

JOINT REPORT

ON THE RESULTS OF THE PARALLEL PERFORMANCE AUDIT — PREVENTION AND TREATMENT OF TUBERCULOSIS

Eastern Partnership Regional Fund
For Public Administration Reform



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PREAMBLE

Note the following

This international parallel audit was carried out as part of the activities of the Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ), on behalf of the German Federal Ministry of Economic Cooperation and Development (BMZ), supported via the EaPRF – Project “Strengthening the capacity of Supreme Audit Institutions (SAI) in the Eastern Partnership countries to monitor the achievement of Agenda 2030 objectives.”

The intended project aimed to strengthen the capacities of SAIs of the Eastern Partnership countries in the application of International Standards of Supreme Audit Institutions (ISSAIs) for Performance Auditing and implement the parallel performance audit on Prevention and Treatment of Tuberculosis.

The project placed a particular emphasis on auditing government policies and measures to implement the Sustainable Development Goals (SDG 3- Health and Well-being).

In the process of planning and carrying out the parallel audit, parties followed INTOSAI standards (ISSAIs 300, 3000 – performance auditing; ISSAI 5800 – Guide on Cooperative Audits) national standards and audit guidelines, as well as the provisions of the “Common position paper concerning the cooperation”, signed by the SAIs of Azerbaijan, Georgia and Ukraine in Kyiv October, 2019.

A parallel audit refers to an audit that is carried out simultaneously in several SAIs with the objective of facilitating mutual learning, capacity building and identification of best practices. Parallel audits share methodologies and audit approaches among cooperating members, but have separate audit teams from each SAI that report to their own institution and act within their own mandate.




Independent audit reports within the national mandates were prepared by the SAIs of Azerbaijan, Georgia and Ukraine. The coordinator of the international parallel audit was the SAI of Georgia.

The scope of the parallel audit mainly covered 2016-2019 period and was determined as follows:

1. Early detection and preventive measures of TB;
2. Proper treatment of TB infected patients.

Project created opportunities for participants to share different experiences and practices through-out the audit process. The project offered blended (trainings, workshops, online conferences) learning formats for participant SAIs on performance audit practices.

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GLOSSARY OF TERMS

TB – Tuberculosis

WHO – World Health Organization.

SAI – Supreme Audit Institution

MDR/XDR Tuberculosis – Drug-resistant forms of tuberculosis

MOH – Ministry of Health

PHC – Primary Healthcare

Epidemiologist – A specialist of the Municipal Public Health Center involved in identifying individuals who come into contact with a TB patient.

Epidemiological study – Finding persons in contact with a patient with tuberculosis for their assesment and further study

Index Patient – A newly identified or previously treated, TB patient with regards to whom there is a risk of his/her contact with other individuals in a family or similar cohabitation.

Contact – Any person who is in contact with a person with pulmonary tuberculosis

Adherence to treatment – Following the prescribed treatment regime by the patient

Involuntary Isolation – TB patient's isolation from the community without his/her consent to avoid an imminent threat to public health

Incidence – the number of new cases of the disease in a given population and defined period of time

Prevalence – The number of cases of the disease in a given population and defined period of time

EXECUTIVE SUMMARY

AUDIT MOTIVATION

Tuberculosis is one of the most dangerous and widespread infectious diseases worldwide.¹ According to the World Health Organization (WHO) data of 2018, about 10 million people worldwide were infected with tuberculosis, of which 1.5 million died.

According to the economic analysis conducted by the international company "KPMG"², the world economies are losing an average from 0 to 2% of their GDP per year due to the damage caused by the spread of tuberculosis. In Western European countries, where the prevalence of tuberculosis is less than 10 per 100,000 people, the economic effect is negligible, while in African countries, where the prevalence is more than 200 on average, the loss is up to 2%.³

The fight against tuberculosis is a challenge for humanity. This disease mostly affects low-income vulnerable groups and increases inequality in society. Therefore, the fight against tuberculosis is one of the important components of the sustainable development goals.

Azerbaijan, Georgia and Ukraine, along with other UN countries, share the SDG objectives, including eradication of TB by 2030.⁴

The fight against tuberculosis has a specific "The End TB"⁵ strategy, which is adopted by WHO and is shared by all participant countries.

The prevalence of tuberculosis in these countries is still high compared to many European countries, therefore, there is still significant potential for improvement.

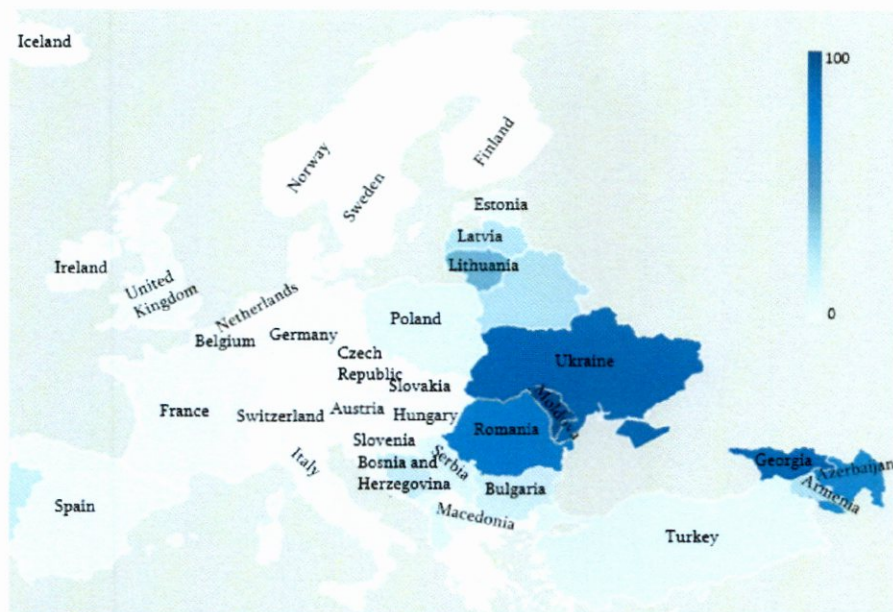
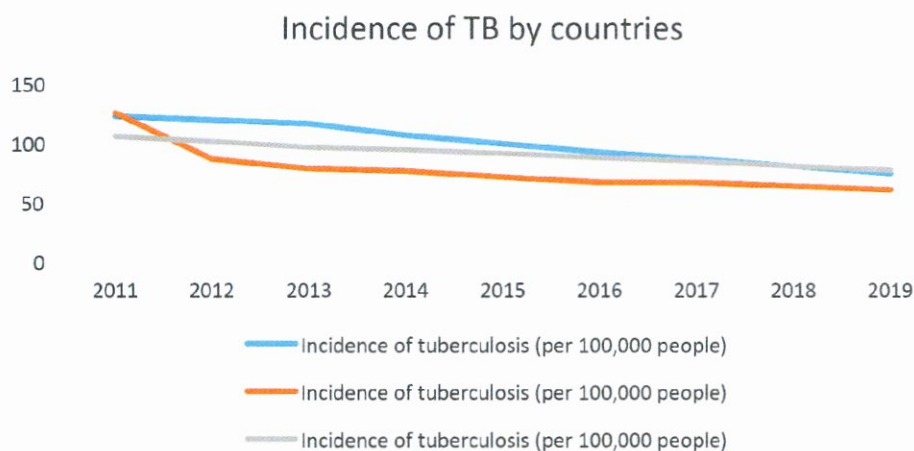
1 https://www.who.int/gho/mortality_burden_disease/causes_death/top_10/en/

2 KPMG, Global Economic Impact of Tuberculosis.

3 In the above calculations, two main factors are taken into account: the loss of the labour force caused by death and the reduction of general capital.

4 SDG 3.3 -end the epidemics of AIDS, tuberculosis, malaria and neglected tropical diseases and combat hepatitis, water-borne diseases and other communicable diseases

5 https://www.who.int/tb/End_TB_brochure.pdf?ua=1

Figure N1. Tuberculosis prevalence per 100,000 in European countries⁶**Figure N2.** Tuberculosis incidence per 100,000 in parallel audit participant countries

Drug-resistant TB is a significant problem on global, regional and country level as well. SAI-s of Azerbaijan, Georgia and Ukraine report the high rate of drug-resistant TB cases. In general, WHO⁷ explains this trend with two reasons: first, improper management of TB treatment, and second, therefore, an increased risk of spreading of the relevant form of TB.

⁶ https://www.who.int/tb/publications/global_report/en/

⁷ [https://www.who.int/news-room/q-a-detail/what-is-multidrug-resistant-tuberculosis-\(mdr-tb\)-and-how-do-we-control-it](https://www.who.int/news-room/q-a-detail/what-is-multidrug-resistant-tuberculosis-(mdr-tb)-and-how-do-we-control-it)

The combination of the above factors entailed the parallel performance audit of anti-TB measures presented in this joint report.

The scope of the parallel audit mainly covered 2016-2019 period and was determined as follows:

1. Early detection and preventive measures of TB;
2. Proper treatment of TB infected patients.

The parallel audit placed a particular emphasis on auditing government policies and measures to implement the Sustainable Development Goals (SDG 3- Health and Well-being).

This Joint Report is based on common findings and conclusions from national audits conducted by the SAIs of the Azerbaijan, Georgia and Ukraine.

FINDINGS AND RECOMMENDATIONS

The SAIs of Azerbaijan, Ukraine and Georgia report some common shortcomings in TB prevention and treatment management systems, which hinder the process of achieving SDG goals and eradication of TB by 2030, specifically:

- › Shortcomings in state policies – Unrealistic goals and indicators; Lack of action plans and efficient coordination of public entities;
- › Lack of medical personnel (doctors; epidemiologists;) – shortcomings in distribution and efficiency of medical personnel that hinder the early detection of disease and proper coverage of the contacts of the TB patient. Epidemiologic studies are performed with a delay that impacts the spread of disease.
- › Lack of qualification and trainings for the medical personnel that cause problems in prevention and treatment of TB.
- › Weaknesses of primary healthcare system (PHC) in detection of high risk groups and early diagnosis of TB;
- › SAIs specially report highest MDR TB infection rate. The treatment of MDR TB is more time-consuming, expensive and, at the same time, less effective. The main factors contributing to the low treatment effectiveness include failed or interrupted treatment. Accordingly, SAIs report that treatment mechanisms are not efficient enough and further improvements of treatment processes are necessary.
- › Lack of public awareness and stigmatizations of disease;
- › Problems of infrastructure – Lack of anti-TB facilities and equipment;

SAIs issued specific recommendations to the auditees (Public Entities), concerning:

- › Improvement of state policies, strategies and actions plans;
- › Improvement of TB detection procedures – epidemiologic database and epidemiologic procedures;
- › Proper distribution of medical personnel;
- › Effective trainings for medical personnel (especially PHC personnel);
- › Strengthening the PHC role in TB management (detection of high risk groups and early diagnosis);
- › Improvement of the treatment mechanisms to decrease MDR TB rate;
- › Increase public awareness about the TB;
- › The proper, optimal and efficient distribution and equipping of anti-TB facilities.

National audit reports include country specific findings and recommendations that are shortly discussed in next sections of the joint audit report.

INFORMATION ON THE NATIONAL AUDITS – FINDINGS AND RECOMMENDATIONS



AZERBAIJAN

Estimates of TB burden*, 2019 ⁸	Number	(Rate per 100 000 population)
Total TB incidence	6 000 (4 600-7 600)	60 (46-76)
HIV-positive TB incidence	94 (65-130)	0.94 (0.65-1.3)
MDR/RR-TB incidence**	1 200 (870-1 500)	12 (8.7-15)
HIV-negative TB mortality	590 (550-640)	5.9 (5.4-6.4)
HIV-positive TB mortality	20 (13-28)	0.2 (0.13-0.28)

AUDIT OBJECTIVE AND QUESTIONS:

The audit objective was to assess the effectiveness of TB prevention and treatment mechanisms in the country. The audit team used a combination of problem-oriented and system-oriented approaches, which foresees analyses of the reasons causing deficiencies and assessment of the proper functioning of the management system.

The audit answered the following questions:

1. How well do TB early diagnosis and prevention mechanisms work?
2. How efficient are the trainings for medical staff?
3. To what extent is efficient allocation of funds for anti-TB actions?

AUDITEES:

A number of organizations are involved in setting-up anti-TB services in Azerbaijan. Hygiene and epidemiology centers are considered one of the important facilities in the system of the Ministry of Health which oversees the implementation of services and sets up the service. TB control facilities are attributed to the other division which provides this service. The following TB control facilities operate in the country:

8 Source – WHO; <https://www.who.int/teams/global-tuberculosis-programme/data>

- › Scientific-Research Institute of Lung Diseases provides scientific and practical assistance to the regions as the center of anti-TB coordination in the country.
- › 6 tuberculosis dispensary
- › 14 tuberculosis hospital
- › 11 tuberculosis departments (with beds)
- › 36 tuberculosis offices under Central District Hospitals
- › 166 DOT (Directly Observed Therapy) facilities
- › 1 Pediatric TB hospitals
- › 4 Pediatric TB sanitarium
- › 3 specialized TB hospitals established for treatment of multidrug and extensively drug-resistant TB (MDR XDR) patients

Audit period covered- 2011 -2018

KEY AUDIT FINDINGS AND RECOMMENDATIONS

LACK OF MEDICAL STAFF AND TRAININGS

Program of Actions on TB Control and the information related to implementation of the measures envisaged in the Program were studied.

No relevant information was provided in the Program of Actions on the number of staff to be trained under the Program, as well as potential measures to address staff shortages in this area. In 2011-2015, training of residents in phthysiology was launched on the basis of the Azerbaijan Medical University (AMU) and 16 phthysiologists completed residency training as a result of that work and in 2017, 5-phthysiologist-resident doctors were admitted to the Scientific-Research Institute of Lung Diseases to take a residency course. Thus, no sufficient measures had been taken to train doctor phthysiologists in higher education institutions to fill the vacancies of 119.0 staff unit doctor phthysiologists.

In 2012, 2014-2016, there were interruptions in short-term courses and training sessions **for primary care physicians**. Moreover, the training of primary care physicians to combat tuberculosis was not ensured completely.

From 2011 to 2017, no training session was held with doctor phthysiologists to study the treatment of drug resistant tuberculosis, and training sessions were not organized in 2012-2014-2015-2016 to transfer the knowledge acquired by the specialists for secondment of the Reference Laboratory to other specialists of the Reference Laboratory to study the susceptibility of anti-TB drugs.

No information was provided on the measures to be taken to relocate the qualified physicians to the vacant doctor phthisiologist positions according to regions under the Program. The number of phthisiologists is insufficient in terms of needs. Concurrently, the existing education and qualification system does not provide healthcare providers with phthisiologists, as well as professional service and awareness-raising of patients.

According to the order of the MOH on approval of regulations of provision of the population with medical personnel in Azerbaijan, 0.04 TB doctors and 0.2 TB beds are defined per 1000 populations. According to the above-mentioned regulation, 1935 beds were provided against 2000 beds in the Republic of Azerbaijan in 2019.

As of January 1, 2018, a total of 329.0 phthisiologist staffs were approved, which comprises 82.25% of the number set forth the adopted regulations. Although the approved number of staff was less than the requirement 119.0 units of the approved staff were vacant. The number of doctor phthisiologists working in the country was 210 persons, which comprises only 63.8% of the approved staff. As a result, according to the regulations of provision of the population with medical personnel approved by the Ministry of Health, the required health workers were provided at the level of 52.5%.

SHORTCOMINGS IN EARLY DIAGNOSIS AND PREVENTION OF ACTIVE AND PASSIVE TUBERCULOSIS

- › The existing system for early diagnosis and prevention of tuberculosis is not entirely effective. This is evidenced by the low level of decline in the number of MDR-TB patients and the poor diagnosis of TB among identified risk groups.

It should be noted that although there had been no impressive reduction in mortality rate in Azerbaijan, (in comparison with Georgia, Russia and Ukraine) this figure has declined since the inception of the Program. There had been 15-20 times less purchase of the tuberculine required for immunodiagnostics in 2011-2018.

- › The diagnosis of tuberculine among the identified risk groups in the country is insufficient, and there are not enough mobile fluorographs for the deployment of active detection among the population groups organized in the country (in industrial and agricultural entities, secondary schools, refugee camps, institutes) and among the people with positive immunodiagnostics.
- › The morbidity rate per 100,000 populations decreased by 1.4 times, while MDR/XDR increased by 1.7 times in 2011-2018. It can be concluded that as a result of improper arrangement of passive and active detection the patients are not detected timely and the level of MDR XDR increases, which requires large financial resources for treatment and prevention. Due to the lack of qualified specialists in phthisiology, the level of sanitation awareness of the population on tuberculosis is low. As a result, awareness of the risk of TB infection is low and TB stigmatization has not been adequately addressed.
- › The program did not include information on the number of activities to be implemented in the field of sanitation awareness of the population on tuberculosis, as well as cooperation with NGOs and the media.

- › The implementation of preventive measures among the population at risk had not resulted in positive changes to combat tuberculosis. There is not sufficient number of bacteriological laboratories. As a result of improper arrangement of passive and active detection, patients are not detected timely and large financial resources are required for treatment and prevention.
- › Concurrently, poor implementation of compulsory health assessment among the entire population, non-compliance of the logistics base of TB control facilities with the established standards have a negative impact on the achievement of the objectives of the Program. Some of the anti-TB drugs purchased prior to 2013 has not been fully utilized. There are delays in reinforcing logistics base of TB control facilities and in the ongoing delivery of TB drugs to patients.
- › While the electronic register and database of patients was expected to be completed in 2011, this work was completed only in 2015.
- › Tuberculosis patients were not also provided with the food ration that met the goal of improving the digestive process, boosting the immunity of the body affected by the infection, and increasing the body's resistance. The food supply system in hospitals increases the risk of TB and other infectious diseases.
- › Although much work had been done for prisoners and ex-prisoners with TB to curb the spread of the disease, these groups remain as high-risk groups. Serious complications were observed along with reduction in the TB content in 2011-2015.
- › The audit shows that in 2011-2015, along with reductions in the TB component, there were serious complications. Thus, the level of tuberculosis, which is considered to be an early form of tuberculosis, remains at the same level and is 4 times lower than the accepted level. the number of primary pulmonary TB patients decreased from 58.3% in 2011 to 1.5% in 2015. The incidence of primary pulmonary TB in 2015 has increased by 10% during the dissolution phase. In 2015, meningitis in primary lung TB patients decreased by 2.7% (242 patients with 882 pulmonary TB) and by 54.2% compared to 5.9% in 2011 (66 patients with 1115 lung cancer). On the other hand, the proportion of fibrosis-cavernous tuberculosis among the lung contingent was 14.3% in 2015, an increase of 18.2% compared to 2011).
- › Thus, as a result of the mantoux test performed on 1,462,997 children aged 1-15 years during the TB prevention campaign in 2011, 16,913 cases of infection (latent tuberculosis) were reported with positive results. As a result of the mantoux test performed on 258,555 children aged 1-15 years over population in the risk group in 2018, 2,374 cases of infection (latent tuberculosis) were reported with positive results. The analysis suggests that the implementation of preventive measures among the population at risk has not led to a positive change to combat tuberculosis.
- › It should be noted that there are other risk areas for the spread of tuberculosis, one of which is livestock. However, in order to take effective measures in this area, it is necessary to establish a system of identification and monitoring in livestock.

SHORTCOMINGS IN ALLOCATION OF FUNDS FOR ANTI-TB ACTIONS

The funds allocated for the Program of Actions has reduced in 2018 compared to 2011.

Although the morbidity rate per 100,000 people in the three main sections of TB control measures decreased by 1.4 times in 2018 compared to 2011, serious complications were observed in the TB component.

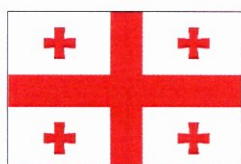
Thus, compared to 2011, the number of MDR-TB patients had increased by 1.7 times in 2018. This requires large financial resources for the treatment and prevention of such patients. In case the required actions are not taken to treat such patients, the probability of serious forms of TB infection will continue to increase across the country. While vaccination, chemical prophylaxis, and treatment of susceptible TB patients detected in a timely manner using infection control are set at 60,0 AZN, the treatment cost of the multidrug-resistant (MDR-TB) patients (who are not detected timely) was 14257,0 AZN.

With regards to the above-mentioned shortcomings, the SAI issued the following recommendations:

- › Implementation of anti-tuberculosis measures in accordance with the National TB Program taking into account the recommendations of the WHO, and review of findings (Achieving criteria such as eradication of tuberculosis meningitis, detection of severe clinical forms, reduction of Extensively drug-resistant and Multidrug-resistant forms) shall be ensured.
- › In order to solve necessary organizational issues:
 - a. Implementation of anti-TB preventive measures in accordance with the clinical protocol;
 - b. Equipping TB healthcare providers with modern laboratory equipment to improve TB diagnosis (TB Dispensary No. 1, TB Dispensary No. 2);
 - c. Organization of simple microscopic and accelerated molecular genetic examination of sputum in primary healthcare facilities;
 - d. Examination of the population by means of mobile fluorographs in enterprises with en masse high risk groups (those with positive immunodiagnostics, the population migrating within the country and abroad, employees of large industrial and agricultural enterprises, institute students, infected secondary school children, etc.);
 - e. Arrangement of infection control in the office, department, dispensary where TB patients are treated (ventilation systems, bactericidal lamps and personal protective equipment);
 - f. To ensure the implementation of necessary measures to restore the operation of kitchens under tuberculosis dispensaries and to eliminate the probability of the spread of tuberculosis and other infectious diseases;

- › To achieve higher performance in the treatment of tuberculosis in order to make more efficient use of public funds:
 - a. It is recommended to define the demand for essential drugs for the detection, treatment and prevention of TB patients, taking into account the indicators of previous years, and to forecast financial resources in accordance with that demand;
 - b. To take necessary measures in this direction to reduce the cost of treatment of TB patients by several times using three main sections of preventive measures in the TB control (Vaccination, chemical prophylaxis, Infection control tools);
- › In order to identify financial needs and sources to increase the logistics base of healthcare providers for TB control;
 - a. Implement necessary measures to bring the logistics base of existing hospitals to the established standards;
 - b. Furnish the TB control facilities with accelerated molecular genetic testing device and fluorescence microscope;
 - c. Furnish the TB facilities with spiral tomography;
 - d. Furnish the primary health care facilities with digital fluorographs;
 - e. To ensure the implementation of necessary measures to provide immunodiagnostics with modern diagnostic equipment (tuberculine, laboratory equipment, mobile fluorographs, etc.) in the country for timely detection of tuberculosis and timely implementation of preventive measures against tuberculosis among the population, especially children and adolescents;
- › Implement the following measures to bring the required number of doctor-phthisiologists to the specified regulations;
 - a. Training of residents in phthisiology on the basis of Azerbaijan State Advanced Training Institute for Doctors named after Aziz Aliyev (ASATID) and Scientific Research Institute of Lung Diseases (SRILD), implementation of necessary measures to organize training sessions on TB treatment and prevention for health workers working in this field;
 - b. To enhance the awareness raising activities of health workers on the methods of primary control of tuberculosis in the treatment and prevention facilities for timely detection of tuberculosis and to take the necessary measures to increase the level of training of health workers in this field;
 - c. Implement necessary measures to increase the knowledge and skills of specialists in the treatment of drug resistant tuberculosis in (DR TB), multidrug-resistant (MDR) and extensively drug-resistant (XRD) tuberculosis;

- d. Involvement of a doctor-phthisiologist and a psychologist in the working group implementing the project "Organization, tracing and social support of TB patients released from prisons in the civilian sector";
- › Necessary work should be done to perform repair work on the basis of the state program of TB control facilities (in the TB dispensary No. 1, Imishli, Sheki hospitals and departments) envisaged in the Program of Actions for 2011-2015.
- › Necessary measures should be taken to increase the awareness of the population about tuberculosis. NGOs and media representatives should be involved in such actions along with phthisiologists, and the scope of awareness-raising activities should be expanded aimed at increased awareness of TB knowledge among population.
- › Necessary work should be done to carry out preventive measures for children aged 1-15 years for timely detection of latent forms of tuberculosis among children, as well as necessary measures should be implemented to deploy a relevant information center on tuberculin testing and the results of relevant preventive measures.
- › Taking into account that proper nutrition is one of the main conditions in the treatment of TB patients, necessary measures should be taken for preparation and norms of dietary food to include into the list of documents.
- › Appropriate measures should be taken to establish an animal identification system.

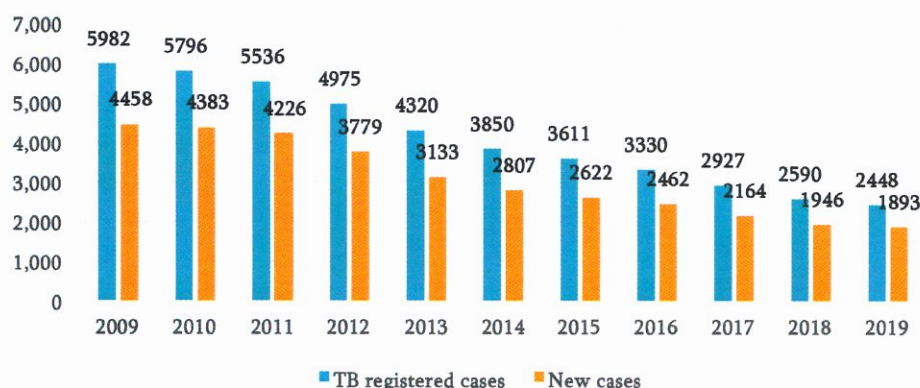


GEORGIA⁹

Estimates of TB burden*, 2019 ⁹	Number	(Rate per 100 000 population)
Total TB incidence	3 000 (2 500-3 500)	74 (62-87)
HIV-positive TB incidence	53 (35-74)	1.3 (0.88-1.9)
MDR/RR-TB incidence**	530 (420-650)	13 (10-16)
HIV-negative TB mortality	150 (140-170)	3.8 (3.5-4.2)
HIV-positive TB mortality	14 (9-20)	0.34 (0.22-0.5)

The significant achievement for the country is the declining trend of the disease, both in terms of prevalence and the number of new cases.

Figure N3 . Prevalence of tuberculosis in Georgia



AUDIT OBJECTIVE AND QUESTIONS:

The audit objective is to assess the effectiveness of TB prevention and treatment support mechanisms in the country. The audit team used a combination of problem-oriented and system-oriented approaches, which foresees analyses of the reasons causing deficiencies and assessment of the the proper functioning of the management system.

The audit answered the following questions:

1. How well do TB prevention mechanisms work?
2. How effective are support mechanisms for TB patient treatment?

⁹ Source – WHO; <https://www.who.int/teams/global-tuberculosis-programme/data>

AUDITEES:

The auditees are as follows:

- › Ministry of Internally Displaced Persons from the Occupied Territories of Georgia, Labor, Health and Social Affairs;
- › LEPL – L. Sakvarelidze National Center for Disease Control and Public Health;
- › JSC “National Center for Tuberculosis and Lung Diseases”.

Audit period covered – 2016 – 2019

KEY AUDIT FINDINGS AND RECOMMENDATIONS**PREVENTIVE MECHANISMS**

Early detection and inclusion of the individuals in contact with TB patients into the treatment is a prerequisite for reducing the risk of spreading the disease. The above mentioned represents a systemic process that involves identification of the contacts within the recommended time, referring them to a doctor for a clinical examination, and, if necessary, inclusion into the treatment process. The treatment process can be for both active and latent forms of tuberculosis in the risk groups.

Epidemiological surveillance mechanism in Georgia is not functioning properly. Most¹⁰ epidemiological studies are performed with delay. The National Center for Disease Control and Public Health lacks the adequate control mechanisms to check if the epidemiological study was carried out in a timely manner and, after its completion, to collect and analyze the information on the identified contact's visit/no visit to the doctor.

For early detection of the disease, in addition to the timeliness of the epidemiological study, the proper coverage of the contacts of the TB patient is necessary, which refers to the number of epidemiological studies conducted for per index-patient. The number of investigated contacts does not ensure that optimal number of cases are identified on early stage of disease.

The epidemiologists' efficiency differs according to the regions as well, being an additional disturbing factor for the proper functioning of epid surveillance mechanism.

One of the important mechanisms for the prevention of tuberculosis is the treatment of the latent TB in the relevant risk groups, especially since the TB prevalence in the country is below 100 per 100,000 people. Although Georgia reached this target 7 years ago, adequate coverage of the risk groups for latent TB treatment is not provided.

¹⁰ In 2016-2019 42-49% of cases.

The human mobility is one of the factors contributing to the spread of TB. In countries with low prevalence, a large portion of cases of tuberculosis is recorded in migrants. As there is a decreasing trend of the spread of the infection in Georgia, the country needs to have a mechanism to assess and reduce the risk of future TB infection originated from the foreign visitors.

PATIENT'S ADHERENCE MECHANISM TO THE TREATMENT

A large proportion of patients (in 2019, 19.4% of patients with resistant TB and 6.2% of those with sensitive TB) discontinue treatment due to the length and side effects characteristic to TB treatment which is a significant impediment to the recovery process. To eliminate the above problem, it is necessary to have mechanisms that support adherence to treatment for patients in order to tailor treatment to the patient's needs.

In Georgia, adherence consultants, psychologists and social workers are helping TB patients to cope with the long and difficult period of treatment. The allocation of these specialists throughout the country is unequal and full range of services is available only in Tbilisi.

There is no unified system of adherence service across the country. Tbilisi Adherence Service and Regional Adherence Consultants are independent entities. This fact leads to different, uncoordinated approaches towards work.

The administration of adherence consultations has some deficiencies. There are no unified data of the conducted adherence consultations. The formation of a unified database of adherence consultations began only in Tbilisi in 2019. Even though this fact can be considered as a step forward, the structure of the database does not allow to record all the necessary information about the patient (information about side effects or other factors that may affect the treatment regimen's safety). There is also no unified guideline for adherence consulting on the country level. While adherence consultations should be organized individually according to the patient's need, it is important to have a unified, pre-defined approach that will be common to adherence consultants across the country.

Improper functioning of the support mechanisms used during treatment contributes to the increase of the number of patients who discontinued treatment, which, in turn, poses a threat to human health and life. Patients who do not follow the treatment regimen result in additional high financial burden. In 31 examined cases of patients who discontinued treatment and developed resistant forms of tuberculosis, the state spent **371,405 GEL** more on their treatment than would have been expected in standard cases of treatment. The latter represents a significant financial resource for the reinvestment in support mechanisms used in treating tuberculosis.

INVOLUNTARY ISOLATION

The Law of Georgia on Tuberculosis Control defines the mechanism of involuntary isolation as an extreme measure.¹¹ Despite the fact that during the audit period in 33 cases there was a need

¹¹ in case the patient with a contagious form of tuberculosis has exhausted all the means, such as taking a mandatory test for tuberculosis, voluntary engagement into the process of treatment, and involuntary isolation is the only way to prevent the spread of infection.

to use the method under the law, no precedent was set for its enforcement due to the lack of an appropriate enforcement mechanism.

With regards to the shortcomings mentioned above, the State Audit Office issued the following recommendations:

National Center for Disease Control and Public Health should:

- › Ensure maintenance of the appropriate unified database for the conduction of the epidemiological studies within the time foreseen under the protocol and tracking the investigated contacts, for the collection and analysis of the information on their visit /absence of a visit to the phthisiologist and elaboration of the necessary control mechanisms which will check the progress of epidemiological studies at pre-determined intervals and, if necessary, take appropriate measures;
- › To increase contact investigation per index patient, take into account the efficiency of epidemiologists in the regional context and, if necessary, consider the possibility of increasing coverage with relevant municipal and public health services.

National Center for Disease Control and Public Health and Ministry of Internally Displaced Persons from the Occupied Territories, Labor, Health and Social Affairs of Georgia should:

- › Develop required mechanisms to increase latent TB preventive treatment coverage in relevant risk groups in collaboration with the involved parties.

National Center for Disease Control and Public Health together with National Center for Tuberculosis and Lung Diseases should:

- › Elaborate unified guideline for conduction of the adherence counseling and the unified database for registration of adherence consultations conducted, the structure of which ensures the collection of the all necessary information about the patient for the improvement of the administration of the adherence consulting process conducted for the TB patients.

Ministry of Internally Displaced Persons from the Occupied Territories, Labor, Health and Social Affairs of Georgia should:

- › Develop a preventive mechanism to assess and reduce the risk of future TB infection by foreign visitors;
- › Together with the involved parties, develop a mechanism for enforcement of the involuntary isolation as a last measure to avoid a threat.



UKRAINE

Estimates of TB burden*, 2019 ¹²	Number	(Rate per 100 000 population)
Total TB incidence	34 000 (22 000-48 000)	77 (50-110)
HIV-positive TB incidence	7 800 (5 000-11 000)	18 (11-25)
MDR/RR-TB incidence**	11 000 (7 100-16 000)	25 (16-36)
HIV-negative TB mortality	3 200 (3 000-3 400)	7.3 (6.8-7.8)
HIV-positive TB mortality	1 900 (1 300-2 700)	4.4 (2.9-6.2)

AUDIT OBJECTIVE AND QUESTIONS:

Evaluate the current situation and assess the scope of the measures being implemented as well as the achievement of the expected results in the fight against tuberculosis; Identify the main causes of the high TB infection rate and the spread of MDR TB in Ukraine; Assess the effectiveness of the use of material supplies for TB diagnostics and treatment purchased in 2018–2019 and financed from the state budget as well as by grants from the Global Fund; Assess the timeliness and completeness of the administrative decisions and the internal control of the audited parties in this area; Provide recommendations to improve the effectiveness of anti-TB measures.

The audit answered the following questions:

1. Are preventive measures against tuberculosis properly organized?
2. Are the existing mechanisms for treating patients with tuberculosis effective enough?

AUDITEES:

- › MOH (Health Ministry of Ukraine);
- › Centre, State Institution "Public Health Centre of the Health Ministry of Ukraine";
- › Institute of Occupational Health.

Audit period covered – 2016 – 2019

¹² Source – WHO; <https://www.who.int/teams/global-tuberculosis-programme/data>

KEY AUDIT FINDINGS AND RECOMMENDATIONS

SHORTCOMINGS IN TB STATE POLICY

State policy pursued by the MOH to fight tuberculosis does not deliver an effective response to the tuberculosis epidemic in Ukraine that has been ongoing since 1995. Hence, this policy needs a comprehensive revision.

The audit identified the risks of non-achievement of the indicators stipulated in the WHO Comprehensive action plan to fight tuberculosis in the European region in 2016–2021, including:

- › the commitments to reduce the TB mortality rate by 35%;
- › to reduce the TB infection rate by 25%;
- › to improve the indicator of the successful treatment of multi-drug-resistant TB to at least 75% of the cases;

Despite the downward trend in the number of TB cases over the last several years (from 67.6 cases in 2016 to 60.1 cases in 2019 per 100,000 persons), the infection level is still above the epidemic threshold (50 cases per 100,000 persons).

At the same time, according to the WHO, approximately 25% of all TB cases remain undetected in Ukraine every year, which fosters the further TB dissemination.

In 2014, Ukraine for the first time joined the list of top-5 countries with the highest MDR TB infection rate. The treatment of MDR TB is more time-consuming, expensive and, at the same time, less effective. Almost 29% of patients who have been diagnosed TB for the first time have a confirmed resistance to anti-TB drugs. The number of MDR TB cases in 2019 went down by 24% compared to 2016 (7778 vs. 5908 cases). However, the share of patients with MDR TB increased from 14.7% in 2016 to 19.8% in 2019.

To fight TB, central and local bodies of executive power worked on the Action Plan to implement the Strategy for a Sustainable Response to the Tuberculosis Infection, including Chemo-Resistant TB, and HIV/AIDS for the period until 2020, approved by the Ordinance of the Government of Ukraine in March, 2017. However, only 20.7% of the planned measures were fully implemented in 2017–2019.

The funding sources listed in the Action Plan do not contain any concrete figures; the performance indicators do not have any references to any figures either, which makes it complicated to assess the effectiveness of the expenditures and the achieved results in a comprehensive manner. The mentioned plan does not contain any measures related to TB prevention, diagnostics and treatment as well as to the improvement of infection control, which are of paramount importance for reducing the TB infection rate.

Also, the MOH, along with central and local bodies of executive power, failed to start the timely implementation of the State Strategy for the development of the system of anti-TB healthcare services.

In November, 2019, the Government approved the State Strategy to fight HIV/AIDS, TB and virus hepatitis for the period until 2030. The Strategy includes targets to reduce the number of infection rate and to reduce the absolute number of TB-deaths by 80% and 90% respectively compared to 2015, as well as to ensure effective TB treatment, including it drug-resistant forms, at a rate of 90%. The target figures for 2020 are higher than the goals set by the WHO Comprehensive action plan to fight tuberculosis in the European region in 2016–2021.

However, contrary to the above resolution, the 3-year action plans for the implementation of the strategy had not been prepared by the MOH jointly with the central and local bodies of executive power. Thus, no concrete actions had been taken to achieve the strategy's goal – to overcome the TB epidemic as a global threat to public health and the well-being of the population, to reduce the infection, disability, and the mortality rates through the build-up and deployment of effective, innovative and flexible systems for the delivery of quality and affordable services for the prevention, diagnostics, treatment, care and support that are based on the rights and needs of citizens and patients.

The MOH and the State Institution "Public Health Centre of the Health Ministry of Ukraine" do not have any information about the total volume of the funds used in 2018–2019 to fight TB.¹³

LACK OF PUBLIC AWARENESS

Measures taken by the MOH, the State Institution "Public Health Centre of the Health Ministry of Ukraine" and local bodies of executive power to raise the awareness of different population groups concerning TB prevention were not helpful in improving the knowledge about this disease and the ways of its transmission, which became one of the reasons for the low effectiveness of TB treatment, high stigmatization and discrimination of patients with TB as well as the low motivation for timely diagnostics and the completion of the full TB treatment plan.

SHORTCOMINGS IN EARLY DETECTION OF TB

The MOH failed to ensure the proper execution of its own powers concerning the implementation of measures to prevent TB and to reduce the TB infection rate. The MOH does not have any information about the results of the mandatory preventive TB checks among high-risk groups, categories of occupations, production facilities and organizations, which can facilitate increases in TB incidents.

¹³ Including funds for the implementation of the Action Plan, except state budget funds amounting UAH 729,063.00 thousand used by the MOH to purchase materials for TB diagnostics and treatment and funds provided by the Global Fund equal to UAH 2,715.40 thousand to implement training measures in TB treatment

At the same time, according to the healthcare units of oblast and city state administrations, the detection rate achieved through such TB checks was quite low and was equal to 0.2% of the total number of examined persons. Along with that, the MOH failed to make effective administrative decisions to organize the procedure for the early TB detection. As a result, a significant number of patients with TB started the treatment, after the disease had advanced too far.

The MOH had mentioned the prevention of diseases among the key tasks of the reformed primary healthcare facilities. However, it did not develop the algorithm for their timely detection. Not all groups of citizens mentioned in the national legislation are determined as high-risk groups for TB in the list of medical interventions belonging to the primary healthcare.¹⁴

Given the lack of control by the MOH, healthcare facilities failed to ensure the proper check and treatment for contact persons. The coverage rate for this group of persons in 2018-2019 was equal to 1.4–1.6 contact persons (recommended by the WHO – 5–6 contact persons for one TB infection case), the achieved treatment rate for contact persons in 2018 and 2019 was equal to 83.9% and 80.2% respectively (recommended by the WHO – 100%).

In 2017, 2018 and 2019, preventive vaccination against TB for children aged under 1 year was made for 83.5%, 90.1% and 88.6% of the children respectively, which is below the value recommended by the WHO (95%) and does not ensure proper protection against TB.

SHORTCOMINGS IN TREATMENT OF TB

- › The rate of successful TB treatment recommended by the WHO was not achieved at the national level. Measures taken by the MOH, the State Criminal Prosecution and Enforcement Service, the Defence Ministry and the administrative-territorial units of Ukraine for TB treatment turned out to be ineffective.

According to the data of the electronic registration system “e-TB Manager” and statistical data, the effectiveness of the treatment for patients with drug-sensitive pulmonary TB that started in 2016, 2017, 2018 was low with 73.2%, 73.1% and 74.3% respectively, compared to 85% recommended by the WHO.

The effectiveness of the treatment for patients with MDR TB and XDR TB that started in 2015, 2016, 2017 was low as well (50.8%, 49.4%, 51.0% as well as 36.7%, 37.1% and 34.4% respectively) compared to at least 75% recommended by the WHO. The main factors contributing to the low treatment effectiveness include failed or interrupted treatment as well as the death of patients with TB resulting from other diseases.

¹⁴ For instance, the list does not mention children and adults with immune system diseases, smokers, persons consuming alcohol in an excessive manner or consuming drugs, immigrants and refugees from regions with the high TB infection rate, internally displaced persons, persons living under the poverty limit, unemployed persons, homeless persons, patients of psychiatric facilities, employees of penitentiary facilities, employees of psychiatric and healthcare facilities who are frequently in contact with TB patients and make TB checks and tests, persons who are or used to be exposed to silicium dioxide in their work (mainly coal-miners and metallurgy workers), persons with fibrotic scarring in their lungs detected for the first time who have not been treated for TB.

Medical and social support in line with the treatment protocol has improved the nationwide effectiveness of TB treatment significantly. However, for TB patients not covered by this support the treatment effectiveness was significantly lower; this makes clear that the criteria for the selection of patients shall be improved, anti-TB facilities shall comply with these criteria, and categories of patients shall be prioritized for selection accordingly.

- › The MOH failed to effectively organize and to coordinate the management reform of the network of anti-TB facilities. As a result, by the decisions of the local bodies of executive power in 2018–2019, the number of anti-TB facilities had been reduced by 32 facilities (18.9%) compared to 2017, the number of beds had been reduced by 3371 units (15.6%). Further 3254 beds (28.6%) are planned to be cut in 2020.
- › Given the implementation of the new funding model for healthcare facilities based on the volume of provided healthcare services (funding through the National Health Service of Ukraine) and the lack of funds in the local budgets, there is a risk that local bodies of executive power will be forced to continue re-organisation or cutting down their anti-TB facilities, which could make TB treatment less affordable and worsen the overall epidemic situation in Ukraine.
- › Local bodies of executive power and healthcare facilities involved in TB treatment in 2018–2019 failed to implement appropriate organisational and administrative measures to ensure control over the spread of TB and to prevent TB by tackling its transmission mechanisms. As a result, the infection rate among the employees of anti-TB facilities in 2018–2019 (this figure serves as the effectiveness indicator of TB infection control) increased by 3.3% and 39.4% respectively compared to 2016 (2018 – 22 and 2019 – 29.7 infection cases per 10,000 employees of anti-TB facilities; 2016 – 21.3 infection cases).
- › The MOH and the State Institution “Public Health Centre of the Health Ministry of Ukraine” failed to fulfil the requirements of the Global Fund concerning the transition from the donor to government funding for anti-TB programmes in 2018–2019. Hence, there is a risk that there could be gaps in government funding for anti-TB measures, if the Global Fund reduces its financial commitments for Ukraine.

In 2018–2019, the MOH did not exercise its powers stipulated in the Regulation on the Health Ministry of Ukraine ¹⁵, nor did it monitor the implementation of the respective programmes and the use of the grants provided by the Global Fund. The MOH did not grant those powers to any of its units.

- › The MOH and the State Institution “Public Health Centre of the Health Ministry of Ukraine” failed to implement an effective system of internal control over the use of material supplies financed from the state budget and by the Global Fund. The availability of medicines, tests and supplies for TB diagnostics and treatment in the administrative-territorial units of Ukraine was not monitored. As a result, medicines and medical supplies in the amount equal to UAH 886.3 thousand financed from the state budget in 2011–2017 and provided to the MOH under the

¹⁵ approved by the resolution of the Government of Ukraine No. 267 of 25 March 2015

budget programme remained unused because of expiration date, a part of those medicines and supplies valued at UAH 686 thousand was disposed of. For the same reason, medicines and medical supplies financed by the Global Fund (UAH 20,853.6 thousand) remained unused as well; a part of those medicines and supplies valued at UAH 19,756.0 thousand was disposed of. Due to the long advance payment procedure established by the Government of Ukraine and the amendments in the treatment plans for MDR TB implemented in line with WHO recommendations, medicines amounting UAH 840.8 thousand remained unused due to their expiry date.

For the same reason, there is a significant risk of financial losses for the state due to the failure to use the medicine "Capreomycin" amounting UAH 52,816.30 thousand before its expiry date.

BASED ON THE AUDIT RESULTS, THE ACCOUNTING CHAMBER RECOMMENDS AS FOLLOWS:

- › The MOH, the Ministry of Justice, the Defence Ministry, oblast (city) state administrations should be instructed to implement effective measures to improve the treatment effectiveness for drug-sensitive pulmonary TB, MDR TB and XDR TB;
- › Oblast (city) state administrations should be instructed to implement measures for TB infection control in anti-TB facilities.
- › The decision of the Accounting Chamber and the report on the results of the performance audit of anti-TB measures should be sent to the MOH along with the following recommendations:
 - State policy to fight TB should be revised to raise TB awareness among the population, to ensure the early detection of patients with TB (including high-risk groups for TB), to improve the effectiveness of the treatment of such patients aiming to overcome the TB epidemic and to fulfil the international commitments of Ukraine;
 - The preparation of the action plan for the implementation of the State Strategy for the Development of the Anti-Tuberculosis Medical Assistance System for the Population (approved by the resolution of the Government of Ukraine No. 1414-r of 27 November 2019) should be accelerated. The action plan should contain measures contributing to the development of the anti-TB healthcare system to overcome the TB epidemic; it should also stipulate measurable performance indicators for these measures, funding sources for these measures and their volume;
 - The preparation of 3-year plans for the implementation of the State Strategy to Fight HIV/AIDS, Tuberculosis and Virus Hepatitis for the period until 2030 (approved by the Resolution of the Government of Ukraine No. 1415-r of 27 November 2019) should be accelerated. These plans should contain measures to ensure the early detection of patients with TB, to reduce the TB infection and mortality rate, to improve the effectiveness of TB treatment. They should also stipulate measurable performance indicators for these measures, funding sources for these measures and their volume;

- Specific measures should be prepared jointly with the State Institution "State Institution F.G. Yanovsky National Institute of Phthisiology and Pulmonology of the National Academy of Medical Sciences of Ukraine" and local bodies of executive power to reform anti-TB facilities taking into account the epidemic situation in the administrative-territorial units and the available equipment of these facilities, qualification of the medical staff and the access of the citizens to healthcare services;
 - Jointly with the State Institution "Public Health Centre of the Health Ministry of Ukraine", the valid criteria for the selection of patients with TB should be revised, priority groups of patients with TB should be determined for medical and social care;
 - The effectiveness of the use of the grants provided by the Global Fund should be analysed to make appropriate administrative decisions;
 - One of the MOH units should be appointed to be responsible for the monitoring of programmes and the use of grants provided by the Global Fund;
 - The needs of the administrative-territorial units of Ukraine for medical supplies and medicines in TB diagnostics and treatment should be analysed to ensure their use before their expiry date;
 - Jointly with the State Institution "Public Health Centre of the Health Ministry of Ukraine", an effective system of internal control should be implemented to ensure the appropriate use of material supplies for TB diagnostics and treatment that are financed from the state budget and by the Global Fund;
 - The high-risk groups for TB should be agreed as per the order of the MOH No. 327 of 15 May 2014 "On the detection of patients with TB and persons infected with Mycobacterium tuberculosis" and the order of the MOH No. 530 of 25 February 2020 "On the approval of healthcare standards for patients with TB";
 - The Procedure for providing primary healthcare services (approved by the order of the MOH No. 504 of 19 March 2018) should be revised to receive an algorithm for the timely detection of patients with TB and the inclusion of all high-risk groups named in the national legislation in the list of medical services belonging to the primary healthcare;
 - Amendments to the current regulations should be considered to regulate the cases of late TB detection and TB diagnostics for deceased persons with whom declarations were signed – these cases should be taken into account when calculating the remuneration for doctors providing primary healthcare services.
- › The Institute of Occupational Health should be recommended to take measures to remedy violations and discrepancies detected during the audit and to bring to account the persons responsible for them.

