	2012	60%	65%	70%	75%	80%	85%
Treatment success rate of MDR-TB: Percentage of bacteriologically confirmed drug resistant TB cases	National Tuberculosis Registry	A	6	6	25%	2011	50%	55%	60%	65%	70%	75%
Intervention 1.1. - Develop universal access to rapid diagnostic methods and universal drug-susceptibility testing												
Intervention 1.2. Improve the timeliness and accuracy of diagnosis of TB												
Number of persons from high risk groups evaluated for TB diagnosis	Subnational project	Q	7	14	N/A	17,850	22,060	22,690	31,060	33,590	35,700	N/A

Indicator	**Source**	**Frequency**	**M&E plan indicator #**	**NSP indicator #**	**Baseline**	**Year**	**Target 2015**	**Target 2016**	**Target 2017**	**Target 2018**	**Target 2019**	**Target 2020**
Percentage of TB patients diagnosed using WHO-recommended rapid tests	National Tuberculosis Registry	*Q*	*8*		*NTP to add baseline data and projections*							
Percentage of new confirmed TB patients with result of DST to 1.line drugs	National Tuberculosis Registry	Q	9	29	58%	2012	60%	80%	90%	100%	100%	100%
Percentage of confirmed previously treated TB patients with result of DST to 1.line drugs	National Tuberculosis Registry	*Q*	*10*		*58.8%*	*2013*	*70%*	*80%*	*90%*	*100%*	*100%*	*100%*
Percentage of patients with R resistance provided second-line drug susceptibility tests	National Tuberculosis Registry	Q	11	30 (with H and/or R resistance)	N/A		80%	100%	100%	100%	100%	100%
Percentage of new cases with DST result	National Tuberculosis Registry	*Q*	*12*		*NTP to use data from new DRS as*							

Indicator	Source	Frequency	M&E plan indicator #	NSP indicator #	Baseline	Year	Target 2015	Target 2016	Target 2017	Target 2018	Target 2019	Target 2020
confirmed with MDR					*baseline.*							
Percentage of previously treated cases with DST result confirmed with MDR	National Tuberculosis Registry	*Q*	*13*		*NTP to use data from new DRS as baseline*							
% detection MDR TB total	National Tuberculosis Registry and WHO estimates	A	14	33	77%	2013	80%	82%	85%	87%	90%	100%
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 recommendations												
Percentage of notified confirmed MDR cases started on any 2.line treatment	National Tuberculosis Registry	*Q*	*15*		*NTP to add baseline data and projections*			*100%*	*100%*	*100%*	*100%*	*100%*
% of confirmed MDR-TB patients receiving WHO recommended	National Tuberculosis Registry, based on MDR committee.	Q	16	39	40%	2013	100%	100%	100%	100%	100%	100%

Indicator	Source	Frequency	M&E plan indicator #	NSP indicator #	Baseline	Year	Target 2015	Target 2016	Target 2017	Target 2018	Target 2019	Target 2020
treatment regimens												
Percentage of XDR TB patients receiving WHO recommended treatment regimens	National Tuberculosis Registry, based on MDR committee.	Q	17	40	A *NTP to add baseline data and projections*			100%	100%	100%	100%	100%
Intervention 1.5. Improve patient support and case holding systems												
% of TB patients receiving DOT	NATIONAL TUBERCULOSIS REGISTRY	Q	18	47	40%	2013	50%	60%	70%	80%	90%	100%
1.6. Prevent transmission of TB through vaccinations, targeted screenings, and infection control												
1.7. Ensure collaborative tuberculosis/HIV activities, and management of co-morbidities												
Percentage of TB patients who know their HIV status	NATIONAL TUBERCULOSIS REGISTRY	Q	19	56	61.0%	2013	65%	70%	75%	80%	90%	95%
Percentage of HIV positive registered TB patients given ART during TB treatment	*NATIONAL TUBERCULOSIS REGISTRY*	*Q*	*20*		*92.1%*	*2013*	*94.9*	*96.0*	*96.5*	*96.9*		

Indicator	Source	Frequency	M&E plan indicator #	NSP indicator #	Baseline	Year	Target 2015	Target 2016	Target 2017	Target 2018	Target 2019	Target 2020
Intervention 2.1. Ensure adequate resources for tuberculosis care and prevention												
Percentage of TB patients who start the treatment in ambulatory phase	NATIONAL TUBERCULOSIS REGISTRY	Q	21	58	0%	2013	8%	12%	15%	20%	30%	50%
Percentage of MDR TB patients who start the treatment in ambulatory phase	NATIONAL TUBERCULOSIS REGISTRY	Q	22	59	0%	2013	5%	7%	11%	15%	25%	40%
2.2. Strengthen the capacity of the National TB Program for TB control												
Number of routine supervision and monitoring visits performed	supervision reports	A	23	67	42	2013	42	42	42	42	42	42
2.3. Develop human resource capacity for tuberculosis care and prevention												
2.4 Establish centralized procurement of first, second and third-line anti-TB medications												

Indicator	Source	Frequency	M&E plan indicator #	NSP indicator #	Baseline	Year	Target 2015	Target 2016	Target 2017	Target 2018	Target 2019	Target 2020
National review of anti-TB drug procurement	separate reports	A	24	74	0	0	1	0	0	0	0	0
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												
3.1-3.3 Innovative Research and Evidence-Based Strategies												
Status of TB surveillance system	Separate reports	Annually	25	85		Non-updated	2014	updated				
Indicator not mentioned in the NSP												
Percentage of new TB cases with epidemiological investigations (contact tracing) from all new TB cases registered	National Tuberculosis Registry	*Quarterly*	*26*		*NTP to add baseline data and projections*							

Table 2: Detailed information about the main indicators

1: TB mortality rate

Indicator	TB mortality rate – Number of deaths due to TB (all forms) per year per 100,000 population. The indicator includes all death cases where TB is mentioned, including TB-HIV cases.
Rationale/Purpose	Impact indicator to measure the number of deaths from TB to occur in a given year per 100 000 population.
Numerator	Number of deaths from TB X 100,000
Denominator	Number of inhabitants in the respective territory at 1st of July of the respective year
Data collection Frequency	Yearly
Measurement tool	The denominator is reported by the National Institute of Statistics, based on vital statistics: death certificates with TB as cause of death
Method of measurement	Measured by the vital registration system
Interpretation	A trend in decreasing over time of the mortality rate usually indicates an efficient National TB Programme.
Other relevant information	NTP should also follow another indicator from NATIONAL TUBERCULOSIS REGISTRY: fatality in TB cases: % of registered TB cases with treatment result "died for any reason".

2: Notification rate of all forms of TB cases (new and previously treated cases)

Indicator	Case notification rate of all forms of TB cases (new and previously treated) per 100 000 population, both bacteriologically confirmed and clinically diagnosed. The indicator includes all TB patients diagnosed in Romania, including migrants.
Rationale/Purpose	The indicator measures the NTPs ability to detect and identify TB cases
Numerator	Number of all TB cases (new and previously treated) registered and reported by the National TB Programme in the past year (x 100,000)
Denominator	Total population in the specified area (country, county, etc.)
Data collection frequency	Annually
Measurement Tool	The numerator is reported by the National TB Programme: The denominator is reported by the National Institute of Statistics
Method of measurement	The data are collected as part of routine TB quarterly reporting

Interpretation	Trends over time in case notification usually indicate changes in program coverage and capacity to detect TB cases. With strengthening of the NTP case finding, the notification rate should increase first, before again declining.
Other relevant information	This indicator include all previously treated cases, not only relapses (as in indicator #3), since the number of all 4 categories of previously treated cases (relapse, after failure, after loss to follow-up and other previously treated) is high in Romania, and should decline more rapidly than new cases with strengthening of the NTP. The indicator may have several variations: - Only relapses - Confirmed cases is defined by ECDC/WHO as confirmed by smear, culture or rapid test approved by WHO, but sub analysis may be made separate for smear microscopy only or culture only. - Limited to pulmonary cases

3 Notification rate of bacteriologically confirmed new and relapse TB cases

Indicator	Notification rate of bacteriologically confirmed new and relapse TB cases
Rationale/Purpose	The indicator is a direct measure of program capacity to identify infectious cases. The number of new pulmonary smear-positive TB cases provides a better comparison and trends over time between countries and areas than the number of total cases, because it uses a more objective method of diagnosis (bacteriological confirmation).
Numerator	Number of bacteriologically confirmed new and relapse TB cases registered and reported by the National TB Programme in the past year (x 100,000)
Denominator	Total population of Romania
Data collection Frequency	Annually
Measurement tool	The numerator is reported by the National TB Programme The denominator is reported by the National Institute of Statistics
Method of measurement	Bacteriological diagnosis is confirmed with smear microscopy, culture and/or rapid diagnostic tests
Interpretation	Trends over time in case notification usually indicate changes in programme coverage and capacity to detect TB cases.

Other relevant information	This indicator is requested by the Global Fund. In Romania bacteriologically confirmed have until the 2014 cohort, been defined by culture, while rapid test were not yet registered.

4 Treatment success rate, in new bacteriologically confirmed TB cases

Indicator	Treatment success rate, in new bacteriologically confirmed TB cases
Rationale/Purpose	Evaluation of successful treatment outcomes of new bacteriologically confirmed pulmonary TB cases is used to determine the quality and effectiveness of DOTS implementation at all levels.
Numerator	Number of new bacteriologically confirmed pulmonary TB cases in a specified period who were successfully treated (sum of WHO outcome categories ”cured” plus ”treatment completed”)
Denominator	Total number of new bacteriologically confirmed pulmonary TB cases registered in the same period, (including patients who died or were lost before treatment start), but excluding patents found to have MDR-TB, as recommended by WHO/ECDC.
Data collection frequency	Quarterly
Measurement Tool	Both numerator and denominator are reported by the National TB Register
Method of measurement	Each patient registered is assigned a treatment outcome which is recorded in the TB register. Outcomes for all new cases are reported by registration period (by quarter or year), usually about one year after the end of the quarter. The two outcomes that together form “treatment success” are defined as follows: Cured: A pulmonary TB patient with bacteriologically confirmed tuberculosis at the beginning of treatment and who was smear- or culture-negative in the last month of treatment and on at least one previous occasion. Completed: A TB patient who completed treatment without evidence of failure (sputum smear or culture is positive at month 5 or later during treatment) BUT there is no record to show that sputum smear or culture results in the last month of treatment and on at least one previous occasion are negative, either because they were not done or because results were not available. First all registered patients should be given an outcome, including those who are found to have MDR-TB and changed to MDR-TB treatment. The difference between those registered and those with an outcome is used to calculate the number “not evaluated”. Then the success rate is calculated excluding patients changed to MDR-TB treatment. (WHO EURO and ECDC definition). (ref. WHO Q&A to definitions)

Interpretation	This indicator measures a program's capacity to retain new bacteriologically confirmed TB cases through a complete course of chemotherapy with a favourable clinical result. There is a direct and immediate link between this outcome of treatment success and the impact of reduced TB mortality.
Other relevant information	A similar indicator is to include all new TB cases, not only confirmed cases, and also to limit the patients to pulmonary cases.

5 Treatment success rate among bacteriologically confirmed previously treated cases

Indicator	Treatment success rate among bacteriologically confirmed previously treated cases
Rationale/Purpose	Evaluation of successful treatment outcomes of previously treated TB cases is used to determine the quality and effectiveness of DOTS implementation at all levels.
Numerator	Number of previously treated TB cases in a specified period who were successfully treated (sum of WHO outcome categories "cured" plus "treatment completed")
Denominator	Denominator: Total number of all previously treated TB cases registered in the same period
Data collection frequency	Quarterly
Measurement Tool	National TB Registry
Method of measurement	Treatment success is defined as the sum of "cured" and "treatment completed", as described in the previous indicator, excluding patients moved to MDR-TB treatment.
Interpretation	This indicator measures a program's capacity to retain the previously treated TB cases through a complete course of chemotherapy with a favourable clinical result. There is a direct and immediate link between this outcome of treatment success and the impact of reduced TB mortality and transmission.
Other relevant information	NTP presents routinely success rate separately for relapses and all other re-treatment cases.

6 Treatment success rate, of bacteriologically confirmed RR and MDR TB

Indicator	Treatment success rate, of bacteriologically confirmed RR and MDR TB
Rationale/Purpose	The indicator measures the effectiveness of treating RR and MDR-TB patients.
Numerator	Number of confirmed RR and MDR-TB cases cured or treatment completed
Denominator	Total number of confirmed RR and MDR TB **registered during one year**
Data collection frequency	Quarterly

Measurement Tool	National TB Registry (in updated version)
Method of measurement	The indicator is measured 24 months after the end of the year of registration. This gives sufficient time for most patients to complete their treatment and for the final culture results to be issued and retrieved. Cured: Treatment completed as recommended by the national policy without evidence of failure AND three or more consecutive cultures taken at least 30 days apart are negative after the intensive phase. Completed: Treatment completed as recommended by the national policy without evidence of failure BUT no record that three or more consecutive cultures taken at least 30 days apart are negative after the intensive phase. **Treatment failed for RR and MDR TB case:** Treatment terminated or need for permanent regimen change of at least two anti-TB drugs because of: • lack of conversion by the end of the intensive phase, or • bacteriological reversion in the continuation phase after conversion to negative, or • evidence of additional acquired resistance to fluoroquinolones or second-line injectable drugs, or • adverse drug reactions (ADRs). (ECDC definition 2015)
Interpretation	This indicator measures a program's capacity to retain RR and MDR TB patients through a complete course of chemotherapy with a favourable clinical result. There is a direct and immediate link between this outcome of treatment success and the impact of reduced RR and MDR TB mortality and transmission. If MDR-TB treatment is expanded to include also patients who have been waiting for a long time (such as so-called "chronics"), treatment success may well temporarily be reduced.
Other relevant information	From the case based electronic Register, both RR and MDR-TB cohorts can be assessed. In the Global TB Report 2015 issued by WHO, RR-MDR-TB cohort is mentioned and in TB Surveillance Report 2015 issued by ECDC, both RR-/MDR-TB and MDR-TB cohorts ae analysed. In the NTP Country presentation, MDR-TB cohorts are analysed. WHO EURO informs (oral information October 2015) that this indicator is being changed (also by ECDC) to include only confirmed RR and MDR-TB patients **who started MDR-TB treatment**. The new definition is in line with WHO definition in the rest of the world. Another indicator (#15) is then needed to assess the proportion of registered MDR-TB patients who started MDR-TB treatment.

7 Number of persons from high-risk groups evaluated for TB diagnosis

Indicator	Number of persons from high risk groups evaluated for TB diagnosis

Rationale/Purpose	The indicator measures how many patents in high-risk groups are investigated for TB.
Numerator	Number of persons from high risk groups investigated for TB diagnosis
Denominator	N/A
Data collection frequency	Quarterly or Annually
Measurement Tool	TB suspect register (presumptive TB register)
Method of measurement	Variable: type of high risk group
Interpretation	This indicator measures a program's capacity to reach high-risk groups with diagnosis.
Other relevant information	Currently GF project is targeting homeless, IDU and prisoners in Bucharest only. WHO EURO indicators: 1A2 coverage of screening of **contacts** and high risk. The NTP indicator only include how many of TB cases have contact tracing done, not counting contacts. Related indicators are: - TB suspects (in total, not only from high-risk groups) per 100 000 population. - Percentage of TB suspects found to have TB ("positivity rate"). These indicators are especially useful to compare counties and dispensaries, to identify areas where few suspects are investigated.

8 Percentage of TB patients diagnosed using WHO-recommended rapid tests

Indicator	Percentage of TB patients diagnosed using WHO-recommended rapid tests
Rationale/Purpose	The indicator measures the percentage of TB patients who are diagnosed with rapid test
Numerator	Number of TB patients diagnosed with rapid test
Denominator	All TB patients registered during the defined period
Data collection frequency	Quarterly
Measurement Tool	National TB Registry
Method of measurement	Diagnostic rapid method in National TB Registry (Xpert, LPA, etc.)
Interpretation	This indicator measures a program's capacity to use rapid test to diagnose TB. It is important to define clearly the algorithm: when is a rapid test indicated to diagnose TB, and when indicated to diagnose DR-TB.
Other relevant information	

9 Percentage of new confirmed TB patients with result of DST to 1.line drugs

Indicator	Percentage of new confirmed TB patients with result of DST to 1.line drugs
Rationale/Purpose	The indicator measures the percentage of new confirmed TB patients with result of DST to 1.line drugs.
Numerator	Number of new confirmed TB patients with result of DST to 1.line drugs
Denominator	All new confirmed TB patients registered during the defined period
Data collection frequency	Quarterly (with 6 months delay to allow for DST results to be available).
Measurement Tool	NTR
Method of measurement	Result of DST in TB register. Method should be included: GeneXpert for Rifampicin, LPA for Rifampicin and Isoniazid, and/or liquid media or solid media testing at least Rifampicin)
Interpretation	This indicator measures a program's capacity to test all new confirmed cases with DST for 1.line drugs. It is necessary to define the algorithm – when is a rapid test indicated to diagnose DR-TB – and which drug.
Other relevant information	More specific indicators may be: - % with rapid test to Rifampicin (GeneXpert or LPA) - % with rapid test to Rifampicin and Isoniazid (LPA) - % of those with rapid test who also has result with conventional DST. - % with result of either rapid or conventional test for RR

10 Percentage of previously treated confirmed TB patients with result of DST to 1.line drugs

Indicator	Percentage of previously treated confirmed TB patients with result of DST to 1.line drugs
Rationale/Purpose	The indicator measures the percentage of previously treated confirmed TB patients with result of DST to 1.line drugs
Numerator	Number of previously treated confirmed TB patients with result of DST to 1.line drugs
Denominator	All previously treated confirmed TB patients registered during the defined period
Data collection frequency	Quarterly With 6 months delay to allow for DST results to be available.
Measurement Tool	National TB Registry
Method of measurement	Result of DST in TB register. Method should be included: GeneXpert for Rifampicin, LPA for Rifampicin and Isoniazid, and/or liquid media or solid media testing at least Rifampicin)

Interpretation	This indicator measures a program's capacity to test previously treated confirmed cases with DST for 1.line drugs. It is necessary to define the algorithm – when is a rapid test indicated to diagnose DR-TB – and which drug
Other relevant information	More specific indicators may be: - % with rapid test to Rifampicin (GeneXpert or LPA) - % with rapid test to Rifampicin and Isoniazid (LPA) - % of those with rapid test who also has result with conventional DST. % with result of either rapid or conventional test for RR

11 Percentage of TB patients with Rifampicin resistance provided DST to 2.line drugs

Indicator	Percentage of patients with Rifampicin resistance provided second-line DST
Rationale/Purpose	The indicator measures the percentage of patients with Rifampicin resistance provided second-line DST
Numerator	Number of patients with Rifampicin resistance provided second-line DST
Denominator	All patients with Rifampicin resistance
Data collection frequency	Quarterly
Measurement Tool	National TB Registry
Method of measurement	Result of DST to 2.line drugs in TB register: rapid tests for resistance to Quinolones and 2.line injectable, and/or conventional DST with liquid or solid media.
Interpretation	This indicator measures a program's capacity to test all patients with Rifampicin resistant TB with DST to 2.line drugs: quinolones and injectable. It is necessary to define the algorithm – when is rapid test indicated.
Other relevant information	

12 MDR-TB prevalence in new TB cases

Indicator	Percentage of new cases tested confirmed with MDR
Rationale/Purpose	The indicator measures the Percentage of new cases tested with DST, who are detected with MDR
Numerator	Number of new cases tested with DST, who are detected with MDR
Denominator	New cases tested with DST
Data collection frequency	Quarterly

Measurement Tool	National TB Registry. In addition the DRS 2015 with more representative data.
Method of measurement	Result of DST to at least Rifampicin and Isoniazid in TB register: rapid tests, and/or liquid media or solid media.
Interpretation	This indicator measures the percentage of new TB cases tested found with MDR-TB. An increasing trend is cause for concern.
Other relevant information	A similar indicator is the prevalence of Rifampicin resistance in new cases.

13 MDR-TB prevalence in previously treated TB cases

Indicator	Percentage of previously treated cases tested confirmed with MDR
Rationale/Purpose	The indicator measures the Percentage of previously treated cases tested with DST, detected with MDR
Numerator	Number of previously treated cases tested with DST, detected with MDR
Denominator	Previously treated cases tested with DST
Data collection frequency	Quarterly In addition the DRS 2015 with more representative data.
Measurement Tool	National TB Registry
Method of measurement	Result of DST to at least Rifampicin and Isoniazid in TB register: rapid tests, and/or liquid media or solid media
Interpretation	This indicator measures the percentage of previously treated TB cases tested found with MDR-TB. An increasing trend is cause for concern, but should be assessed also by the absolute number of cases.
Other relevant information	The retreatment groups should also be analysed separately, and not only relapses as in the GF indicator. Each of the 3 groups of previously treated patients should be assessed separately. A similar indicator is the prevalence of Rifampicin resistance in previously treated cases.

14 Bacteriologically confirmed MDR-TB cases notified as percentage of all MDR-TB cases (including RR) estimated by WHO

Indicator	Confirmed MDR-TB cases detected as percentage of all estimated MDR-TB (including RR) cases by WHO
Rationale/Purpose	The indicator measures confirmed RR and MDR-TB cases detected as percentage of all estimated by WHO

Numerator	Number of confirmed RR and MDR-TB cases notified
Denominator	Number of confirmed RR and MDR-TB cases estimated by WHO
Data collection frequency	Annually
Measurement Tool	Routine TB registration: Number of RR and MDR-TB cases registered: WHO annual statistics: Estimated number of RR and MDR-TB
Method of measurement	Confirmed RR and MDR-TB patients in TB register, by rapid tests, and/or liquid media or solid media)
Interpretation	This indicator measures the percentage of estimated RR and MDR-TB cases who have been registered. This indicator should be assessed also with the indicator on coverage of DST.
Other relevant information	DRS 2015 should make estimates more accurate

15 Percentage of notified confirmed RR and MDR cases started on any 2.line treatment

Indicator	Percentage of notified confirmed RR and MDR cases started on any 2.line treatment
Rationale/Purpose	The indicator measures the percentage of notified confirmed MDR cases started on any 2.line treatment
Numerator	Number of confirmed RR and MDR-TB cases notified during a defined period who are started on any 2.line treatment
Denominator	Number of confirmed MRR and DR-TB cases notified during a defined period.
Data collection frequency	Annually
Measurement Tool	Routine TB registration
Method of measurement	Notified confirmed RR and MDR-TB patients in TB register Number of RR and MDR-TB patients with information of start with 2.line drugs by the time the report is submitted
Interpretation	This indicator measures the percentage of notified confirmed RR and MDR cases started on any 2.line treatment, and needs to be compared with the indicator on adequate treatment. Inadequate treatment may be worse than no treatment, since resistance may be amplified.
Other relevant information	Those started on treatment should include also inadequate treatment with 2.line drugs. GF indicator has numbers not percentage. To get the full picture of the MDR-TB situation, also confirmed MDR-TB cases not on MDR-TB treatment (and not already included) should be included, as a separate group. They may not be on MDR-TB treatment because they refused treatment, drugs were not available or the patient was considered "without therapeutic chances". These MDR-TB patients are very important as possible sources of infection, and candidates for treatment as soon as adequate drugs become available.

16 Percentage of confirmed RR and MDR-TB patients started on WHO recommended treatment regimens

Indicator	Percentage of confirmed RR and MDR-TB patients started on WHO recommended treatment regimens
Rationale/Purpose	The indicator measures the percentage of confirmed RR and MDR-TB patients started on WHO recommended treatment regimens
Numerator	Number of confirmed RR and MDR-TB patients started on WHO recommended treatment regimens
Denominator	Number of all confirmed RR and MDR-TB patients notified
Data collection frequency	Quarterly
Measurement Tool	NTR
Method of measurement	Notified confirmed RR and MDR-TB patients in TB register Number of RR and MDR-TB patients started with WHO recommended regimen as described in the National Guidelines on PMDT and assessed by the DR-TB committee should be available also from NTR (NTP to clarify how to include in National TB Registry)
Interpretation	This indicator measures the percentage of notified confirmed RR and MDR cases started on WHO recommended regimen
Other relevant information	NTP needs to describe in the National PMDT Guideline the MDR-TB treatment regimens in line with WHO recommendations. This indicator addresses a key challenge in the NTP, and is specified in the NSP, by the last rGLC visit and the NTP review.

17 Percentage of XDR-TB patients started on WHO recommended treatment regimens

Indicator	Percentage of XDR-TB patients started on WHO recommended treatment regimens
Rationale/Purpose	The indicator measures the percentage of XDR-TB patients started on WHO recommended treatment regimens
Numerator	Number of XDR-TB patients started on WHO recommended treatment regimens
Denominator	Number of all XDR-TB patients notified
Data collection frequency	Quarterly
Measurement Tool	National TB Registry
Method of measurement	Notified confirmed XDR-TB patients in TB register Number of XDR-TB patients started with WHO recommended regimen as described in the National Guidelines on PMDT and assessed by the DR-TB committee should be available also from National TB Registry

	(NTP to clarify how to include in National TB Registry)
Interpretation	This indicator measures the percentage of notified XDR cases started on WHO recommended regimen
Other relevant information	NTP needs to describe in the National PMDT Guideline the MDR-TB treatment regimens in line with WHO recommendations. This indicator addresses a key challenge in the NTP, and is specified in the NSP, by the last rGLC visit and the NTP review.

18 Percentage of TB patients receiving DOT

Indicator	Percentage of TB patients receiving DOT
Rationale/Purpose	The indicator measures the percentage of TB patients receiving DOT
Numerator	Number of TB patients receiving DOT
Denominator	Number of all TB patients
Data collection frequency	Annually
Measurement Tool	National TB Registry
Method of measurement	Notified TB patients in TB register Number TB patients with information of DOT in National TB Registry (may need to be established)
Interpretation	This indicator measures the percentage of TB cases receiving DOT
Other relevant information	Need to define which period the indicator refers to. Currently almost all TB patients start treatment in hospital where treatment is supposed to be under DOT. The indicator should therefore probably refer to DOT after discharge from hospital. NTP also needs to define what is "acceptable" DOT: facility based, community based, family? The indicator may be more useful if asking about the type of DOT provided, not only yes/no.

19 Percentage of TB patients with HIV test result recorded in TB register

Indicator	Percentage of TB patients with HIV test result recorded in TB register
Rationale/Purpose	The indicator measures the Percentage of TB patients with HIV test result recorded in TB register
Numerator	Number of TB patients with HIV test result recorded in TB register
Denominator	Number of all TB patients notified
Data collection frequency	Quarterly
Measurement Tool	National TB Registry
Method of measurement	HIV test result recoded in TB register

Interpretation	This indicator measures the percentage of TB cases with HIV result recorded in TB register. All TB cases should have a HIV test result, in order to know about infectiousness and to provide ART.
Other relevant information	NTP indicator only includes new smear positive pulmonary case. It should include all.

20 Percentage of HIV positive registered TB patients given ART during TB treatment

Indicator	Percentage of HIV positive registered TB patients given ART during TB treatment
Rationale/Purpose	The indicator measures the Percentage of HIV positive registered TB patients given ART during TB treatment
Numerator	Number of HIV positive registered TB patients given ART during TB treatment
Denominator	Number of all HIV positive TB patients notified
Data collection frequency	Quarterly
Measurement Tool	National TB Registry
Method of measurement	"ART provided" in TB register
Interpretation	This indicator measures the percentage of HIV positive TB cases given ART during TB treatment. All TB cases with HIV infection should start ART, usually after a short delay.
Other relevant information	Usually ART is started a few weeks after TB treatment has been started. There may therefore be under-registration of coverage of ART

21 Percentage of TB patients who start the treatment in ambulatory care

Indicator	Percentage of TB patients who start TB treatment in ambulatory care
Rationale/Purpose	The indicator measures the percentage of TB patients who start the treatment in ambulatory care
Numerator	Number of TB patients who start the treatment in ambulatory care
Denominator	Number of all TB patients
Data collection frequency	Quarterly
Measurement Tool	National TB Registry (in future).
Method of measurement	"Start treatment ambulatory" in TB register. Currently ambulatory care is a project in 6 counties with separate data collection.
Interpretation	This indicator measures the percentage of TB cases starting TB treatment in ambulatory care. An increasing proportion of TB cases should start TB treatment outside hospital. The indicator treatment success should also be followed.
Other relevant information	

22 Percentage of MDR-TB patients who start the treatment in ambulatory care

Indicator	Percentage of MDR-TB patients who start the treatment in ambulatory care
Rationale/Purpose	The indicator measures the percentage of MDR-TB patients who start the treatment in ambulatory care
Numerator	Number of MDR-TB patients who start the treatment in ambulatory care
Denominator	Number of all MDR-TB patients
Data collection frequency	Quarterly
Measurement Tool	National TB Registry (in future)
Method of measurement	"Start treatment ambulatory" in TB register. Currently ambulatory care is a project in 6 counties with separate data collection.
Interpretation	This indicator measures the percentage of MDR-TB cases starting TB treatment in ambulatory care. An increasing proportion of MDR-TB cases should start TB treatment outside hospital. The indicator treatment success should also be followed.
Other relevant information	

23 Number of routine supervision and monitoring visits performed

Indicator	Number of routine supervision and monitoring visits performed
Rationale/Purpose	The indicator measures the number of routine supervision and monitoring visits performed
Numerator	Number of routine supervision and monitoring visits performed
Denominator	N/A
Data collection frequency	Annual
Measurement Tool	Supervision reports. Planning documents.
Method of measurement	Supervision and monitoring visits carried out with a written report.
Interpretation	This indicator measures the number of routine supervision and monitoring visits performed
Other relevant information	Another more useful indicator could be the percentage of planned visits with report available, separately for NTP to county and for county to local sites.

24 Percentage of new TB cases who were TB contacts from all new TB cases registered

Indicator	% of eligible index cases of tuberculosis for which contact investigations were undertaken
Rationale/Purpose	The indicator measures percentage of new TB cases who are introduced in the database as TB contacts from all new TB cases registered
Numerator	Number of new TB cases who had been TB contacts
Denominator	Number of new TB cases registered
Data collection frequency	Annual
Measurement Tool	National TB Registry
Method of measurement	National TB Registry variable on contact tracing carried out
Interpretation	This indicator measures if contact tracing has been done
Other relevant information	