**National Programme for Prevention, Surveillance and Control of Tuberculosis**

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Ministry of Health

Institute of Pulmonology and Phthisiology “Marius Nasta”

National Programme for Prevention, Surveillance and Control of Tuberculosis (PNPSCT)

Methodological Guide

How to implement the National program for Prevention, Supervision and Control of Tuberculosis

National Programme for Prophylactics, Supervision and Control of Tuberculosis

Bucharest - 2015

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ABBREVIATIONS

|  |  |
| --- | --- |
| ABG | Antibiogram |
| ACSM | Advocacy, Communication and Social Mobilisation |
| AE | Epidemiological survey form |
| BAAR | Acid- Alcohol- resistant bacilli |
| BCG | Calmette- Guerin Bacilli |
| C | Culture for mycobacteria |
| CF | Pharmaceutical College |
| Cl | Claritromicin |
| CM | Medical College |
| CNSCBT | National Centre for surveillance and Control of communicable diseases |
| CNSISP | National Centre of Statistics and Information Technology for Public Health |
| Cr | Chronic |
| CTJ | District Technical Co-ordinator |
| DPF | Pulmonary and Phthisiology Dispenser |
| DSPCSP | Public Health and Control Administration |
| DSPJ/DSPMB | District Administration of Health/ District Administration of Bucharest Municipality |
| DR |  Anti-TB Drug or medication resistance |
| ECDC | European Centre for Disease Prevention and Control |
| IEC | Inform, Educate, Communicate |
| IGRAs | Interferon-Gamma Release Assays |
| IPMN | Institute of Pulmonology and Phthisiology named after Marius Nafta  |
| INH,H | Isoniazid |
| LNR | National Reference Laboratory |
| LRR | Regional Reference Laboratory |
| MAI | Ministry of Internal Affairs |
| MAN | Ministry of National Defence |
| MDR | Resistant to at least Isoniazid and Rifampicin |
| MF | Family Doctor |
| MOTT/ NTM | MOTT-Mycobacterium Other than TB, Non Tuberculous Mycobacterium |
| MS | Ministry of Health |
| MT | Mycobacterium Tuberculosis |
| PNRSCT | Programme for TB Prevention, Surveillance and Control of tuberculosis |
| PNF | Pulmonology and Phthisiology |
| RAI | Annual Risk of Infection |
| RMP, R | Rifampicin |
| TB | Tuberculosis |
| TB DR | TB with resistant germs |
| TB MDR | TB with microorganisms resistant to at least Isoniazid and Rifampicin |
| TB XDR | TB resistant to at least HIN, RMP, Q and injectable as per line 2 |
| Tessy | The European Surveillance System |
| TCT | Cutaneous Tuberculin Test |
| UATM | Unit of Technical Assistance and Management |
| WHO | World Health Organisation (OMS) |

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Introduction

The Ministry of Health in Romania considers Tuberculosis as a major problem to Public Health. Due to such approach - all anti- tuberculosis activities guided by the Programme for TB Prevention, Surveillance and Control of tuberculosis (PNPSCT), that is: TB Diagnosis and treatment of TB patients, control of their contacts and contact tracing measures, preventive treatment, information, education, communication activities – are free of charge.

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Particular attention must be given to multidrug resistant tuberculosis medication (MDR TB) and comorbid TB ‐ HIV associations.

The epidemiological survey carried out in Romania between July 2003 ‐ June 2004 showed that TB was found in 2.9% of new cases and 10.7% in previously treated patients. In these circumstances, the number of MDR TB cases expected to be reported annually was 1200, which indicates an important public health problem.

In reality, approximately 600 – 700 cases are reported annually (almost 2 times less than expected), because more than one third of the confirmed TB cases have not been tested for sensitivity.

Regarding the prevalence of MDR TB (the number of patients requiring treatment throughout the period of one year), there are approximately 1500 cases registered in Romania. Worldwide, 10% of MDR TB cases are TB XDR.

The results of the National Chemo-resistance Survey on 2nd line drugs in 2009 ‐ 2010 showed that the percentage of XDR cases among those MDR was 11.4%: 9.9% for new cases and 11.9% for previously treated cases.

In Romania, 265 TB ‐ AIDS cases were registered in the year 2013. In June 2014 there were

19,696 cases combined with HIV/AIDS; among those, 13,643 were AIDS cases, and

6,053 were cases of HIV infection. Since a study on the evaluation of the prevalence of TB-HIV infection has not been carried out yet, the magnitude of the phenomenon is not exactly known.

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The final goal is to exterminate TB in Romania by the year 2050 (less than 1 case with a positive microscopy per 1 million inhabitants per year), PNPSCT is considering application of the following major measures to achieve these long-term objectives:

1. Continuous implementation and improvement of the DOTS strategy on a national level:

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 b) Early detection of cases by means of bacteriological quality examination;

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 5. Contribution to the consolidation of the health system by means of:

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 b) Reinforcement of the TB control network;

 c) Reinforcement of the control measures of the transmission of TB infection in health units of the Pulmonary Phthisiology Network;

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 7. Consolidation of public and public-private approaches (PPM):

 a) to encourage patients with TB and communities in general to combat TB by means of advocacy, communication and social mobilization (ACSM);

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ORGANIZATION OF THE NATIONAL PROGRAMME FOR PREVENTION, SURVEILLANCE, SUPERVISION AND CONTROL OF TUBERCULOSIS (PNPSCT)

PNPSCT is technically coordinated by the Pulmonary Phthisiology Institute named after Marius Nasta (IPMN), benefiting from specialized advice from ECDC and WHO.
PNPSCT activities are developed via a hierarchic structure organized on 3 distinct levels, each level being organised based on well-established assignments and functional relationships.
**The first level** consists of the following components:

1. *Primary care network* (family physicians / doctors in medical offices
of educational establishments) that ensure the identification of TB suspects and contacts
and who provide treatment to patients under direct observation in the outpatient phase prescribed by Pulmonary and Phthisiology specialists of the Ministry of Health network, as well as other ministries who have health services within their infrastructure.
2. *The territorial Pulmonary Phthisiology dispensaries (PPD/DPF)*, 2 to 8 in each district and one in each sector of Bucharest. The ministries with their own sanitary network also have 1 or 2 PPD. They represent the basic health care structures coordinating all issues of surveillance and control of TB in the adjacent territory;

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 4*. TB bacteriological network* .

 1. The primary medical network shall participate in the following:

a) identification of TB suspects and contacts;

b) administration of anti-tuberculosis medication under direct observation;

c) carrying out of the epidemiological inquiry;

d) IEC activities (Information, Education, Communication).

 Thus, family doctors (FD) and physicians working in the medical offices of the educational institutions have the following tasks:

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 e) to identify and send suspected cases of tuberculosis for consultation and analysis to the specialists of the Pulmonary Dispensaries to which the patient is assigned as per his/her resident address and as required by the legal regulations in force

 f) to record in a dedicated register all cases of suspected tuberculosis and to follow up via specialised consultations, organised within the Pulmonary Dispensaries

 g) to participate in collaboration with the medical specialist in epidemiological investigation. To participate in collaboration with the implementation of the necessary measures to detect the cases of tuberculosis ; in the case of TB outbreaks ( at least 3 cases), to carry out the same activity together with the doctor epidemiologist of the DSPJ (District Administration of Health).

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i) in cooperation with the pulmonologist, to provide prophylactic treatment to the persons who have been in contact with the contagious cases within the age group of 0-19, and other categories

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of people with a high risk of tuberculosis disease: HIV infection, congenital immune deficiencies , immunosuppressive treatments, long-term cortisone therapy, cytostatic etc.

 j) to ensure administration of treatment along with direct observation of patients with registered tuberculosis in the epidemiological territory to which they have been assigned

pe liste sau aflaţi în teritoriul pe care îl au arondat epidemiologic.

1. **Pulmonary Phthisiology dispenser duties are as follows:**
2. asigură depistarea cazurilor de tuberculoză prin: controlul simptomaticilor respiratori şi PPD ensures the detection of tuberculosis cases by means of control of the respiratory symptoms and TB suspects via clinical examination, thoracic radiography and, where appropriate, sputum examination- microscopy and culture, as well as control of TB contacts and other groups at high risk of developing tuberculosis via clinical examination, thoracic radiography, and additionally, for children, by means of IDR in PPDs (tuberculin skin test);
3. in collaboration with a family doctor, PPD ensures prophylactic treatment via self-administration for persons who have been in contact with contagious cases, age group 0-19, and for other categories of people at high risk of developing tuberculosis (HIV, congenital immune deficiencies, diseases or conditions with permanent or temporary immune deficiency, immunosuppressive treatments, long-term cortisone therapy, cytostatic etc., as well as continuous and complete high quality treatment administration along with direct observation of patients with tuberculosis whose effective actual residence is located within specific epidemiological territory;
4. PPD collaborates with family doctors and supervises their work in detecting TB cases and defining their treatment under direct observation;
5. in collaboration with the family doctor, PPD carries out epidemiological investigation and ensures implementation of all necessary measures when a case of tuberculosis is discovered;
6. in collaboration with the epidemiologist in DSPJ and the family doctor , PPD participates in epidemiological investigation and implementation of necessary measures in tuberculosis outbreaks with at least 3 registered cases ;
7. PPD provides specific sanitary materials for bacteriological, radiological and other examinations, specific and non-specific sanitary materials necessary for the running of the program;
8. PPD ensures active evidence of specific health status of tuberculosis patients, transmits information and recommendations concerning health status of identified sick person to the family doctor who manages the case, as well as to the National Register of Records of the Institute of Pulmonology and Phthisiology "Marius Nasta" in Bucharest;

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1. **Bed units/wards** provide isolation, diagnosis and treatment of TB cases.

Doctors in hospitals and their sections collaborate with the doctors of PPDs by making a mandatory announcement of the existence of a case of TB in the respective PPD territory within 48 hours, announce the transfer to another bed unit, along with the transfer of medical documentation of the discharged patient , as well as laboratory results that are completed and received after discharge. Hospitals, departments and offices of other specialised institutions, such as Pulmonology offices, including private ones, who detect localized tuberculosis cases of

Pulmonary or those of extra pulmonary type, have the same obligations as those described above.

TB treatment is free of charge for all patients, and anti-tuberculosis drugs are provided for both hospitals and DPF through a closed chain of pharmacies.

There are two treatment centres for the treatment of MDR / XDR TB patients and a special treatment centre for medication resistant patients located in Bucharest and Bisericani (Neamţ District) and MDR departments that must adhere to the methodology applied in the industry by means of ensuring regional accessibility to the cases. Within each centre there is a "MDR Commission” with highly qualified pulmonologists with the corresponding authorisation rights, who analyse the cases and establish corresponding treatment plans.

The MDR Commission within the centre examines all cases diagnosed with TB MDR / XDR,

including the cases of the patients not admitted to these centres, and establishes treatment plans.

The cases where patients are not hospitalised in centres, shall be treated within the specialized territorial network.

A TB MDR Coordinator is assigned to each district level with a responsibility to assist with the cases.

1. **The network of TB bacteriology laboratories**

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 The existence of the laboratory network allows:

a) aplicarea tehnicilor standardizate recomandate de PNPSCT la nivelul întregii ţări; a) to apply the standardized techniques recommended by the PNPSCT across the country;

b) asigurarea unor investigaţii speciale disponibile numai în laboratoarele specializate (ex. b) to ensure special investigations available only in specialized laboratories (eg.

testarea sensibilităţii tulpinilor, teste genetice, identificarea speciilor de micobacterii); species sensitivity testing, genetic testing, identification of mycobacterial species);

c) obţinerea informaţiilor necesare planificării şi evaluării activităţii la toate nivelurile; c) to obtain necessary information for the planning and evaluation of activity held at all levels;

d) obţinerea informaţiilor privind activitatea de diagnostic şi identificarea eventualelor d) to obtain information on diagnostic activity and to identify eventual deficienţe, cu corectarea lor;deficiencies allowing for their correction;

e) aprecierea tendinţei confirmărilor bacteriologice (indicator de performanţă pentru programul e) to carry out appreciation of trends in bacteriological confirmations (performance indicator for the TB program ) ;TB)

f) asigurarea controlului intern şi extern al calităţii diagnosticului bacteriologic. f) to ensure the internal and external control of the quality of bacteriological diagnosis;

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The optimal volume of microscopic examinations for a day of work (for an assistant)

conform recomandărilor OMS, de 20 - 25 produse/zi, cu un minim de 10 produse/săptămână. according to WHO recommendations, is 20-25 clinical samples / day, with a minimum of 10 clinical samples / week. Cu cât The less the volumul de lucru/zi scade, cu atât creşte costul/investigaţie.workload volume per day, the higher the cost

of the investigation.

**Clasificarea laboratoarelor** în funcţie de gradul de competenţă şi complexitatea activităţilor **Classification of laboratories** according to their level of competence and complexity of activities se prezintă astfel: is as follows:

1. *Laboratoare de nivel I* – efectuează examen microscopic pentru evidenţierea bacililor 1. *Level I laboratories* - Perform microscopic examination to highlight

acido-alcoolo-rezistenţi (BAAR) acid-alcohol-resistant bacilli (BAAR)

2. *Laboratoare de nivel II* : 2. *Level II laboratories* :

2.1. 2.1. asigură efectuarea examenului microscopic pentru evidenţierea bacililor acidoalcoolo- ensure microscopic examination for highlighting the acid-alcohol-

rezistenţi (BAAR) şi cultura micobacteriilor în mediul solid Lowenstein resistant bacilli (BAAR) and mycobacterial culture in Lowenstein Jensen solid environment Jensen, cu identificarea complexului *M. tuberculosis* ;, with the identification of the *M. tuberculosis* complex ;

2.2. 2.2. trimit cultura pentru efectuarea antibiogramei la laboratorul de nivel III; send culture to undergo antibiogram test at the level III lab;

2.3. 2.3. trimit pentru identificare genetică în laboratorul de referinţă toate tulpinile send all non-tuberculous samples for genetic identification in appropriate laboratory

netuberculoase (test imunocromatografic Ag MPT64 negativ). (Ig MPT64 negative immune chromate graphic test).

3. *Laboratoare de nivel III* : 3. *Level III laboratories* :

3.1. 3.1. asigură efectuarea examenului microscopic pentru evidenţierea BAAR, cultura în ensure microscopic examination with the purpose of highlighting BAAR , culture in

mediul solid Lowenstein Jensen, cu identificarea micobacteriilor din complexul MT şi the Lowenstein Jensen solid environment, with the identification of mycobacteria in the MT and antibiograma (ABG) acestora pentru Rifampicină (RMP) şi Izoniazidă (INH) prin antibiotics (ABG) for Rifampicin (RMP) and Isoniazid (INH) by

Metoda Concentraţiilor Absolute;Absolute Concentration Method;

3.2. 3.2. în unele laboratoare de nivel III din zone cu incidenţa mare a TB sau a prevalenţei TB in some Level III laboratories in areas with a high incidence of TB or prevailing resistant TB cu rezistenţă, care au în dotare sistem automat de cultivare a micobacteriilor în mediul, which have an automatic system of cultivation of mycobacteria in the environment

lichid Middlebrook 7H9 şi personal instruit pentru folosirea lui, pentru cazurile Middlebrook 7H9 fluid and staff trained for its use, for some cases

selectate conform algoritmului de diagnostic se efectuează cultura în mediul lichid şi selected according to the diagnostic algorithm, the culture is examined out in the liquid environment and antibiograma pentru substanţele antiTB de linia întâi. Antibiogram test is performed for the anti-TB first-line.

3.3. 3.3. pot efectua teste genetice pentru identificarea complexului MT şi a rezistenţei la can perform genetic tests to identify the MT complex and resistance to

rifampicină (GeneXpert Rif TB). rifampicin (GeneXpert Rif TB).

4. *Laboratoare Regionale de Referinţă (LRR)* , în număr de 8: 4. *Regional Reference Laboratories (LRR)* of 8:

4.1. 4.1. coordonează activitatea din câte 3 - 7 laboratoare judeţene arondate şi din municipiul coordinate activity of 3 to 7 adjacent district laboratories and those from the municipality of Bucureşti;Bucharest;

4.2. 4.2. la acest nivel se efectuează, în plus faţă de laboratoarele de nivel III, alte teste genetice at this level, in addition to Level III laboratories, other genetic tests are carried out

pentru detectarea complexului MT şi a rezistenţei la HR (ex. LPA). for detection of MT complex and HR resistance (eg LPA).

5. *Laboratoarele Naţionale de Referinţă* (LNR), din cadrul Institutului de Pneumoftiziologie 5. *National Reference Laboratories* (LNR), Institute of Pulmonology and Phthisiology

„Marius Nasta“ şi din cadrul Spitalului Clinic de Pneumoftiziologie „Leon Danielo“ - Cluj- "Marius Nasta" and "Leon Danielo" Pulmonology and Phthisiology Clinic - Cluj-

Napoca: Napoca:

5.1. 5.1. National Reference Laboratoriesconstituie nivelul la care se realizează coordonarea, planificarea, organizarea, monitorizarea represent the level of coordination, planning, organization, monitoring şi evaluarea reţelei, instruirea personalului cu studii superioare din laboratoarele and evaluation of network, with the highly educated and trained staff in regional and district laboratories ;

regionale şi judeţene;

5.2. 5.2. în plus faţă de laboratoarele regionale, testează sensibilitatea pentru substanţele antiTB in addition to regional laboratories, tests sensitivity for anti-TB substances

 of line II is carried out by means of phenotypic methods (the method of proportions in the Lowenstein Jensen environment and in Middlebrook 7H9) and to genetically identify the species of the M. complex tuberculosis , common non - tuberculous mycobacterial species and genetic testing of molecular epidemiology;

5.3. 5.3. desfăşoară activitate de supervizare, asigurare a calităţii rezultatelor, informare, educare - performs supervision activity, quality assurance of results, provides information, education -

instruire, management al resurselor şi cercetare.training, resource management and research.

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Toate laboratoarele, indiferent de nivelul lor, pot participa la activitatea de cercetare All laboratories, regardless of their level, can participate in scientific researchştiinţifică..

***Al doilea nivel*** este reprezentat de: ***The second level*** is represented by:

1. coordonatorul tehnic judeţean (CTJ) al PNPSCT; 1. District Technical Coordinator (CTJ) of PNPSCT;

2. epidemiologul judeţean de la nivelul DSPJ; 2. District epidemiologist at DSPJ level;

3. alte structuri implicate în controlul TB. 3. other structures involved in TB control.

**1. Coordonatorul Tehnic Judeţean** (CTJ) al PNPSCT este medic de specialitate pneumologie **1. The PNPSCT District Technical Coordinator** (CTJ) is a specialist in pulmonology

nominalizat de către Coordonatorul UATM-PNPSCT şi confirmat de Direcţia de Sănătate Publică nominated by the UATM-PNPSCT Coordinator and confirmed by the District Administration of Public Health Judeţeană, cu avizul Direcţiei de specialitate din cadrul MS., with the opinion of the MS Specialised Administration. CTJ asigură aplicarea PNPSCT în CTJ ensures the application of the PNPSCT on teritoriul judeţului respectiv.the territory of such district.

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**2. Epidemiologul de la nivelul DSPJ** , cu responsabilităţi în derularea PNPSCT, este desemnat de **2. The Epidemiologist at DSPJ level** , assumes the responsibilities of running PNPSCT, is designated by the Deputy Director of Public Health and has the following specific duties:

către directorul executiv adjunct de sănătate publică şi are următoarele atribuţii specifice:

a) supravegherea epidemiologică a teritoriului; a) epidemiological surveillance of the territory;

b) controlul focarelor de tuberculoză cu minim 3 cazuri în colaborare cu pneumologul şi MF; b) control of tuberculosis outbreaks with at least 3 cases in collaboration with pulmonologist and MF;

c) evaluarea endemiei TB în teritoriu pe baza datelor furnizate de către CTJ; c) assessment of TB endemic within the territory based on data provided by the CTU;

d) controlul respectării normelor de prevenire a infecţiilor nosocomiale şi a infecţiei TB în d) control of compliance with the norms for the prevention of nosocomial infections and TB infection in the units of Pulmonology and Phthisiology, in collaboration with the county technical coordinating unităţile de pneumoftiziologie, în colaborare cu medicul coordonator tehnic judeţean alphysician of PNPSCT (in units where there is no hospital epidemiologist).

**3. Alte structuri implicate în controlul TB** **3. Other structures involved in TB control**

Ministerul Justiţiei, Ministerul Apărării Naţionale şi Ministerul Afacerilor Interne au în cadrul The Ministry of Justice, the Ministry of National Defence and the Ministry of Internal Affairs have health service networks within reţelelor proprii de servicii de sănătate şi compartimente TB în secţii de pneumologie. their own structure as well as TB compartments in pulmonology departments. Aceste unităţi

These units au aceleaşi responsabilităţi în aplicarea PNPSCT ca şi cele ale MS (anunţarea cazurilor cătrehave the same responsibilities in the application of the PNPSCT as those of the Ministry of Health MS (declaration of TB cases to dispensarul de pneumoftiziologie teritorial).the territorial Pulmonology and Phthisiology dispensary).

Având în vedere situaţia specială şi specificitatea sistemului penitenciar, pentru gestionarea Given the nature of a special situation and the specificity of the penitentiary system, for the purpose of management of cazurilor TB, se colaborează cu dispensarele teritoriale de pneumoftiziologie şi direcţiile de sănătateTB cases, they collaborate with the territorial departments of Pulmonology and Phthisiology and public health administrations in fields such as identification of TB cases, epidemiological investigation, and implementation of measures necessary to detect tuberculosis cases or TB outbreaks ( at least 3 cases).

În cadrul reţelei de asistenţă medicală a MAN şi MAI funcţionează unităţi cu paturi încadrateWithin the medical care network of the Ministry of National Defence MAN and that of the Ministry of Internal Affairs MAI there are special wards with beds assisted by pulmonologists who ensure cu medici pneumologi care asigură activităţi de control al TB pentru angajaţii ministerelorTB control activities for ministry employees and patients of family doctors from the same network. To complete such research they are sent to the specialized units of the Ministry of Health MS.

The Cele 3 ministere cu servicii de sănătate proprii au şi unităţi cu atribuţii similare unităţilor dethree above-mentioned ministries with their own health services also have units with the assignments and responsibilities similar to those of the units of Level I of the PNPSCT.

nivel I ale PNPSCT.For the Ministry of Justice, the level II equivalent corresponds to the Medical Administration within the National Administration of Penitentiaries; for the Ministry of National Defence it corresponds to Pulmonology and Phthisiology Section within the Central Military Hospital, for the Ministry of Internal Affairs it corresponds to the Pulmonology and Phthisiology office

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within the ambulatory of the ministerial Hospital “ D. Gerota” , for SRI it corresponds to the PNF office of SRI Policlinics.

In the special situation of treating TB cases associated with HIV / AIDS, doctors and
pulmonologists work with the specialists from the Regional HIV / AIDS Centre where patients are registered, according to the Joint Protocol of Collaboration between the PNPSCT and the HIV / AIDS Program.

***The third level is represented by***:
Technical Assistance and Management Unit (UATM) - PNPSCT, designated by the
Ministry of Health as a structure without legal entity status within the Institute of Health
Pulmonology and Phthisiology "Marius Nasta" (IPMN), with the following departments:
1. supervision - evaluation - monitoring, comprising: the Supervisory Board of
PNPSCT and the TB / HIV-AIDS Control Commission;
2. medication management;
3. DR-TB management;
4. Laboratories - with Laboratory Working Group;
5. control of TB infection;
6. research and project development;
7. information - education - communication.
The position of the coordinator of the Technical assistance and Management unit is filled in by a person with a higher education in medicine.

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1. SCREENING OF TUBERCULOSIS
Symptom detection of TB - also known as passive detection – is an activity carried out by both : doctors in the primary care network and various specialists.
Patients visiting a physician on their own initiative with symptoms such as cough, sub fever, physical asthenia, weakness, paleness, night sweats, insomnia, nervousness, weight loss, with a duration of the symptoms for over 2-3 weeks should be considered as potential TB patients and TB suspects. In these cases, it is necessary to direct them to DPF, where their cases will be investigated to specify the diagnosis.
Any person with signs and symptoms which could suggest TB diagnosis should
contact their GP or DPF specialist. The family doctor should send the suspected patient to DPF or Pulmonology and Phthisiology department / hospital (if considered to be major medical emergency).
If, following investigations, the diagnosis of TB is confirmed, the pulmonologist in
the Pulmonology and Phthisiology department / hospital must declare this case within 48 hours to the DPF of the territory where patient has his / her effective residence address declared in completed TB case notice (irrespectively of his / her residence address showing in ID documents or identity card).
The pulmonologist of the territorial DPF shall inform the family doctor
of the occurrence of the TB case via medical letter, while the epidemiologist / public health doctor shall do so only in the case of TB outbreaks with over 3 cases, or in case of the potential risk for communities (schools, kindergartens, prisons, socially assisted elderly care homes, etc.), with the purpose of launching the epidemiological inquiry, within 3 days of receiving the notice form or case detection.
Intensive screening is targeted among the following TB vulnerable groups:
1. contacts of TB patients;
2. extreme paupers, homeless persons or persons on social welfare;
3. HIV / AIDS infected persons;
4. drug users;
5. population in prisons and other correctional institutions;
6. chronically hospitalized persons in psychiatric units;
7. cases of neoplasm, diabetes, chronic hepatitis or cirrhosis with B or C virus with
specific treatments;
8. people who undergo immunosuppressive treatments for various diseases, transplantation of organs, treated collagenases, and other conditions for which immune depressors are applied (e.g. example anti-TNF alpha);
9. chronic ethyl users;
10. personnel working in sanitary units;
11. workers exposed to pneumoconiosis, construction site workers accommodated in shared dormitories, commuters;
12. persons in the socially assisted elderly care homes, in hospital homes;
13. haemodialysis patients.

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Intensive screening consists of identification of suspects by means of the assistance services, primary care physicians, school doctors, physicians who oversee the state of health of employees, specialist doctors who take care of the TB risk groups, nursing network, community mediators, health mediators. Diagnosis is determined by clinical examination, followed by the examination of bacteriological sputum for TB and radiological examination performed by the pulmonologist.
The selection of the persons to be examined as well as the frequency of these checks is carried out depending on the degree of risk, through collaboration between family doctors, doctors who are responsible for these vulnerable categories and pulmonology physicians from Territorial DPF.
Taking into account that prisons are closed communities characterized by a high degree of mobility of detainees (i.e., within a period of 30 days there is a possibility that a detainee may be transferred to a minimum of 2 prisons, which, in the case of a lung TB case, can lead to a significant growth of contacts) before including them in the penitentiary system, all persons deprived of their liberty have to be sent to perform pulmonary X-ray test and a specialized test, so that at the moment of registration in the penitentiary system the "Pulmonology and Phthisiology status"
of the patient is already known to the doctors working in the prison institution.
Performing the radiographic and bacteriological examination bK on all who present any signs and symptoms, allowing to detect active tuberculosis, this will be performed at the PNF dispensary on the territory where the arrest and detention unit is located.

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1. DIAGNOSIS OF TUBERCULOSIS
A. **Diagnosis of pulmonary tuberculosis**
Clinical diagnosis: some patients (20-40% of cases) are asymptomatic, but in most
cases there is at least 1 or two symptoms that require medical assistance: common symptom is cough (95% of cases), lasting at least 3 weeks; other
signs: weight loss, asthenia, fever, night sweats, chest pain, dyspnoea, haemoptysis.
Bacteriological diagnosis: it is the only criterion that verifies the certainty of the diagnosis of TB. It is mostly done spontaneously by sputum test, but other pathological clinical samples can also be used.
**Bacteriological examination is the main method for the diagnosis of certainty of TB.**Sputum collection from TB suspects is essential for verifying the diagnosis.
Always take 2 separate sputum samples, even from the suspects who passed the Radiological pulmonary examination.

The speed of bacteriological investigation depends on the quality of collected sputum samples.
Sputum samples are collected within 2 consecutive clinical evaluation days to reduce the number of patient visits to the medical cabinet: two sputum samples are collected during patient visits to the dispensary under the direct supervision of a health worker. One of the samples may be taken by the patient at home, early in the morning, before eating, after the patient has brushed his/her teeth.
For details on the collection of sputum and other biological clinical samples, refer to Appendix 7 attached to this Methodological Guide.
After the sputum collection, the " Bacteriological TB test request / report form" shall be completed, provided in Annex 8 of this Methodological Guide.
If the first 2 samples collected are negative after their microscopic examination, but suspicion of TB remains, collection is repeated after challenging procedure and bacteriological examination are carried out under the same conditions (maximum 4 specimens).
Microscopic examination of sputum smear using the Ziehl-Neelsen colouring method or with the help of the fluorescent substances (as recommended by the WHO) is essential in controlling TB because it helps to identify the most contagious and most at-risk patients among the people around. A large number of BAAR on smear indicates a large number of bacilli expectorant. The result is positive if the sputum contains more than 5,000 bacilli /ml.
BAAR identification in the direct microscopic examination does not necessarily mean MT identification.
Cultivation of sputum mycobacteria is a more sensible method for confirmation of TB diagnosis (result is positive if sputum contains more than 50 bacilli / ml)
and increases the number of bacteriologically confirmed TB cases by up to 25%. It is carried out in specialized laboratories.

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MT Cultivation: obtaining the positive culture, followed by MT identification is the confirmation test for the suspected case. Cultivation of MT on solid environment may take 3-8 weeks to obtain a result. Cultivation in a liquid environment shortens time to 1-2 weeks.
It is imperative to identify positive crops for confirmation of all cases belonging to the M. tuberculosis complex. An unidentified positive culture is not considered to be completed.
Confirmation of the diagnosis of pulmonary TB and choice of treatment establishment are made by the pulmonologist.

**MT identification and sensitivity testing:**
After identifying MT, sensitivity testing for anti-TB medication is carried out with the purpose of the detection of bacterial resistant species.
Rapid diagnostic tests will be implemented, especially in the case of suspicion
of TB MDR / XDR.
The test result for anti-TB medication is transmitted by completing the "Outcome Form of antibiogram of Mycobacterium tuberculosis "as set out in Annex 9 attached to this Methodological Guide.
Appropriate funding is needed to test everyone's sensitivity for isolated species of anti-TB line I (HR for new cases - initial antibiogram and repeated treatment test). If crops are maintained or repositioned, repeat testing of the positive culture of T4 as quickly as possible.
Sensitivity tests are mandatory for all TB cases confirmed by culture.
The PNPSCT aims not only to identify and treat the source of infection, but also
to limit the appearance and spreading of species resistant to anti-tuberculous medication.
Resistance generally results from nonadherence, improperly prescribed treatment, or incorrectly administered treatment, leading to therapeutic failure. Species of sensitivity / resistance mycobacterial spectrum can be determined by antibiogram or other sensitivity tests (genetics).
**Initial resistance** to MT species is found in patients who have never received
any anti-tuberculosis treatment or have received it for a shorter period of time of one month only.
**Acquired resistance** to MT species can be found in patients who received at least
one month of anti tuberculous treatment.
**Radiological diagnosis:** Radiological test is the commonly used method for
Pulmonary TB diagnosis.
Radiological changes in pulmonary TB (infiltrative, cavity, fibrotic lesions) have
high sensitivity but low specificity.
It is imperative that each TB patient has a known HIV status.
The diagnostic algorithm for tuberculosis is presented in Annex 10 attached to this Methodological Guide.
The data on the results of the bacteriological examination is recorded in the laboratory register set out in Annex 11 attached to this Methodological Guide.

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**B. Detection of latent tuberculosis infection**
**Definition:** latent tuberculosis infection (ITBL) is asymptomatic in people
infected with MT and without clinical, radiological or bacteriological evidence of active disease. The patient with latent tuberculosis infection is not contagious.
The tests currently used for the diagnosis of latent tuberculosis infection are:
1. Tuberculin skin test (TCT): used as the current conventional method for
detection of MT infection. The only test accepted for diagnostic and epidemiological purposes is tuberculin IDR, by using the Mantoux technique.
The tuberculin skin test is used:
a) for diagnostic purposes to detect tuberculin sensitization in the event of a suspicion of TB infection in symptomatic or TB infected children (symptomatic or not) in
epidemiological survey;
b) as a method of epidemiological investigation for the calculation of the prevalence of infection and risk of annual infection (RAI) as indicators of the TB endemic;
c) in patients with HIV infection;
d) in patients treated with immunosuppressive medication (eg anti-TNF alpha)
e) children entering placement centres, auxiliary schools and correction schools;
f) to assess the effectiveness of the BCG vaccination.
So far, the biological product used intra dermally in Romania is PPD
(protein purified derivative). The ampoules are marked with the date of validity. The vials are kept in a refrigerator, the product is sensitive to light and heat.
Positive TCT response is a marker of TB infection but does not certify active TB.
The technique of tuberculin testing and the interpretation of the results are done according to the provisions of Annex 12 of this Methodological Guide. For details, please read the prospectus of the product used carefully.
2. **Interferon gamma detection tests (IGRAs)** - example QuantiFERON TB Gold,
set out in Annex 13 attached to this Methodological Guide, have the same recommendations and contents as TCT, but allow the exclusion of BCG post vaccine false positive results and NTM; research is not carried out routinely.
Testing for latent tuberculosis infection is used in conjunction with assessment
risk, radiological examination of the thorax and other medical and diagnostic evaluations of tuberculosis.
**C. Diagnosis of chemically resistant tuberculosis and especially TB MDR / XDR**The National Anti-TB Medication Control Survey was
conducted in Romania during the period from July 2003 till June 2004. This investigation revealed TB DR to be 13.3% of new cases and 33% of the cases previously treated.
To identify the spectrum of resistance of isolated MT species it is essential
to carry out correct testing of sensitivity to anti-tuberculosis medication. Suspicion of
resistance to anti tuberculous medication may be clinical, but the certainty is obtained by the outcome in vitro of the sensitivity test (antibiogram, genetic tests).

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Depending on the number and association of the medications to which the resistance is established, there are several types of chemical resistance (see Table 1).
**Table 1. Types of resistance based on resistances identified in vitro** for **susceptibility tests**

|  |  |
| --- | --- |
| **Type of Resistance**  | **Resistance to** |
| Mono resistance | single substance |
| Poli resistance | 2 or more substances (excluding combination INH + RMP) |
| Multidrug resistance- MDR | INH + RMP with or without resistance to other substances |
| Extensive resistance - XDR | INH + RMP associated with resistance to a quinolone and one line II aminoglycoside |
| Resistance to RMP | RMP - Definition associated with the GeneXpert test result |

D**. Diagnosis of TB-HIV / AIDS morbid association**
Between HIV infection and TB there is a strong, mutually reinforcing link, known for several decades.
HIV-infected people have a 20 to 30 times higher risk of developing TB disease compared to
HIV-negative people.
On the other hand, TB adversely affects the natural evolution of HIV infection.
According to the Collaboration Protocol between the HIV / AIDS Program and the PNPSCT, all cases of pulmonary and extra pulmonary TB HIV will undergo HIV testing according to the legislation in force, after consultation is
carried out prior testing.
Also, all HIV-infected persons will be TB bacteriologically and radiologically investigated with the purpose of early detection of TB in hospitals for infectious diseases.
The treatment scheme of tuberculosis for a HIV / TB patient is established by the
pulmonologist, who also has the obligation to announce / declare the case to the territorial anti-tuberculous dispensary.
**E. Diagnosis of extra pulmonary tuberculosis**
It is the responsibility of the specialist-examining organ, supported by the bacteriological examination and / or histopathological test.
It is recommended that whenever possible, it is necessary to perform a test of the pathological clinic sample of bacteriological TB.
Diagnosis of extra pulmonary TB is difficult and requires the exclusion of other pathological conditions which is carried out by the doctors and specialists involved.
If there are multiple locations, at least one of which is pulmonary, the diagnosis of pulmonary TB prevails.
The most common extra pulmonary localizations of TB are: TB pleurisy, TB lymphadenitis, TB meningitis (with or without TB billion), TB pericarditis, peritoneal TB and TB ascites, osteo articular TB, urogenital TB, gastrointestinal TB, TB laryngitis, Ocular TB, otic TB, endocrine TB, and cutaneous TB.
**Disseminated TB affecting multiple organs** is particularly serious, and represent a disseminated form. It may affect lungs, meninges and / or other organs (liver, spleen, lymph nodes, etc.). The signs and symptoms are non-specific:

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fever, chills, anorexia, weight loss, asthenia, signs of disease, and / or meningeal signs.
The acute form is rapidly progressive. There may be hepatomegaly and rarely, splenomegaly. Examination of the eye can show corroded tubers.
Thoracic radiography (in the case of pulmonary localization) shows a diffused micronondular evenly distributed appearance.
Diagnosis of certainty: the bacteriological examination for TB is rarely positive in sputum. As TB lesions are generalized, pathological clinical samples collected from the lung, liver, spleen, marrow, lymphatic organs can provide confirmation of the diagnosis.
**F. Diagnosis of TB in a Child**
Diagnosis of TB in children is very difficult. For the positive diagnosis, the
following criteria have to be considered:
1. Epidemiological context (known contact with a case of tuberculosis with positive bacteriology).
2. Positive tuberculin skin test (over 9 mm in those BCG-vaccinated or more than 5 mm in those with immune depression.)
3. Significant clinical signs and symptoms (cough, fever, sub fever, weight loss over 10%, flictenular keratoconjunctivitis, nodular erythema, peripheral adenopathy); in a very young child - signs of ganglion-bronchial compression (run-out, cornea), hepatosplenomegaly, seizures, paresis or other meningo-encephalitis signs which allow to suggest mildew releases.
4. Radiological / CT suggestive appearance: mediastinal adenopathy, pneumonic condensation or broncho pneumonic one with hyper transparencies included, with / without pleural effusions or atelectasis.
5. Bronchoscopy examination: fistula, compression or bronchial stenosis, perifistular granulation tissue.
6. Bacteriologically positive examination in the morning or bronchial gastric aspiration, induced or spontaneous sputum.
7. Gene amplification tests (GeneXpert MTB RIF).
8. Other investigations for extra pulmonary tuberculosis - suggestive histopathological examination (eg glandular, pleural, pericardial biopsy), cytochemical examination (pleural, rahidic, pericardial).
9. HIV test in any confirmed or suspected TB infant.

**G. Mycobacteriosis diagnosis (NTM, MOTT)**The term mycobacteriosis includes all diseases caused by mycobacterial species
other than Mycobacterium tuberculosis \* \*.
The term MOTT is used to describe this group of mycobacteria, Other Than TB, NTM: Non-Tuberculous Mycobacterium, suggesting that these are the causes of different diseases, other than TB.
Most mycobacteria are produced by M. avium complex (MAC) and other
mycobacteria, including M. kansasii, M gordonae, M. fortuitum and M. kelonae. Very rarely, they can cause disseminated or localized mycobacteriosis of M. xenopi, M. scrofulaceum, M. szulgai, M. flavescens, M. asiaticum, M. malmoense, M. genavense.
The increase in the number of NTM-related illnesses can be associated, at least partly, with the use of immunosuppressive medication, HIV / AIDS infection, the increase in the average age of the population and the decrease

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 in BCG vaccination rate. Aerosolized particles containing mycobacteria may be inhaled by the susceptible host; occasionally, infection can occur with several different species.
The most common manifestation of clinical syndromes associated with NTM infection are chronic pulmonary disease, ganglion l damage, skin and soft tissue damage and disseminated disease.
The identification of mycobacteria is done in the LNR, using genetic sensitivity testing.
Mycobacterial species are not standardized, so it is not routine.
Cases from which NTM are isolated and which meet the criteria for inclusion in
mycobacteriosis will be recorded in the electronic data base, noting that they are not
tuberculous mycobacteria in the rubric allocated to the bacteriological examination.

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**5. PREVENTION OF TUBERCULOSIS, MEASURES TO
LIMIT THE EXTENSION OF TUBERCULOSIS OUTBREAKS
Definitions**

The case of TB is defined in Annex 14 of this Methodological Guide.
The outbreak of tuberculosis represents a cumulative minimum of 3 recorded cases between which there is an epidemiological link.
Epidemiological research (EA): is a complex action where the starting point is a newly discovered case of tuberculosis called "index case", of a person alive or recently deceased, intended to identify all persons who have been in contact with this patient.
**Measures applied in the TB outbreak location**
AE are triggered in case of suspicion of any TB case within a maximum of 72
hours by the DPF pulmonologist within the territory that the case / outbreak had occurred.
The methodology of the epidemiological research refers to the use of anamnesis for the identification of contacts and use of specific and non-specific investigations (TCT, radiological, examination, bacteriological examination), the instructions and interpretation of which represent the responsibility of the pulmonologist.
Tasks in conducting AE are the following:
1. DPF pulmonologist:
a) initiates the epidemiological investigation, organizes and participates directly, whenever necessary, in the application of prophylactic and ant epidemic measures in the outbreak location (index case);
b) performs (together with the family doctor / school / occupational physician) the epidemiological investigation of cases of tuberculosis, ensuring contact control (clinical, TCT, radiological, bacteriological control).
Contact = person situated near the contagious TB person at a conversation distance for a minimum period of time of 4 hours.
c) is responsible for the quality of the epidemiological research and its completion;
d) reports outbreaks (with more than 3 cases) in a school / college to DSPJ / MB -
Epidemiology Department.
Minimum data to be reported:
a) start date;
b) number of cases;
c) location of the event: type of community / actual number of persons at risk;
d) current status of cases;
e) measures taken.
The form used for EA is contained in Annex 15 attached to this Methodological Guide.
**2. Family, school or occupational health practitioner:**
a) effectively participates in epidemiological investigation of filiation in the territory where the suspected TB person is domiciled or is working by identifying all contacts and sending them for a specialist control after the clinical examination;

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b) efficiently applies measures indicated by pulmonologist of DPF (prophylaxis);
c) provides health education and training concerning tuberculosis among patients and their families.
**3. The epidemiologist:**a) coordinates the epidemiological investigation in outbreaks of at least 3 cases;
b) reports outbreaks to INSP - CNSCBT;
c) collaborates with the Pulmonology and Phthisiology network with regard to training of the medical personnel to ensure application of the program’s provisions;
d) monitors at district level the running of the program, in collaboration with the coordinating district physician of the TB outbreak, and proposes, if necessary, additional measures for the surveillance and control of the outbreak.

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6. **MANAGEMENT OF TUBERCULOSE CASES**

The case of TB is a bacteriologically or histopathological (HP) TB patient or a patient with no confirmation, but where the pulmonologist has decided to start the anti-tuberculosis treatment.
Any anti-tuberculosis treatment, regardless of the location of the disease and the existence of a possible coinfection of HIV / AIDS, should be prescribed based on the opinion of the pulmonologist only.

The pulmonologist who prescribed / approved such treatment has the obligation to report the respective case of TB to the local DPF situated within the effective (declared) residency where it was registered..
**Declaration**. For any case of TB where the anti-tuberculosis treatment has to be applied, the "Tuberculosis Case Notification Sheet" shall be completed, no later than within 48 hours, as set out in Annex 16 attached to this Methodological Guide. The notification form is completed by the doctor who diagnosed the case and / or who initiated the treatment and is immediately sent (by fax or mail) to the DPF within the territory of actual residency of the patient, irrespective of the address in his identification documents.
Documentation of the TB MDR case (therapeutic history record, any other relevant clinical and radiological data) is completed by the treating physician and sent to the TB Excellency Centre and to TB MDR District Coordinator. Initiation of treatment for this category of patients will only be carried out based on the opinion of the commission of the TB MDR Centre.
Proof of completion and sending of the case notice to the DPF within the territory of actual residency of the patient will have to be placed in the patient's observation sheet. Thus, the sheet sent to DPF shall contain the dispatch date and the exit reference number under which it was recorded.

**Declaration and registration**
After a TB case notification (even if it is for a person who is deceased) has been received, if the patient lives or lived at the communicated address, local DPF shall announce within 3 days the occurrence of the TB case, by means of a medical letter addressed to the local family doctor, to activate AE investigation .
Simultaneously, the patient is registered both in the TB Register and in the electronic database in the computer of the unit.
After registration, the case registered in the national electronic data base appears both in the District Unit (UJ) and on the UATM-PNPSCT server.
The case of TB is defined in Annex 14 of this Methodological Guideline depending on:
a) location of the disease: pulmonary or extra pulmonary,
b) therapeutic history (WHO system),
c) bacteriological or histopathological confirmation (ECDC system),
d) HIV status.
Both types of definitions will be used within this Program: WHO and ECDC.

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***Depending on the therapeutic history***, a case of TB may represent:
1. **A New case (N)** – if it is a patient who has never been treated with anti- tuberculosis medication for more than one month. Cases of unconfirmed TB can be registered in this category based on the decision of the medical team.
 For a Patient marked as a "New Case" preventive chemotherapy is not taken into account.
2. **Recurrent case** - is one of the following categories:
a) **Relapse (R)** – a patient who was evaluated for cure or complete treatment after anti-tuberculous treatment and who has a new bacteriologically confirmed episode.
Cases of unconfirmed TB can be recorded as "recurrent" based on the decision of the
medical team.
b) **Retreatment after failure (E)** - a patient who starts a new series of treatments after initial therapy has been evaluated as a "failure".
c) **Retreatment after abandoned treatment (A)** - a patient who begins a new treatment after having been assessed as "abandoned" or "quit" relating to previous treatment and is bacteriologically positive or negative, where a resumption of treatment is prescribed.
d) **Chronic (Cr)** – a patient who begins a new treatment after the "re-failure" of his/her previous repeated treatment.
With the appearance of the European Centre for Disease Prevention and Control (ECDC) and TB integration to the list of other communicable diseases, TB cases will also be classified as confirmed, probable and possible from an epidemiological point of view.
Cases according to the ECDC definitions will be automatically extracted by
 processing data from the national electronic database. These definitions are set out in Annex 14 of this Methodological Guide.
**The TB case statement** - generated by a software application - is printed,
signed, and initialled. All records generated throughout the period of one month are transmitted to DSPJ / MB in the first 5 days of the following month. They are sent to UATM-PNPSCT from DSPJ / MB no later than on the 10th day of the month following the reporting.
If the patient does not live at the indicated address, all steps shall be taken to find out
his/her real address. If it cannot be identified, the case will still be recorded by DPF within the radius of which the patient declares his/her residence; if the patient does not present themselves within 2 months after discharge, such patient will be evaluated as "Lost".
Reporting, Registration and Declaration of TB cases shall be carried out in accordance with the provisions of Annex 16 attached to this Methodological Guide.
**The invalid status of a TB case**. If, after the record is done, it is discovered that the active TB diagnosis was not correct, the case is rejected by the DPF pulmonologist who recorded the case. When the rejection is made by another unit, it is communicated to DPF through the "TB Diagnostic Trouble Sheet", as set out in Annex 16 of this Methodological Guide. Confirmation of invalid status
(I) can only work between the time of the declaration and the evaluation, and after its inclusion in both: TB Register and the electronic databases, it will correspond to final evaluation category.
**Death.** In the event of the death of a TB patient in the hospital, "Hospital Death Statement Sheet" will be produced within 48 hours, as set out in Annex 16 of this Methodological Guidelines, and sent to DPF. If the TB diagnosis is made at the necropsy stage

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the TB case notification sheet is completed for the purpose of conducting the epidemiological investigation by DPF and post-mortem case reporting carried out by DPF .
**Transfer.** If a patient representing a TB case, changes his/her address after the registration and before the evaluation, the transfer will be electronically applied to the application, and upon receipt of the patient's acknowledgment, he/she will be
assessed as "Transferred" (T) by the first DPF and the medical documentation will be sent to the second. The DPF receiving such patient will record it in its TB Registry under the category "Transferred".
If the patient does not appear at the new address within two months of the transfer, the first DPF will evaluate the case as "Lost" (P).
**MDR TB cases** will be classified both: as a TB case category, according to the definition of cases at the moment of registration, and as one of the following categories, according to the treatment history:
1*. New case of TB MDR*: a patient who has not received anti-tuberculous treatment before current episode for more than a month;
2. *Case of MDR TB previously treated with line I medications only*: a patient who previously received anti-tuberculosis treatment for more than one month but only with medications of line I;
3. *Case of MDR TB previously treated with line II medications*: a patient who received a previous anti-tuberculosis treatment for more than one month with line II, regardless of whether he received line I medications or not.

*The suspected TB MDR (unconfirmed MDR case)* is a patient suspected of
multi-medication resistance but where there is no temporary confirmation by ABG of the following - examples:
a) failure of treatment / retreatment for TB;
b) relapse of a patient who had a history of MDR TB treatment;
c) close contact with a known case of TB MDR;
d) children with TB MDR;
e) positive result for GeneXpert test with detected RMP resistance.
For the TB MDR suspect, individualized anti-tuberculosis treatment may only be initiated if the agreement of the MDR Commission is provided, and the case has been re-evaluated to obtain the phenotypic antibiogram. At the time of initiation of individualized treatment, the case is declared according to the situation under one of
the TB MDR case categories.
MDR patients will be evaluated every 12 months (during which time the treatment continues), but the final assessment will be done 24 months after MDR treatment
and 36 months after for XDR cases or at any time before the above mentioned deadlines, if an irreversible situation occurs (abandonment, treatment failure,
lost patient, death).During an interval between 24 and 36 months regular monthly monitoring is performed for bacteriological evolution (microscopy and culture). In the case of a persistence of a positive culture, antibiogram will be performed
using the most recent culture obtained within 6 months after the previous ABG.
The patient who maintains quasi-positive positive culture 8-12 months after the start of individualized treatment, will be declared "Failure" and shall be re-registered accordingly (see page 37).
**Conversion of culture** is recorded when after starting treatment for TB MDR, an initially positive culture patient, has two consecutive controls (performed in the interval of at least 30 days) with a negative result in culture.

**Page 32**TB MDR cases are reported, declared and registered both in the TB Register and in
the electronic application for the management of TB endemic data.
When MDR TB diagnosis is confirmed and case registration is completed, it should be input in a special field for TB MDR, where registration data, treatment schedules , adverse reactions, monitoring and evaluation are recorded.
MDR TB cases can be introduced into the application from both the DPF database and the two Centres for Drug-Resistance to TB Treatment in Bucharest and Bisericani.

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8. TUBERCULOSIS WITH GERMS RESISTANT TO ANTI-TB MEDICINES**In the case of H or R mono resistance, an extension of the individualized anti-tuberculous treatment of up to 9-18 months is recommended according to Annex 11 of this Methodological Guide.
Drug-resistant TB treatment is of particular practical importance due to high costs
, which also involve difficulties caused by prolonged duration, with drugs that are hard to tolerate.
……..

It is recommended to hospitalise all positive patients . Care and Treatment Centres for drug-resistant patients (MDR Bucharest Centre within IPMN and IPMN) and MDR Bisericani Centre of Neamţ District) should be used for the treatment of as many as possible patients in the intensive phase. Other hospital units undergoing drug treatment line type II must provide the bacteriological investigations necessary for monitoring in a laboratory equipped with a high quality management system. Also, these units must take appropriate measures to control the transmission of TB infection. It is recommended that patients remain hospitalized at least until the microscopic sputum result is negative, preferably until conversion of culture (minimum 2 consecutive negative cultures).
For patients where MDR Centre Committees do not identify therapeutic resources, it is required to take all necessary measures to isolate the cases in order to limit the transmission of the infection, at home or in the appropriate hospital settings.

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**2. Prophylactic treatment (chemoprophylaxis**)
The purpose of prophylactic (chemoprophylaxis) TB treatment is to prevent the development of active tuberculosis in people who have come into contact with a source of infection (TB patient with pulmonary positive microscopy), or individuals with ITBL.
It specifically targets children, adolescents (12-16 years) and young people (up to 19 years).
When determining the indications for the administration of the prophylactic treatment, the following criteria of interpretation of the tuberculin skin test has to be taken into account, but also the age and state of immunity of the person under examination (see ITBL treatment).
**Indications of prophylactic treatment:**
The first step is to exclude an active TB!
1. New-born in the TB outbreak location:
a) untreated TB source case found at the moment of a birth of a child: BCG is administered in maternity, the new born is isolated for 2-3 months (until the source gives negative results), without administration of treatment.
b) known TB source case, known in the DOT for at least 6 weeks: BCG is administered in maternity; no new-born treatment is given to new-born.
c) when source or new-born cannot be isolated: Isoniazid prophylaxis as a daily rate for 3 months at home for a new-born, then TCT (IDR to PPD); in the following situation:
i. Negative TCT - the new- born is vaccinated with BCG;
ii. Positive TCT - chest X-ray is performed and if:
• X-ray scan is without alterations - prophylactic treatment for another 3 months;
• X-ray scan with alterations – considered as TB disease, so anti TB treatment to be applied.
2. **children and adolescents up to 19 years from TB outbreak location:**a) those with positive TCT will undergo prophylactic treatment for at least 6 months;
b) those with negative TCT, prophylactic treatment for 3 months, then repeated TCT. In the event of a tuberculin (TCT positive) prophylaxis continues for at least 6 months, and in the case of TCT negative treatment it is discontinued only if the contagious source disappears (negative bacteriological result or isolation).
**3. adults up to 35 years of age, only among those at risk and with positive TCT:**a) immune deficient diseases (leukaemia, lymphomas, Hodgkin's disease, acquired immune deficiencies or acquired);
b) drug immunosuppression (anticancer chemotherapy, steroids);
c) chronic renal failure;
d) pneumoconiosis;
e) insufficiently controlled insulin-dependent diabetes mellitus;
f) malabsorption syndrome, chronic undernutrition, chronic duodenal ulcer;
g) gastrectomised patintes, especially those with poor nutrition.

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1. **persons subject to anti-TNF alpha immunosuppressive biological therapy, regardless of age, if a latent TB infection can be proven;
5. organ transplants or stem cells, regardless of age, if latent tuberculosis infection is confirmed;**Diagnostic algorithm of latent tuberculosis infection in patients undergoing biological therapy is set out in Annex 27 of this Methodological Guide.

**Therapeutic Treatment schemes:**
a) Contagious drug-sensitive TB cases - ITBL treatment consists of monotherapy with
Isoniazid (H) given daily (7/7) 10 mg / kg / day in children, 5 mg / kg / day, in adults
(maximum 300mg / day) for 6-9 months for immune competent cases or 9-12 months for
immunocompromised ones. For drug prophylaxis with isoniazid, association is recommended
with pyridoxine (vitamin B6), 5-10 mg / day for the child and 250 mg for adults.
Double or multi-drug prophylaxis is, in principle, prohibited.
b) HB-resistant TB cases - ITBL treatment can be considered with rifampicin for 4-6 months for daily administration.
c) TB cases MDR / XDR - there is no international consensus on indications and
therapeutic treatment schemes used to treat ITBL in these situations, the decision to institute
prophylactic treatment will be taken by the medical team in the following way:
i. In the case of contacts at high risk of progression of latent infection with germs multidrug resistant to disease (poor immune status)`, a prophylactic treatment is recommended, whereas immunocompetent contacts may have a treatment without supervision for at least 2 years; the algorithm for diagnosis of ITBL in TB MDR / XDR contacts is provided in Annex 28 of this Methodological Guide;
ii. recommended schemes of prophylaxis (in daily administration):
• Pirazinamide (25-30 mg / kg body weight / day) plus Etambutol (15-25 mg / day);
• Pirazinamide (25-30mg / kg / day) plus a fluoroquinolone with anti-TB activity
(Ofloxacin or Levofloxacin).
iii. recommended duration: 12 months for immunosuppressed and at least 6 months for
immunocompetent cases to whom initiation of prophylactic treatment was indicated.
The prophylactic treatment leaflet (chemoprophylaxis) is provided in Annex 29 of this Methodological Guide.
Prophylactic treatment (chemoprophylaxis) is performed once in lifetime!
Repeating of prophylactic treatment is questionable - only if there is evidence of infection with a new stem and it is also recommended for HIV infected children and children with a new TB case positive microscopy.

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**3. Control over transmission of tuberculosis infection**
Measures to prevent tuberculosis transmission aim to limit the transmission of the disease originating from the potentially contagious sources (patients with a positive microscopic examination, aerosols that contain infective particles) to persons who inhaled air that is contaminated with infected aerosols . Airborne transmission of TB is by far the most important, other routes of transmission (through contact, blood, secretions) are considered exceptional.
The most effective method of control over tuberculosis transmission is through
early diagnosis and prompt and effective treatment of tuberculosis cases.
In each health department and for each department, it is necessary to evaluate the risk of transmission of tuberculosis; this is due to the presence of sources and procedures in the concerned area. Depending on the degree of risk, tuberculosis control measures are established and to be applied, as set out in a Tuberculosis Transmission Control Plan
unit (CT-TB).
The CT-TB plan includes a set of managerial activities and three types of control measures:
administrative, environmental control (sometimes called "engineering") and respiratory protection.
Managerial activities are used by the management / manager of the sanitary unit to
provide support and authority for the implementation and monitoring of the CT-TB plan.
Managerial activities at the level of the Pulmonology and Phthisiology health unit:
1. Identifying and appointing a person (s) responsible for CT-TB in the unit;
2. Tuberculosis transmission risk assessment in the unit and separately for each unit /
compartment;
3. Elaboration of Tuberculosis Transmission Control Plan in the Sanitary Unit, taking the risk assessment and allocated budget into account;
4. Reorganization or arrangement (where appropriate) of premises, and epidemiological schemes depending on the risk of transmission of tuberculosis;
5. Training of CT-TB personnel;
6. Advocacy, Communication and Social Mobilization (ACSM) in collaboration with Health Administration and other institutions;
7. Supervising the occurrence of tuberculosis among employees;
8. Participation in operational research activities;
9. Monitoring and evaluation of CT-TB activities.
Administrative measures are designed to reduce risk by avoiding contact with people with
contagious tuberculosis; have high efficiency and relatively low deployment costs. The main
administrative measures to control the transmission of tuberculosis are represented by:
1. Triage (quick identification, separation, and monitoring of people with TB)

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a) suspected cases of tuberculosis will be isolated in special wards until obtaining
bacteriological test result;
b) patients diagnosed will be separated by a level of resistance spectrum, multidrug
resistant patients being placed in wards with as few beds as possible
c) the period of hospitalization should be reduced to a minimum; negative bacteriological results cases and cases where home isolation is possible can be treated as outpatient if treatment is provided directly and can be observed with the appropriate monitoring; hospitalized cases will be maintained as long as necessary to ensure the effectiveness of the treatment, and monitoring of the side effects.

It is accepted that the period of infectivity for the sensitive cases does not exceed 2 weeks after initiation of treatment; for cases with multi-drug resistance to tuberculosis, the contagiousness also decreases rapidly after the start of the effective treatment, however, it is recommended to maintain the isolation until negative sputum microscopy is obtained.
Environmental control measures aim to reduce the concentration of infectious particles
from the air. They are represented by ventilation and ultraviolet radiation.
Maximum use of natural ventilation is recommended in the absence of mechanical ventilation. In the areas with a high risk of transmission of tuberculosis (sections with contagious patients, in particular , MDR or XDR, mycobacteriology laboratories, potentially procedures rooms with infective aerosols) mechanical ventilation with negative pressure is recommended.
The use of UV radiation is recommended as an additional measure in the spaces where infected aerosols can be encountered (wards dedicated to patients with suspected TB or transmissible forms of TB, waiting rooms, TB patient consultation rooms, procedure rooms,
transit of patients with tuberculosis, mycobacteriology laboratories). Use of the devices that irradiate the top of the room is recommended (preferably those that produce a horizontal flow of UV radiation), allowing people to live permanently. Intensity of radiation at the height of 1.80m should not exceed 0.2uw / cm2. Calculation of norms for the
devices will take into account that a 30W UV lamp has an average efficiency to cover an 18m2 room.
Respiratory protection applies where administrative and engineering measures do not sufficiently protect against inhalation of infective particles and consists of the use of surgical masks
and their application to suspects or patients with potentially contagious TB; they will wear the masks in closed spaces whenever aerosols can be generated in the presence of other people: in waiting rooms during the period of transportation by healthcare car or an ambulance, or in wards in the presence of other people (medical staff, visitors).

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**Information Scheme for TB MDR / XDR cases**
TB MDR cases are reported, declared and registered both in the TB Register and in the
software.
When the TB MDR case is diagnosed, a special field must be filled out for TB MDR where additional data is added to the data already registered for that case, this is for
both purposes: for registration and monitoring, and for evaluation. Thus, it will be mentioned whether the patient is an alcoholic, if he lives alone or with other people in the house, the degree of agglomeration of the dwelling. The source of the medication must be mentioned: PNPSCT, GLC or Norwegian funds. In addition to bacteriological monitoring, clinical monitoring will be recorded, as well as body weight, adverse reactions and radiological development.
TB MDR / XDR cases can be entered into the software data from both :DPF and CMS
Excellence for TB MDR in Bucharest and Bisericani. The moment such patient appears
in-house or out of the Centers of Excellence, the data will be transferred to the software

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in the same way it is transferred for any case between 2 DPFs. Validation of evaluation of the treatment results of a MDR / XDR TB case where a patient is admitted to one of the Centres of Excellence has to be done by that Centre and not by the CTJ.
Case’s input in the software data at the DPF level will be automatically viewed by the 2 Centres of Excellence of TB MDR in Bucharest and Bisericani. They will prepare the National Registry of TB MDR / XDR cases in both electronic and paper formats.
**Statistical reports**
Various reports are presented to the Bureau of Statistics on a regular basis: monthly, quarterly, and yearly, by the District Public Health Administrations or MS, CNSCBT, CNSISP.
**1. Sickness record of TB patients**
Local units report to the DSPJ as often as quarterly and annually, the morbidity indicators (global incidence, the incidence of new cases and relapses, the incidence of TB illness among the infant population) for each district, from where the data is transmitted to UATM and hence after centralization, they are reported to MS - DSPCSP and CNSISP.
The delivery term is the 31st day of the month following the analyzed quarter.
At a national level, statements reflecting statistics for the previous year will be handed over by March 31 both at MS, CNSCBT and CNSISP.
TB Patient Record or TB File will be sent to ECDC in TESSy format.
(TESSy is the software for collecting data on TB and other communicable diseases in the EU) under the delivery deadline established by the ECDC. At the time of writing this document, the deadline for submission is August 30th, for previous year statements.
2. **The instantaneous prevalence of patients in treatment as per December 31st**
It includes all cases that are currently in treatment (those where the completion of treatment has not been registered). This prevalence offers values ​​close to prevalence
of the registered patients with TB at a certain date that are situated under normal epidemiological surveillance of the territory (without therapeutic abandonment, lost for treatment or chronic diseases with poly-chemo-resistance, who have no possibility to have therapeutic treatment).
3. **Evaluation of the results of anti-tuberculous treatments administered to patients with TB registered during the previous year**

This report is completed at the end of the year in progress, for cases declared during the previous year. The therapeutic success rate is one of the relevant indicators on the efficiency of the TB control measures applied within this certain territory. Failure rates, therapeutic abandonment cases, death during treatment, transfer from one territory to another and patients lost for
observation have to be calculated as well.
These rates are calculated differently, by categories of patients, depending on bacteriological confirmation and location, referring to the number of evaluable patients (difference between the number of registered patients and unconfirmed cases).
For ECDC-TESSy, the status of treatment evaluations for TB patients will be available at
a time set by the ECDC as follows:
- 12 month assessments for the previous year of registered declaration,

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- 24 month assessment for the previous year with registered declaration for 12
month assessment;
- 36 month assessment for the year before for the year before with registered declaration for 24 month assessment;
At the time of writing this document, the deadline for submission is August 30th, for 12 month assessments for the previous year of registered declaration.

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**Annex 7**

**COLLECTION OF BIOLOGICAL CLINICAL SAMPLES**
Bacteriological investigation is central for both: the diagnosis and monitoring
of TB cases, and for the evaluation of PNPSCT, that is why all its stages - from the patient's preparation and collection of clinical samples until the reading and interpretation of results - should be treated with great attention.
**General aspects**The quality of pathological clinical samples is essential for achieving trusted results. The following has to be taken into account:
1. The collection and handling of pathological clinical samples has to be done in such way as to:
a) avoid bacterial and fungal contamination of the pathological sample;
b) avoid the spread of germs in the environment;
c) avoid infection of the medical staff involved.
2. The collection and handling of pathological clinical samples is carried out under the supervision of medically trained staff in order to reduce the risk of sample contamination, which has to ensure that a clinical sample from the outbreak area was collected from a correctly identified case and be of a sufficient amount to allow laboratory treatment.
3. Compliance with the GENERAL COLLECTION RULES, namely:
a) In the case of suspected TB, the clinical samples are collected prior to the commencement of anti-tuberculosis treatment.
b) Repeat the bacteriological examination during the days that follow (for suspected pulmonary TB one can collect up to 4 sputum, if the first examinations were negative and suspicion of TB remains).
c) Characteristics of RECIPIENT CONTAINER for sputum collecting:
- made of plastic, non-visible, transparent - to observe the quantity and
the quality of the pathological sample without opening the container;
- with opening (minimum 35 mm diameter) - to avoid contamination of the walls
outside of the container;
- 30-50 ml capacity for sputum and adapted for each type of pathological sample;
- equipped with a cap that tightly closes the container;
- can be easily labeled.
Spontaneous sputum collection in the clinical sector. The first step for a reliable diagnosis
is getting quality clinical samples. Sputum collection:
a) It is performed whenever the diagnosis of Pulmonary TB is suspected;
b) It is carried out in specially designed spaces;
c) It is done after the patient is prepared and informed;
d) It is under the supervision of a medical facility (glass / visor at the collecting box);
e) Follow-up of infection control measures and optimum pathological sample storage conditions: proper ventilation (window), U.V. lamps, masks, refrigerator for storage of
samples (up to a maximum of 4 days), the window door for the collection control.

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Patient should be informed and prepared for the procedure before the collection:
a) Rinsing the mouth with water to remove remainders of food and contaminating bacteria;
b) Making two deep inhalations of air followed by breathing out after each of them
for a few seconds, then a third deep breath is followed by a forced expiration. It
triggers a cough that will ease production of sample;
c) Sputum deposition in the container / vial held below the lower lip.
Junior staff members should check the quality of the sputum after collection. Sputum of good quality is: 3-5 ml in volume, with purulent particles; is often viscous and mucoid; may be fluid, but contains fragments of necrotic tissue; can be stratified in colours from matte white to green.
• If the sputum is insufficient in its quantity, the patient should be encouraged to wait again until the desired result is obtained (some patients take longer for this procedure);
• If you do not get any expectoration, consider the container to be an infectious waste and dispose of it;
• If it is properly collected, make sure the container is tightly closed and label it clearly (on its body, not on the lid);
• Wash your hands with soap and water;
• Give another recipient container to the patient and make sure he understands that the next day a new sample has to be taken, produced immediately after awakening in the morning (in case of unattended collection at home);
• Show the patient how to tightly close the container.
• Take 2 samples for each bacteriological examination, both under medical surveillance
or one self-collected as first sputum emitted spontaneously in the morning.
For people who do not cough and do not emit sputum spontaneously or who swallow sputum (by ex. women) special techniques of sputum collection shall be applied:
a) Expectorant aerosols with 10% NaCl solution;
b) Laryngo-tracheal lavage with sterile physiological serum;
c) Gastric tube using Nelaton or Einhorn probes;
d) Bronchial aspiration or bronchoalveolar lavage by bronchoscopy.
Sending samples to the laboratory is carried out as follows:
a) a sample is sent together with the standard request form, completed in all its parts; a single
form for all samples, with identical identification data per container and per request form.
b) Labeling of the bottles/containers with the name and surname of the patient on the container body, not on its cover/cap.
c) a sample is sent by the designated trained person, in special plastic boxes provided with
compartments for separating the sample containers.
d) Transportation of samples to the laboratory has to be carried out immediately after the collection, or, if this is not possible, they should be kept in the fridge ( at a temperature of 40 degrees), for no longer than 3-4 days ( in order to reduce associated multiplication of flora).

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APPLICATION /REQEUST/ REPORTING FORM
BACTERIOLOGICAL TESTING FOR TUBERCULOSIS
(MICROSCOPY AND CULTURE, GENETIC TEST)

……..

 DR suspect: Contact with MDR case

Repeated Abandon case

Relapse

Overcrowded community

Homeless person

Anti – TB treatment in the last 30 days : YES NO

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Suspect DR: Contact MDR (MDR), Repeated Abandon (AR), Relapse (R), overcrowded (S)
Homeless person (PFA). SPUTA derived from one of these categories of patients is processed by genetic testing and marked “high priority”. Mandatory information: The patient is under anti-TB treatment or not. No genetic test is performed directly for patients during the monitoring period while under anti-TB treatment. Only indirect testing of a culture can be done.

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Annex 10

ALGORYTHM OF TUBERCULOUSIS DIAGNOSTICS

Risk Factors

Risk factors for appearance of TB

* contact with TB patients
* person from the outbreak location of TB
* presence of chronic illnesses which compromise adequate immune system ( DZ, chronic alcoholism, HIV/SIDA infection, smoking)
* pollution of environment
* professional hazards
* poor living conditions
* poor diet

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b) if it is a case eligible for cultivation in the liquid medium, ie suspected of medication resistance to TB (contact with an MDR case, repeated abandon, relapse, overcrowded community, homeless person), infected HIV patient suspected of TB, suspected TB child, one of the processed clinical samples shall be sowed on two tubes with the Lowenstein - Jensen environment and one tube with the liquid environment, the other product sowing only in the Lowenstein-Jensen environment.

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e) positive BAAR samples can be tested genetically through direct testing to confirm MT and
highlighting changes in resistance to RMP or RMP / INH (GeneXpertRif
TB and GenoType-LPA respectively). Eligible cases: suspected tuberculosis with medical resistance (contact with a MDR case, repeated abandon, relapse, overcrowded community,
homeless person), HIV infected patient suspected of tuberculosis, child suspected of tuberculosis.
For cases with a direct preliminary result indicating suggestive changes for
medical resistance, immediately after culture positivity (preferably liquid environment), the sample has to be sent to LNR to make indirect genetic test GenoType (second line) and complete phenotypic antibiogram (line I, line II-a).

k) the culture from T0 for the new contact with MDR will be tested by a conventional method for anti-TB line I and line II immediately after positivity.

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Table 1. Classification of the positive TCT reaction as per CDC/OMS

|  |  |
| --- | --- |
| **Tct ( mm)** | **Risk Group** |
| **>\_5 mm** | **High Risk*** Person infected with HIV
* Recent contact with the TB case
* Persons with fibrotic modification as per chest X-ray with antecedent TB
* Recipients of organ transplantation
* Patients with immunosuppressive medication (equivalent to at least 15 mg / day of prednisone for 1 month or longer, treatment with cytostatic orTNF-alpha).
 |
| **>\_10 mm** | **Average risk:•** recent immigrants (<5 years) from high-prevalence countries• injecting drug users• residents and employees of high-risk institutions (prisons, care facilities for the elderly, hospitals and other health care facilities, institutions for AIDS and homeless patients)• staff in microbiology laboratories• people with clinical conditions that place them at high risk (silicosis, diabetes, chronic renal failure or hemodialysis, gastrectomy, jejunal-ileal bypass,organ transplant, neoplasm, conditions requiring prolonged use of corticosteroids or other immune suppressants such as TNF antagonists)• children <4 years old• children and adolescents at high risk of TB |
| **>\_15 mm** | * people without known risk factors of TB
 |

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If the TCT result is negative, but there is suspicion of TB infection (infant in
close contact with an active TB source), it can be repeated in 6-8 weeks to
check if the negativity is maintained.

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Among the BCG vaccinated population, the greater specificity of the ELISPOT test , the better the accuracy of identification of infected contacts.

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**ALGORITM OF ITBL DIAGNOSTIC AMONG TB MDR/XDR CONTACTS**

|  |
| --- |
| TB MDR/XDR contacts children, teenagers and adults \* |

|  |
| --- |
| Initial ExaminationMedical history Clinical examinationX ray Chest scan  |

|  |  |
| --- | --- |
| TB contacts children/ teenagers  | TB contacts Adults |

|  |  |  |
| --- | --- | --- |
| NORMALClinical examinationX ray Chest scan | TB symptoms orR chest scan results with modifications | NORMALClinical examinationX ray Chest scan |

TCT Evaluation for active TB

NEGATIVE POSITIVE

TCT in 6-8 weeks

NEGATIVE

|  |
| --- |
| Reevaluation in 6 months Clinical examinationX ray Chest scan + TCT for children/teenagers( if initial is negative) |

NB: If reevaluation after 6 months is normal annual reevaluation, as long as the source remains ( index case of TB MDR/XDR)

\*Clinical/para clinical observation for TB MDR/XDR cases where prophylactic treatment has not been applied!

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ANNEX 30
THE MAIN SUBJECTS FOR DISCUSSION WITH PATIENTS AT DIFFERENT
STAGES OF TREATMENT AND IN PARTICULAR SITUATIONS
I. Basic topics to be discussed at the first meeting with the patient, after establishing the diagnosis of TB
The first meeting with the patient provides an opportunity to communicate important information about TB and its treatment. At the first meeting with a patient diagnosed with TB, the following should be discussed :
1. What is TB - infectious disease produced by the Koch bacillus;
2. TB is curable - in 6-8 months of correct and complete treatment;
3. TB treatment - has two phases: an intensive phase and a follow-up phase;
4. The importance of complete treatment;
5. The need for direct treatment follow-up;
6. The spread of TB - airborne disease;
7. Symptoms;
8. Methods of transmission prevention: cough hygiene, adequate ventilation of the premises, necessity for hospital isolation;
9. The importance of collaborating on contact control (family, collectivity, entourage);
10. Disease included in Ministry of Health programs: hospitalization, investigations and treatments are free.

III. What to say or to do when:
1. The patient feels better and wants to discontinue treatment
It should be explained that symptoms can considerably improve in the initial phase of treatment (first 8 weeks). However, if the patient does not continue treatment for the next 6 months, some bacilli tuberculous can survive, inducing the resurfacing and development of microorganisms resistant to medication. Even if the patient feels better, it is important to continue treatment.
2. A new patient wants to take his medication at home (without supervision)
Ask questions to determine the reasons for this decision. Explain that the most newly diagnosed patients are hospitalized during the intensive phase of treatment so that they can be
carefully monitored.

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During the follow-up phase, if it is difficult to get to the dispensary, ask for support
from the family in favour of the treatment. Explain that there is a firm policy to insist that the treatment be monitored directly.
3. The patient missed treatment for 2 days during the follow-up phase (missed two appointments for treatment).
Find out the reasons. Try to solve the problems. Remind the patient as well as
his/her parent / parents about the need to take all doses during treatment. Make another appointment.

4. The patient does not want to do the sputum examination after 5 months of treatment
Explain the need for the exam. Tell both the patient and his / her parent / parents that it is important to be sure that the treatment progresses in a favorable way.
5. The baby's mother says her husband who coughs has no time to investigate TB,
Find out if this mother has told her husband that she has a TB infected baby. Explain that it is important for him to be tested because he could infect others, or re-infect the mother or
the child. Offer to visit her husband or arrange with a colleague to visit him and explain the need of control.
6. Mother is afraid to tell the family that the baby has TB.
Offer to talk to this family about TB. Enlighten the family: the child is not contagious, he is in treatment. Explain how to transmit and how to prevent TB.
7. The patient feels bad about the treatment and wants to stop it
Determine whether the patient's symptoms are caused by anti-TB medication and whether they have minor or major adverse effects. If there are major effects, stop the treatment and send the patient to DPF . If there are minor effects, help him/her to continue his /her treatment. Explain to his/her parents the importance of the right treatment.
8. The patient has no means of transport to attend the dispensary
Find out the reasons. Try to work with the patient / parent-s to find a solution. Ask for
support of local authorities to solve the problem.

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