



E. Lesnic¹, L.D. Todoriko², I.O. Semianiv², A. Niguleanu¹

¹ Nicolae Testemițanu State University of Medicine and Pharmacy, Chisinau, Republic of Moldova

² Bukovinian State Medical University, Chernivtsi, Ukraine

The Impact of the Risk Factors on Generalisation of Tuberculosis Infection During COVID-19 Pandemic

The epidemiological indicators of tuberculosis during the COVID-19 pandemic showed an increased rate of late detected forms of tuberculosis (TB) with multiple sites involvement and unfavourable treatment outcome.

Objective – to establish the impact of the risk factors on progression and generalisation of TB infection in epidemiological context of COVID-19 pandemic (2020–2023) for identification of targeted interventions to mitigate the pandemic's impact on healthcare control efforts, addressing both clinical and social determinants of TB.

Materials and methods. A prospective, case-control study which included 270 patients with pulmonary TB registered during 2020–2023, when the COVID-19 pandemic was declared in the Republic of Moldova, was conducted. The patients were distributed in two groups: study group included 84 patients diagnosed with pulmonary location with associated at least 2 extrapulmonary locations (generalised TB) and control group – 186 patients, diagnosed with pulmonary TB.

Results and discussion. The major risk factors for progression and generalization of TB infection in extrapulmonary sites were: male gender, patient's disadvantaged social economical state, and harmful habits (tobacco smoking and alcohol abuse). The late detection was caused by the barriers in accessing the healthcare services specific to the COVID-19 pandemic period, lack of health insurance and low rate of microbiologically confirmed cases. A strong correlation was obtained between unfavourable treatment outcome and patient's disadvantaged social economical state harmful habits, and lung destruction.

Conclusions. The risk factors which are involved in the generalisation of tuberculous infection are social economical disadvantaged state with associated harmful habits, and conditions defining low accessibility to healthcare services. It is recommended to screen annually the patients with enumerated risk factors and to facilitate their accessibility to specialised healthcare services for early diagnosis and for ensuring the treatment success.

Keywords

Tuberculosis, risk factors, treatment outcome.

COVID-19 infection was assessed by WHO as a pandemic on 11th March 2020 and was established as a public health emergency of international concern [1, 7, 8, 14–16]. The COVID-19 pandemic reduced the number of notified tuberculosis (TB) cases by 18 % from 7.1 million in 2019 to 5.8 million in 2020 with a slight increase to 6.4 million in 2021, 7.5 million in 2022 and stabilization to 10 million in 2023–2024 [14–16]. The dynamics of TB epidemiological indicators reflected the changes in acces-

sibility of TB specialized services and restructuring of the healthcare system, temporary closure or transformation of healthcare facilities into COVID-19 dedicated centers, reallocation of the healthcare staff to COVID-19 centers, financial barriers, isolation and difficulties in accessing transportation to medical facilities and lack of information [1, 8]. These barriers disproportionately affected certain high risk groups, including people with chronic health conditions, older adults, and socioeconomically

disadvantaged populations, marginalized subpopulations, which finally led to an increased rate of late detected generalized TB. The COVID-19 pandemic had a significant impact on specialized TB healthcare system [7]. The main changes were: financial (loss of revenue), operational (shortage of personal, equipment, supplies, delayed care), modification in healthcare delivery (compulsory hospitalisation was replaced with ambulatory anti-TB treatment) which led to long-term changes (weakened the preparedness to a larger health crisis), exacerbated existing healthcare disparities, making vulnerable risk groups to miss the screening measures (chest X-ray/ tuberculin skin test), and in recovery period was identified the requirement to reinforce the BCG vaccination [1, 8].

Despite the decreasing of the epidemiological indicators of TB during the COVID-19 pandemic (by 39 %) from 2019 till 2020 there was identified an increased rate of late detected and generalised forms [2, 5, 6, 9–12]. Generalised TB (GTB) occurs when uncontrolled *Mycobacterium tuberculosis* infection disseminates through the bloodstream, spreads in the lungs and other extrapulmonary organs [2, 8, 11]. According to the specialized publications, the most affected extrapulmonary sites in GTB were: peripheral lymph nodes, bone and joints, meninges and brain, urogenital and gastrointestinal tracts [9]. Findings from multiple studies revealed that GTB follows after the primary tuberculous infection in severely immunocompromised patients (children under 5 years old, elders (≥ 65 years old), in people living with HIV and patients taking the immunosuppressive treatment or anti-TNF drugs) [2–6, 9–12]. Less frequently GTB develop after the reactivation of latent tuberculous infection localized in the dormant foci on the background of diabetes mellitus, malnutrition, smoking and associated chronic respiratory diseases, silicosis or heavy alcohol consumption [9, 12]. The social-epidemiological conditions which were frequently encountered in patients with GTB were close contact with a source of TB infection, lack of BCG vaccination and probably genetic susceptibility. Poverty and overcrowding were identified in almost all patients with TB [2–6, 9–12]. Academic publications showed that beside the complexity of the risk factors, the non-specific symptomatology contributed to late detection and dissemination of the pulmonary TB infection in extrapulmonary sites [2, 6, 10]. General and systemic symptoms which were encountered in patients with GTB were weakness, loss of appetite, weight loss, fever/feverish, night sweats and chills. Constant pulmonary signs were persistent cough lasting more than 3 weeks, progressive dyspnea, hemoptysis and thoracic pain [2, 6, 10]. The extra-

pulmonary symptoms revealed the affected site or organs. In meningeal TB the patients complain were headaches, nausea and vomiting, which progress in stupor and coma. In genitourinary TB there were lumbar pain, pyuria, hematuria and can progress with the enlargement of the scrotal mass and sterility. The patients with abdominal and peritoneal TB often complained abdominal pain, from mild till acute abdomen and melena. In pericardial TB mostly evident are the chest pain, dyspnea and tachypnea, pericardial tamponade with hypotension, tachycardia, peripheral edema, neck vein distention, paradoxal pulse or week/absent peripheral pulses. For tuberculous lymphadenitis there was an enlargement of the peripheral lymph nodes, more often of the posterior cervical and supraclavicular chains with possible fistulation on the skin and scrofuloderma [2, 6, 10].

Scholarly publications concluded that the diagnosis of GTB is a challenge due to a large spectrum of clinical signs and low sensibility of laboratory tests in extrapulmonary TB [2–6, 9–13]. A limited number of researches targeted the clinical and laboratory aspects of GTB, and no one identified the evolving risk factors, difficulties in diagnosis and treatment during the COVID-19 pandemic, which constituted the premise of our study.

Objective – to establish the impact of the risk factors on progression and generalisation of TB infection in epidemiological context of COVID-19 pandemic (2020–2023) for identification of targeted interventions to mitigate the pandemic's impact on healthcare control efforts, addressing both clinical and social determinants of TB.

Materials and methods

The research was a prospective case-control study in which were included 270 patients diagnosed with TB, distributed in two groups: study group (SG) – 84 patients diagnosed with generalized TB (one pulmonary and more than two TB extrapulmonary sites) and control group (CG) – 186 patients with pulmonary TB. All patients were registered during the period 01.01.2020–31.12.2023 and they signed the informed consent. Selected period was defined by the declared in the Republic of Moldova as COVID-19 pandemic [3].

The including criteria in the SG were: age older 18 years, TB diagnosed through the conventional methods (clinical, radio-imagistic, microbiological, histological tests), primary location – pulmonary TB and at least 2 extrapulmonary TB locations. In the CG the including criteria were: age older 18 years, TB diagnosed through the conventional methods (clinical, radio-imagistic, microbiological) and pulmonary location. The patients were investi-

gated by collecting the sputum and other relevant clinical samples from which were performed the Ziehl–Neelson staining for the detection of the acid-fast bacilli, molecular genetic test GeneXpert MTB/Rif and were performed the conventional cultures (solid Lowenstein–Jensen and liquid BACTEC).

The study's schedule included data about:

- biological and social peculiarities, demographic characteristics (living in urban/rural area);
- economical peculiarities: economical state (employed, unemployed, retired, disabled) and health-insurance coverage (presence/lack of health insurance);
- characteristics with high risk: homelessness, migration, infectious contact;
- case-management: methods used for TB detection, medical staff involved in detection, comorbidities, complications and HIV status;
- TB-related characteristics: location (pulmonary/extrapulmonary), results of radiological, microbiological and histological assays, the anti-tuberculosis drugs and the final treatment outcome.

Associated investigations – hemoleucogramme, urine analysis, serum biochemical tests (transaminases, urea, creatinine, lactate dehydrogenase) and the tests for HIV markers were performed in all patient.

The statistical assays used were: the analysis of variance (ANOVA test) and Pearson chi-square test. Statistical significance was determined by the value of $p < 0.05$. Multiple linear regression (RML) was performed for calculating the odds ratio (OR) for evaluation of the risks, which were classified in low (1.1–1.59), medium (1.6–2.59) and high (> 2.61).

Results and discussion

Assessing the extrapulmonary sites, which were associated with affected lungs, it was established that abdominal organs (small intestine, liver, peritoneum and mesenteric lymph nodes) were affected in 26 (25 %) cases, followed by the lymph nodes in 19 (18 %), pleura in 19 (18 %), kidneys in 16 (15 %), spine in 13 (12 %), upper respiratory ways in 12 (11 %), skin-subcutaneous tissues in 4 (3 %) and central nervous system-meninges in 3 (3 %) patients. The most common associations were between pleura, abdominal organs and kidney, which was diagnosed in 19 (22 %) cases, followed by the association between pleura and upper respiratory ways in 12 (14 %). All patients with scrofuloderma were diagnosed with the TB of latero-cervical lymphnodes. Diagnosis of pulmonary TB was established by microbiological methods in 55 (65 %) and by clinical-radiological methods in 24 (35 %) patients. Extrapulmonary TB was confirmed using

the clinical-radiological methods in 28 (33 %), microbiologically in 17 (20 %) and histologically in 9 (11 %) patients. Other investigations established etiological diagnosis in 30 (36 %) cases with extrapulmonary involvement

Assessing patients general data, was determined that in the SG predominated men *vs.* women, with the male/female rate 6/1 compared with 1.4/1 in the CG. Men were 72 (86 %) in SG *vs.* 126 (67 %) cases in the CG and male gender represented a high risk factor for progression and generalisation of TB (OR = 2.9 (95 % CI: 1.45–5.63), $p = 0.04$). While distributing patients in the age groups according to the WHO classification was identified that the youngest groups (between 18 and 44 y.o.) predominated in the SG compared with CG, 61 (73 %) *vs.* 38 (20 %) patients and the age less than 45 was a high risk factor for progression of GTB (OR = 9.1 (95 % CI: 4.5–16.5), $p = 0$). The rate of patients residing in urban localities was statistically higher in the CG 156 (84 %) *vs.* 60 (71 %), while the patients from rural localities were more often in the SG 24 (29 %) *vs.* 28 (16 %). Living in rural area, which is associated with lack of specialised health-care services was a high risk factor for progression of TB infection in GTB (OR = 3.8 (95 % CI: 1.9–7.4), $p = 0$). The demonstrably higher proportion of patients without a stable place of living was found in the SG and was identified as a high risk factor for GTB (OR = 3.1 (95 % CI: 1.4–6.9), $p = 0.02$). So, patients with such risk factors: male gender, young age, residing in rural localities and in disadvantaged social economical state should be the targeted by the systematic screening procedures aimed to promote early detection and reduce the risk for generalisation of TB infection. The data were displayed in Table 1.

Table 1. Distribution according to the biological and demographic peculiarities, n (%)

Indicators	Study group (n = 84)	Control group (n = 186)	p*
Men	72 (86)	126 (67)	< 0.001
Women	12 (14)	60 (33)	< 0.001
<i>Age, years old</i>			
18–24	2 (2)	0	> 0.05
25–34	18 (21)	8 (4)	< 0.001
35–44	41 (49)	30 (16)	< 0.001
45–54	14 (17)	42 (23)	> 0.05
55–64	11 (13)	57 (30)	< 0.001
≥ 65	2 (3)	49 (26)	< 0.001
Urban	60 (71)	156 (84)	< 0.05
Rural	24 (29)	18 (19)	< 0.05
Homeless	15 (18)	12 (6)	< 0.05

Note. * p-value in ANOVA test.

Table 2. Distribution according to the social peculiarities and harmful habits, n (%)

Indicators	Study group (n = 84)	Control group (n = 186)	p*
Low level of academic education	68 (81)	68 (36)	< 0.001
Optimal level of academic education	16 (19)	118 (64)	< 0.001
Employed	12 (14)	61 (33)	< 0.01
Unemployed, students, people with disabilities	76 (90)	125 (67)	< 0.001
Single, divorced, widowed	54 (64)	76 (41)	< 0.001
Active smokers	74 (89)	71 (40)	< 0.001
Active/past drug users	8 (8)	12 (6)	> 0.05
Heavy alcohol drinkers	32 (38)	29 (15)	< 0.001
Returned from abroad	10 (11)	21 (11)	> 0.05
TB contact	21 (25)	19 (10)	< 0.01

Note. * p-value in ANOVA test.

The social peculiarities, which were assessed were: the last level of the academic education, economical state, harmful habits (tobacco smoking, alcohol abuse) and migrational history (returned from abroad, refugee, displaced). The academic state was divided in two categories: the low level (primary and incomplete secondary), which statistically predominated in the SG 68 (81 %) vs. 88 (47 %) and optimal level (secondary and high education), which was more often identified in the CG 118 (63 %) vs. 16 (19 %). The low academic education was identified as a high risk factor for GTB (OR = 4.6 (95 % CI: 2.6–8.1), p = 0). Disadvantaged economical state (unemployment, people with disabilities, retired and students) was established in a statistically larger share in the SG 76 (90 %) vs. 125 (67 %) cases, and was identified as a high risk factor for GTB (OR = 3.1 (95 % CI: 1.5–6.1), p = 0.04).

Patients without a medical insurance statistically were substantially more identified in the SG – 54 (64 %) vs. 87 (47 %). Single state patients, were more frequently in the SG 54 (64 %) vs. 76 (41 %), being established as a medium risk factor for GTB (OR = 2.4 (95 % CI: 1.5–4.9), p = 0). The harmful habits, such as active tobacco smoking predominated in the SG 74 (89 %) vs. 71 (40 %) cases in the CG, and the chronic alcoholism/heavy drinking in 32 (38 %) vs. 29 (21 %), respectively. So, both unhealthy habits were identified as high risk factors, with a more elevated value attributed to tobacco smoking (OR = 11.5 (95 % CI: 5.4–23.6), p = 0.01), then to chronic alcoholism/heavy drinking (OR = 3.5 (95 % CI: 1.9–6.2), p = 0). Every tenth patient from both groups, was a migrant returned from abroad during the last 12 months, after a staying for more than 3 months. The TB contact in the frame of the family cluster was established in a higher proportion in the SG, 21 (25 %) vs. 19 (10 %) cases in CG, constituting a high risk factor for GTB (OR = 2.9 (95 % CI: 1.4–5.8), p = 0).

Concluding exposed data, was established that the social unfavourable characteristics and harmful habits were the risk factors TB with multiple sites and it would be recommended to be annually screened to prevent the late detection of TB. Exposed data were reflected in the Table 2.

National clinical policy based on international recommendations requires the examination of the symptomatic patients through microbiological assays of the symptomatic cases and the radiological investigation of the high risk groups in the frame of the systematic screening [10]. Studying the case-detection of the patients, it was found that the rate of the new cases was higher in the CG 165 (89 %) vs. 60 (71 %) in the SG and those who were already exposed to anti-tuberculous drugs predominated in the CG 21 (11 %) vs. 24 (19 %) cases.

By the general practitioners were detected more often the patients from the CG 171 (92 %) vs. 51 (61 %) and by the different specialised physicians in the SG 33 (39 %) vs. 15 (8 %) in the CG. Through the symptomatic screening were detected majority of the cases from the SG 168 (91 %) vs. 61 (73 %) in the CG and through the systematic screening predominantly in the CG 23 (27 %) vs. 18 (10 %) cases. While collecting the anamnesis, the acute onset (0–30 days) of the diseases was perceived in 25 (13 %) cases and subacute (30–90 days) in 82 (44 %) cases. All patients from the SG and 79 (42 %) of the CG complained for more than 90 days before diagnosis was established. Such signs of the intoxication syndrome – asthenia, lost of weight, night sweats, fever/feverish and the bronchopulmonary syndrome – cough, muco-purulent expectorations were identified in all patients of the SG and in 112 (60 %) cases of the CG. Assessing the clinical diagnosis, infiltrative form statistically predominated in the CG, 186 (100 %) vs. 61 (72 %) in the SG. Disseminated and cavernous forms were diagnosed more often in the SG, 21 (25 %) vs.

Table 3. Distribution according to the case-detection and case-types, n (%)

Indicators	Study group (n = 84)	Control group (n = 186)	p*
New cases	60 (71)	165 (89)	< 0.001
Previously treated	24 (19)	21 (11)	< 0.001
Detected by the primary healthcare staff	51 (61)	171 (92)	< 0.001
Detected by the specialist	33 (39)	15 (8)	< 0.001
Detected through the symptomatic screening	61 (73)	168 (91)	< 0.001
Detected by active case-finding	23 (27)	18 (10)	< 0.001
HIV-infected	21 (25)	20 (11)	< 0.01
Presence of co-morbidities	80 (95)	96 (51)	< 0.001
Lung destruction	61 (73)	41 (22)	< 0.001
AFB positive (sputum)	47 (56)	38 (20)	< 0.001
GeneXpert MTB/Rif positive	51 (61)	61 (33)	< 0.001
LJ/BACTEC culture positive	55 (65)	40 (21)	< 0.001
MDR-TB	7 (5)	11 (6)	> 0.05

Note. * p-value in ANOVA test.

2 (3 %) in CG, respectively. Both lungs were affected in 65 (77 %) cases and extensive TB in more than 3 lung segments was detected in all patients from the SG compared with 23 (13 %) cases of CG.

Lung parenchymal destruction or cavitation was radiologically identified in a statistically higher proportion in the SG 61 (73 %) vs. 41 (22 %) cases of CG. Microbiological tests were positive in a higher proportion in the SG: AFB assays in 46 (56 %) vs. 38 (20 %) cases of CG, GeneXpert MTB/Rif 51 (61 %) vs. 61 (33 %) and conventional cultures in 55 (65 %) vs. 40 (21 %) cases, respectively. Despite important differences between the rate of positive microbiological tests between the groups, the rate of MDR-TB was similar 7 (5 %) in SG vs. 11 (6 %) in CG. To assess the correlation between the indicators was used Pearson correlation test. It was established a strong correlation between the positive sputum smear results for AFB assays and parenchymal lung destruction (Pearsons $R = 0.7$; $p = 0$), positive GeneXpert MTB/Rif results (Pearsons $R = 0.81$; $p = 0$) and conventional conventional cultures (Pearsons $R = 0.84$; $p = 0$). The microbiologically positive results in feces were obtained in 18 (21 %), in pleural liquids in 12 (14 %) and in urine in 9 (11 %) cases of the SG. It is important to emphasize a higher rate of comorbid patients in the SG – 80 (95 %) vs. CG 96 (51 %). HIV-infected was every fourth in the SG and every tenth in CG. Other comorbidities such as diabetes mellitus were diagnosed in 6 (7 %) vs. 10 (11 %), mental disorders in 12 (15 %) vs. 31 (32 %), respectively (Table 3).

The standardised anti-TB treatment for drug susceptible TB followed 77 (92 %) patients of SG and 175 (94 %) of CG. The treatment for MDR-TB was administrated in 7 (5 %) patients from the SG and 11 (6 %) in the CG. Adverse drug events were

detected in 9 (11 %) patients in the SG vs. 15 (8 %) in the CG. The treatment outcome was unfavourable in 55 (64 %) cases of the SG and among them 37 (41 %) died. Successfully treated were 31 (36 %) patients. Pearson's correlation test was used to assess the correlation between the poor treatment outcome (failure, lost to follow-up and death) with the high risk factors. In the SG it was tightly correlated with low level of academic education ($R = 0.56$; $p = 0$), unfavourable economical state ($R = 0.9$; $p = 0$), tobacco smoking ($R = 0.5$; $p = 0$), and parenchymal lung destruction ($R = 0.7$; $p = 0$).

The actual research evaluated the impact of the conditions associated with COVID-19 pandemic on the share of the risk factors and case-detection of TB, taking into account as a study group the patients diagnosed with severe, generalised TB with multiple locations. The results demonstrated that the biological peculiarities, which contributed to late detection and generalisation of TB were complex, intricate and were related to disadvantaged social economical state and other associated risk factors-harmful habits (active tobacco smoking, alcoholism) and TB contact. Similar results were reported in several local and international research papers [2–6, 9–13]. Other associated risk factors with the greatest impact on the generalization of TB were comorbidities – symptomatic HIV infection, diabetes mellitus, mental disorders similar data obtained in research papers [2–6, 9–13].

Assessing the exposure to the anti-TB treatment was established that those patients were in a larger share diagnosed with GTB and were at the evidence of pneumophysiologist service. Such data were not found in international researches, because the dispensarisation of TB patients is characteristic for former soviet republics. Because the pulmonary TB

location was the including criteria in the research and the lung parenchymal destruction was radiologically detected in a higher share in patients with GTB, the rate of microbiologically positive patients was higher in that group. While evaluating the extrapulmonary location, was established a higher rate of patients which had affected the organs of the gastro-intestinal system, pleura and kidneys, which were confirmed by the microbiological investigations. Synthetically analyzing the clinical research results, was concluded that patients with GTB had a long lasting evolution, clinically expressed and microbiologically positive which contributed to the spread of the infection into the body. The treatment outcome was unfavourable and was tightly correlated with disadvantaged social economical level, tobacco smoking and parenchymal lung destruction.

Conclusions

The case-control study which included patients diagnosed with generalised tuberculous infection

diagnosed during the COVID-19 infection identified that the major risk factors for progression and generalization of TB were: male gender, patient's disadvantaged social economical state, and harmful habits (tobacco smoking and alcohol abuse).

The late detection was caused by the barriers in accessing the healthcare services specific for COVID-19 pandemics period, lack of health insurance and low rate of microbiologically confirmed cases.

A strong correlation was obtained between unfavourable treatment outcome and patient's disadvantaged social economical state harmful habits, and lung destruction.

As practical recommendation with applicative value: screening of the subpopulations with multiple high risks should be supported and continuously ongoing despite the barriers caused by associated pandemic infection aiming early detection, prevent generalisation of TB and ensuring high treatment effectiveness.

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Е. Леснік¹, Л.Д. Тодоріко², І.О. Сем'янів², А. Нігулеану¹

¹Державний університет медицини та фармації Ніколая Тестеміцану, Кишинів, Республіка Молдова

²Буковинський державний медичний університет, Чернівці

Вплив чинників ризику на генералізацію туберкульозної інфекції під час пандемії COVID-19

Епідеміологічні показники захворюваності на туберкульоз під час пандемії коронавірусної хвороби-2019 (COVID-19) свідчили про підвищення кількості занедбаних форм туберкульозу з множинним ураженням легень і несприятливим результатом лікування.

Мета роботи — встановити вплив чинників ризику на прогресування та генералізацію туберкульозної інфекції в епідеміологічному контексті пандемії COVID-19 (2020–2023) для визначення цільових втручань з метою зменшення впливу пандемії на зусилля з контролю як клінічних, так і соціальних детермінант туберкульозу.

Матеріали та методи. Проведено проспективне дослідження типу «випадок—контроль», в яке було залучено 270 хворих на туберкульоз легень, зареєстрованих у 2020–2023 рр. у Республіці Молдова під час пандемії COVID-19. Пацієнтів розподілили на дві групи: основну — 84 пацієнти з легеневою локалізацією та принаймні 2 позалегеновими локалізаціями (генералізований туберкульоз), і контрольну — 186 хворих із діагностованим туберкульозом легень.

Результати та обговорення. Основними чинниками ризику прогресування та генералізації туберкульозної інфекції в позалегенових локалізаціях були: чоловіча стать, несприятливий соціально-економічний стан хворого, шкідливі звички (тютюнокуріння та зловживання алкоголем). Пізнє виявлення було спричинене перешкодами в доступі до медичних послуг, характерними для періоду пандемії COVID-19, відсутністю медичного страхування та низьким рівнем мікробіологічно підтверджених випадків. Отримано сильний кореляційний зв'язок між несприятливим результатом лікування та незадовільним соціально-економічним станом пацієнта, шкідливими звичками й деструкцією легень.

Висновки. Чинниками ризику генералізації туберкульозної інфекції є незадовільний соціально-економічний стан із супутніми шкідливими звичками та умови, що визначають низьку доступність до медичних послуг. Рекомендовано проводити щорічний скринінг пацієнтів із зазначеними чинниками ризику та сприяти їхньому доступу до спеціалізованих медичних послуг для ранньої діагностики та забезпечення успіху лікування.

Ключові слова: туберкульоз, чинники ризику, результат лікування.

Контактна інформація / Corresponding author

Леснік Евеліна Володимирівна, к. мед. н., доц. кафедри пневмофізіології
<https://orcid.org/0000-0002-4259-0227>
MD 2001, Республіка Молдова, м. Кишинів, бульв. Штефан чел Маре, 165
E-mail: evelina.lesnic@usmf.md

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