Current Trends in Tuberculosis Pharmacotherapy: Availability of Essential Medicines

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Received: March 03, 2025
Published: May 22, 2025

Abstract. The article analyzes current trends in tuberculosis pharmacotherapy and the availability of essential medicines. The introduction of short-term treatment regimens, in particular BPaL (Bedaquiline, Pretomanid, and Linezolid), significantly reduces the duration of multidrug-resistant tuberculosis therapy and increases its effectiveness. Expanding diagnostic capabilities, especially the use of artificial intelligence, contributes to improving the detection of the disease. Analysis of legislative initiatives indicates improved access to treatment, but financing remains an important challenge, especially under conditions of martial law. The dynamics of the incidence demonstrates an increase in the number of tuberculosis cases, which requires strengthening preventive measures and screening programs. The prospects for further research and the need to increase state funding to reduce dependence on international donors are highlighted.

Additionally, the growing emphasis on patient-centered care is reshaping programmatic management of tuberculosis. At the same time, integration of tuberculosis services with HIV and diabetes screening is becoming standard practice, reflecting the high prevalence of comorbidities. To meet the WHO End Tuberculosis Strategy milestones for 2030, policymakers must prioritize sustained domestic investment, ensure uninterrupted supply chains, and expand community-based education to address stigma and the social determinants driving transmission.

Keywords: tuberculosis, pharmacotherapy, BPaL (Bedaquiline, Pretomanid, and Linezolid), multidrug-resistant tuberculosis, diagnostics, artificial intelligence, legislation, financing, prevention.

Introduction. Tuberculosis (TB) remains one of the most pressing public health problems, especially in countries with a high prevalence, including Ukraine [1-5]. According to the World Health Organization, in 2022, Ukraine ranked 4th among countries in the European Region in terms of the rate of spread of drug-resistant tuberculosis [6, 7]. In 2023, 18,510 cases of the disease were registered in the country, which is 2.5% more than in the previous year [8].

Despite significant progress in the treatment of tuberculosis, barriers remain that limit the effectiveness of the fight against the disease, in particular, insufficient availability of drug treatment, the complexity of diagnostics, and financial difficulties of patients. In recent years, legislative initiatives have been adopted in Ukraine aimed at improving access to treatment, in particular, Law of Ukraine No. 9147, which provides for expanding the capabilities of diagnosing and treating tuberculosis through regional phthisiopulmonological centers [9].

The global COVID-19 pandemic has significantly impacted TB programs, disrupting access to medical, pharmaceutical services, and pharmacotherapy, reducing funding, which has led to an increase in COVID, post-COVID, and long-COVID disorders, and TB mortality rates of up to 1.5 million in 2020 [10-13]. In addition, the World Health Organization emphasizes the need to intensify measures to restore access to TB care and introduce new treatment methods, including short-term pharmacotherapy regimens, available over-the-counter drugs, and the use of artificial intelligence for diagnostics [14-17].

The purpose of the study was to analyze current trends in TB pharmacotherapy in Ukraine and the world, to assess the availability of life-saving drugs and the impact of legislative changes on the TB care system, and to highlight the prospects for the introduction of new diagnostic and treatment methods.

Materials and methods. The study was conducted by analyzing scientific and regulatory literature on the problems of tuberculosis pharmacotherapy and access to essential medicines. The study period is 2020-2025.

Research materials:

- Official statistics of the World Health Organization on the prevalence of tuberculosis, including drug-resistant forms (https://moz.gov.ua/article/news/358-ukrainciv-projshli-bezoplatne-likuvannja-likarsko-stijkogo-tuberkulozu-za-novitnoju-shemoju-bpal) [18].
- National regulatory acts regulating the system of diagnostics, treatment and prevention of tuberculosis in Ukraine (https://moz.gov.ua/article/news/verhovna-rada-uhvalila-zakon-pro-podolannja-tuberkulozu-v-ukraini) [19].
- Scientific publications on the latest approaches in tuberculosis pharmacotherapy, including the use of the BPaL regimen (Bedaquiline, Pretomanid, and Linezolid) and the use of artificial intelligence for diagnostics [20].
- Data on financing of anti-tuberculosis programs and availability of medicines in different countries.

Research methods:

- System analysis – to summarize modern approaches to the treatment and prevention of tuberculosis.
- Comparative analysis – to assess changes in legislative regulation and availability of medicines in different countries.
- Analysis of regulatory acts and official reports of the World Health Organization to identify the main trends in the fight against tuberculosis.
- Statistical analysis – to assess the dynamics of morbidity and the effectiveness of the implementation of new treatment methods.

The use of an integrated approach made it possible to assess the impact of modern pharmacotherapeutic strategies on tuberculosis control and to determine the prospects for improving the system of medical care for patients with this pathology.

The research of the article is a fragment of research works of Lviv Medical Institute on the topic of "Improving the system of circulation of drugs during pharmacotherapy on the basis of evidentiary and forensic pharmacy, organization, technology, biopharmacy and pharmaceutical law" (state registration number 0120U105348, implementation period 2021-2026); Private Scientific Institution "Scientific and Research University of Medical and Pharmaceutical Law" on the topics "Multidisciplinary research of post-traumatic stress disorders during war among patients (primarily combatants)" (state registration number 0124U002540, implementation period 2024-2029) and «Interdisciplinary scientific and methodological research in the field of pharmaceuticals and veterinary medicine: innovations, modernization, technologies, regulation» (state registration number 0125U000598, implementation period 2025-2031).

Results and discussion.

Modern approaches to the treatment and pharmacotherapy of tuberculosis: a systematic review

The treatment and pharmacotherapy of tuberculosis is a complex and multicomponent process that involves the use of a combination of anti-tuberculosis drugs, the introduction of new treatment regimens, and ensuring the availability of treatment for all categories of patients.

1. Pharmacotherapy of tuberculosis: main trends. The World Health Organization recommends the use of both standard and shortened treatment regimens depending on the type of disease. Traditional therapy for susceptible tuberculosis lasts 6 months and includes 4 main drugs: isoniazid, rifampicin, pyrazinamide, and ethambutol. In the case of multidrug-resistant tuberculosis and extensively drug-resistant tuberculosis, long-term combinations of drugs are used, which can last up to 24 months [21].

   The new standard in pharmacotherapy of drug-resistant tuberculosis is the BPaL regimen (Bedaquiline, Pretomanid, and Linezolid), which significantly reduces treatment times from 18–24 months to 6–9 months. This regimen was introduced in Ukraine in 2022. According to the results of 2023, 1024 patients underwent screening under the BPaL program (Bedaquiline, Pretomanid, and Linezolid), of which 358 were included in treatment. In 80% of patients who completed the three-month course, cessation of bacterial excretion was observed, which indicates high effectiveness of therapy [22].

2. The role of artificial intelligence in the diagnosis of tuberculosis. Innovative approaches to the diagnosis of tuberculosis are being introduced in Ukraine, in particular the use of artificial intelligence for the analysis of X-ray images. In 2024, such systems were installed in phthisiopulmonology centers in Lviv, Sumy, and Ivano-Frankivsk regions. Artificial intelligence analyzes lung images, detecting even minimal pathological changes, which allows improving the accuracy of diagnostics [23].
3. Legislative initiatives and accessibility of treatment. The Law of Ukraine No. 9147, adopted in 2023, provides for the expansion of diagnostic capabilities, the creation of regional phthisiopulmonology centers, and ensuring free access to preventive treatment. It also establishes social guarantees for medical professionals working in the field of phthisiology [24].

   At the same time, global trends indicate a decrease in funding for anti-TB programs: in 2021, global spending on combating TB decreased to 5.4 billion US dollars, which is less than half of the required amount. The main source of funding remains government budgets, but low-income countries are largely dependent on international donors [21].
4. Impact of the COVID-19 pandemic on the fight against tuberculosis. The COVID-19 pandemic has caused a significant reduction in access to tuberculosis services. In 2020, the number of registered tuberculosis cases worldwide decreased from 7.1 million to 5.8 million, indicating underreporting of patients. At the same time, tuberculosis mortality increased to 1.5 million cases due to limited access to treatment [21].

Thus, modern approaches to the treatment, pharmacotherapy and prevention of tuberculosis are based on the introduction of new pharmacotherapy regimens (in particular, BPaL (Bedaquiline, Pretomanid, and Linezolid)), the use of artificial intelligence in diagnostics and expanding access to medication. However, the problems of insufficient funding and the impact of the COVID-19 pandemic significantly complicate the fight against the disease, which requires further improvement of health policy and attraction of additional resources.

Comparative analysis of changes in legislative regulation and availability of medicines in different countries

The fight against tuberculosis requires an integrated approach, including effective pharmacotherapy, a developed diagnostic system and appropriate legislative regulation. This section provides a comparative analysis of the policy to combat tuberculosis in Ukraine, the European Union and countries with a high burden of the disease (Fig. 1, 2, 3).

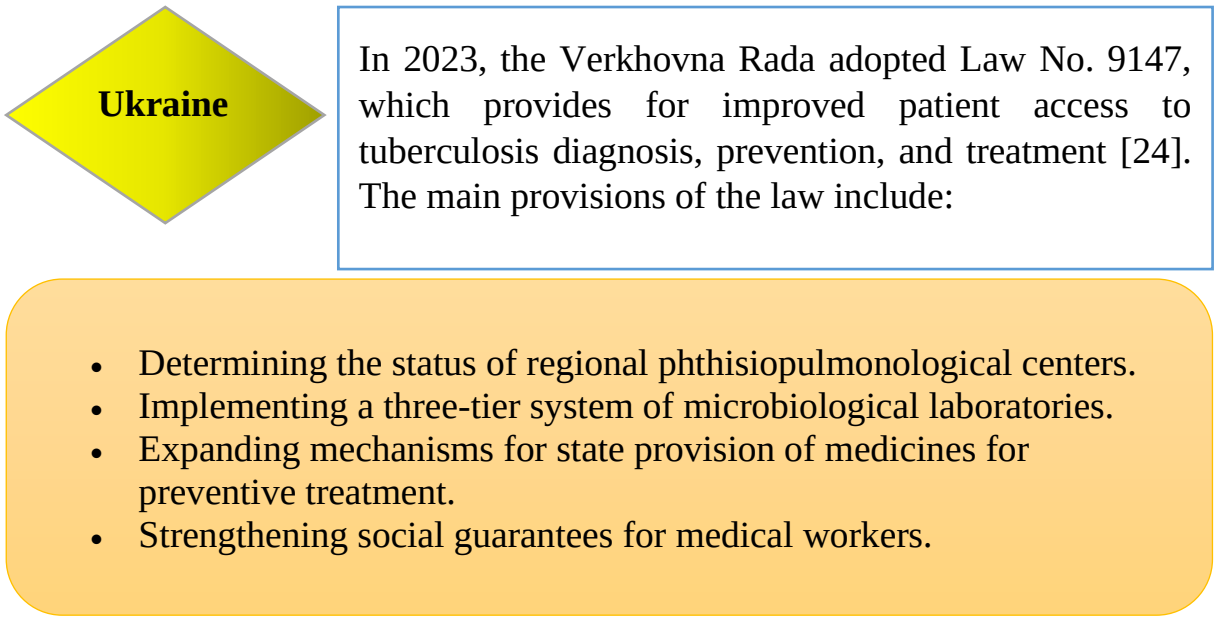

Fig. 1. Legislative changes in the field of tuberculosis prevention in Ukraine.

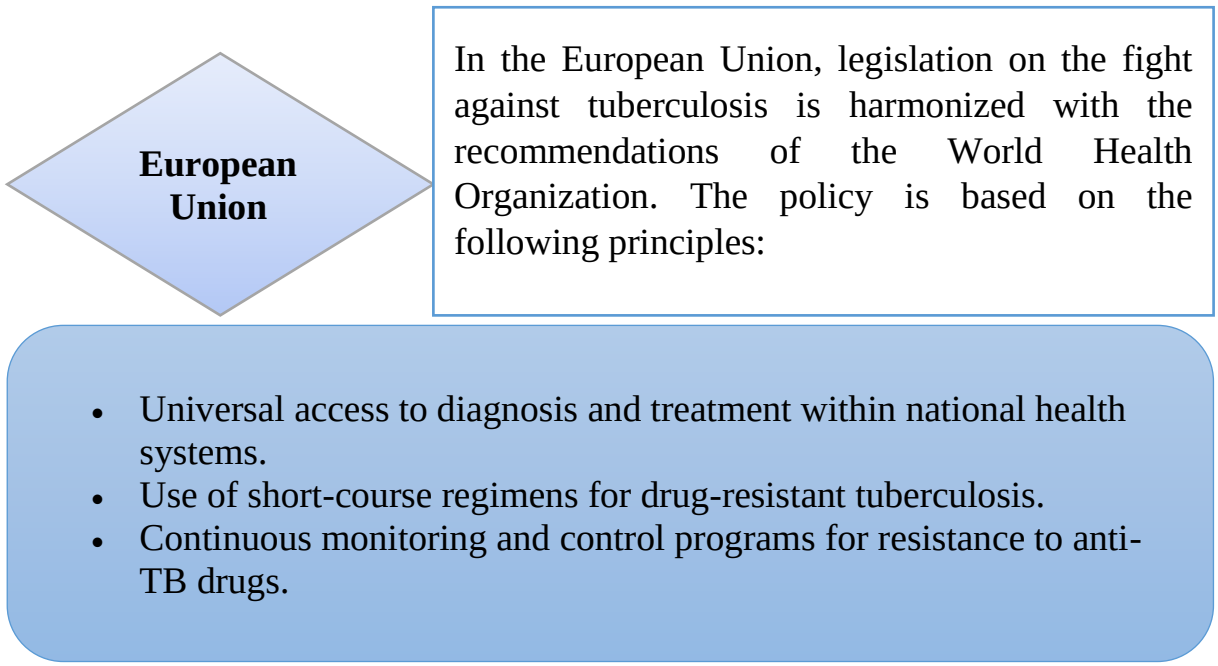

Fig. 2. Legislative changes in the field of tuberculosis prevention in the European Union.

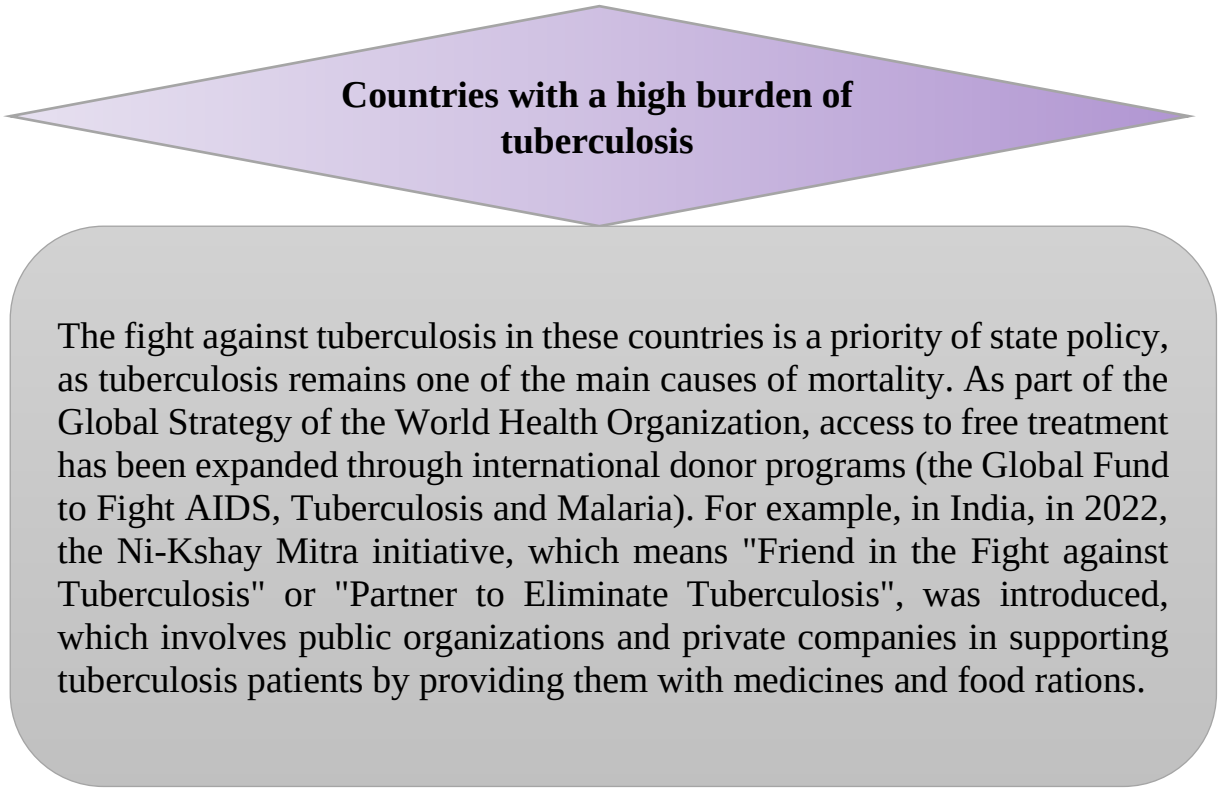

Fig. 3. Legislative changes in the field of combating tuberculosis in countries with a high burden of tuberculosis (India, South Africa, Bangladesh).

Figures 4, 5 and 6 illustrate the availability of anti-TB drugs in different regions, namely in Ukraine, the European Union and countries with a high burden of the disease. The data presented reflect the availability of life-saving drugs, the features of their regulation, as well as possible barriers that affect the timely provision of patients with effective therapy. A comparative analysis of these regions allows us to assess differences in approaches to tuberculosis pharmacotherapy and identify key aspects that need improvement.

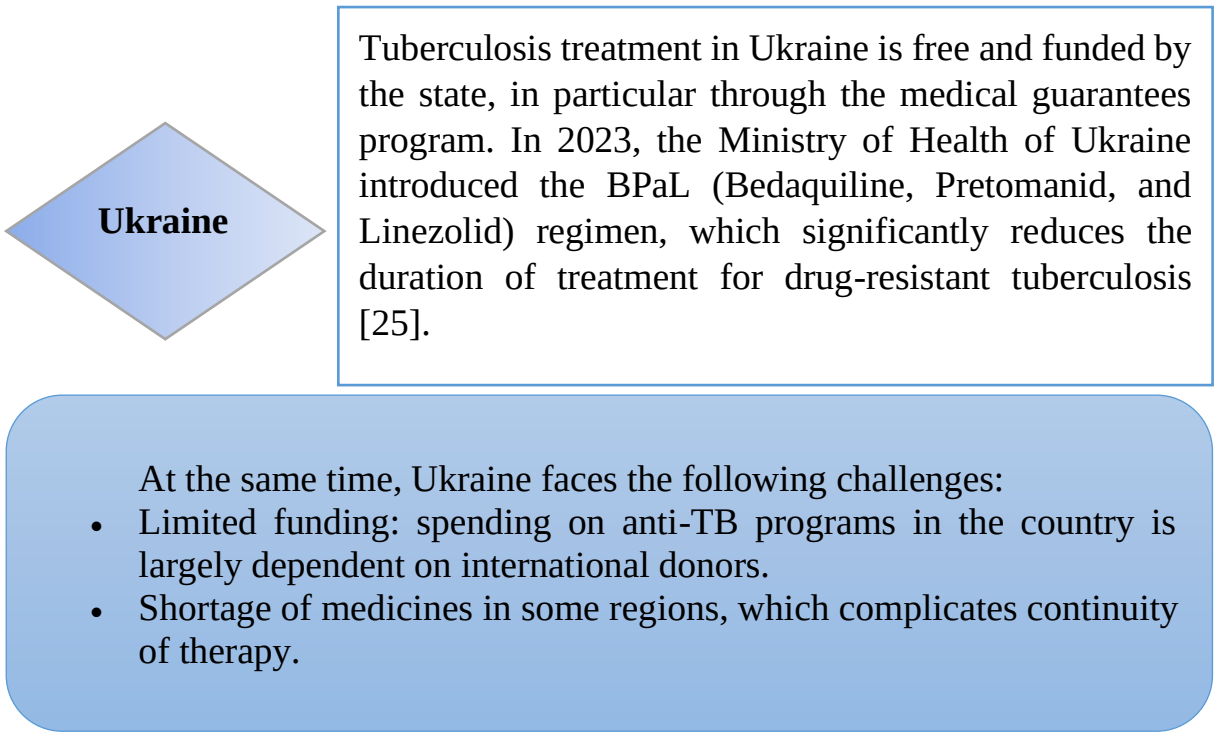

Fig. 4. Availability of anti-tuberculosis drugs in Ukraine.

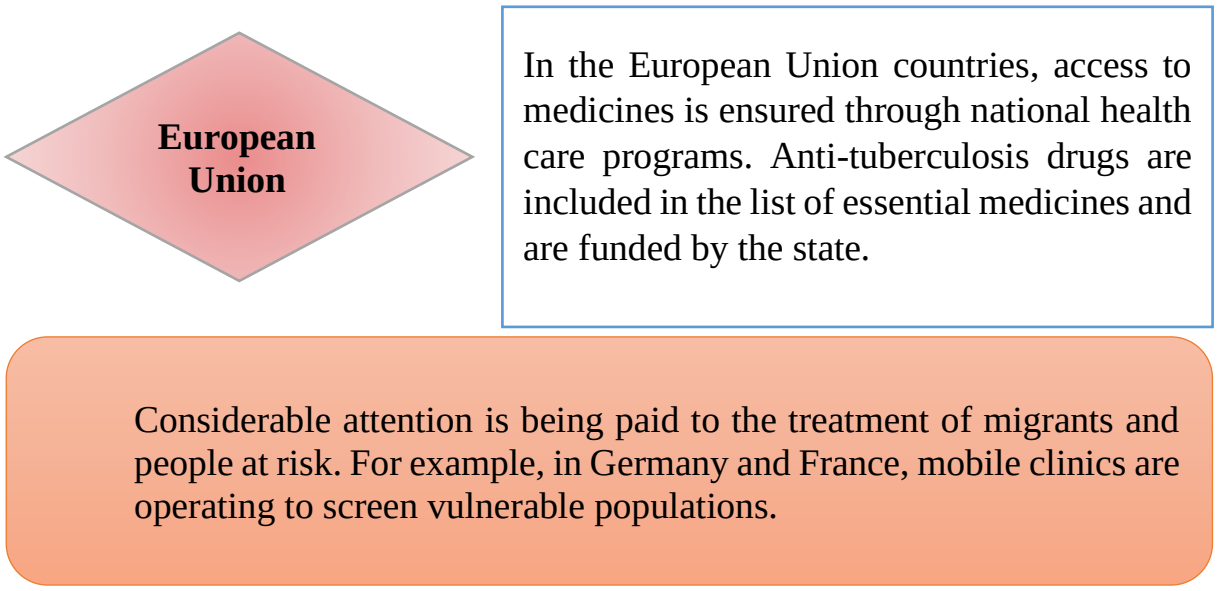

Fig. 5. Availability of anti-tuberculosis drugs in the European Union.

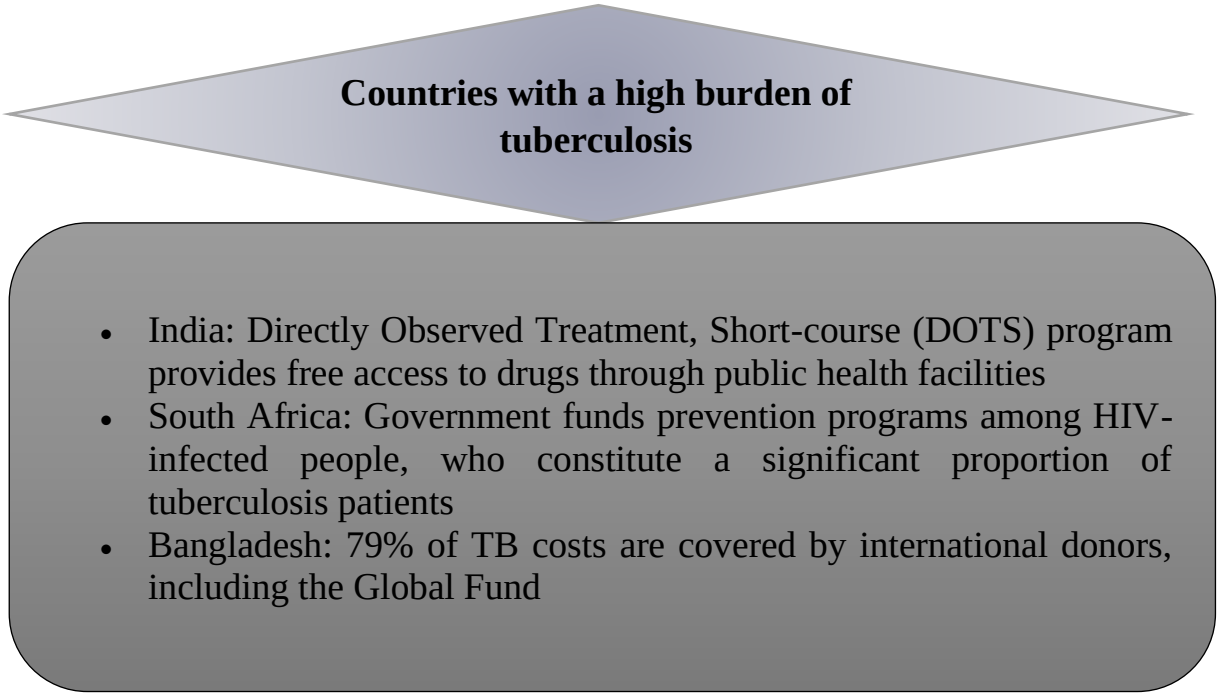

Fig. 6. Availability of anti-tuberculosis drugs in countries with a high burden of tuberculosis.

Figures 7, 8 and 9 illustrate the use of modern methods of tuberculosis diagnosis in Ukraine, the European Union and countries with a high burden of the disease. The data presented reflect the level of implementation of modern molecular genetic tests, rapid diagnostic methods and imaging technologies in the indicated regions. Comparative analysis allows to assess the availability of advanced diagnostic approaches, their effectiveness in early detection of tuberculosis and their role in reducing the prevalence of the disease.

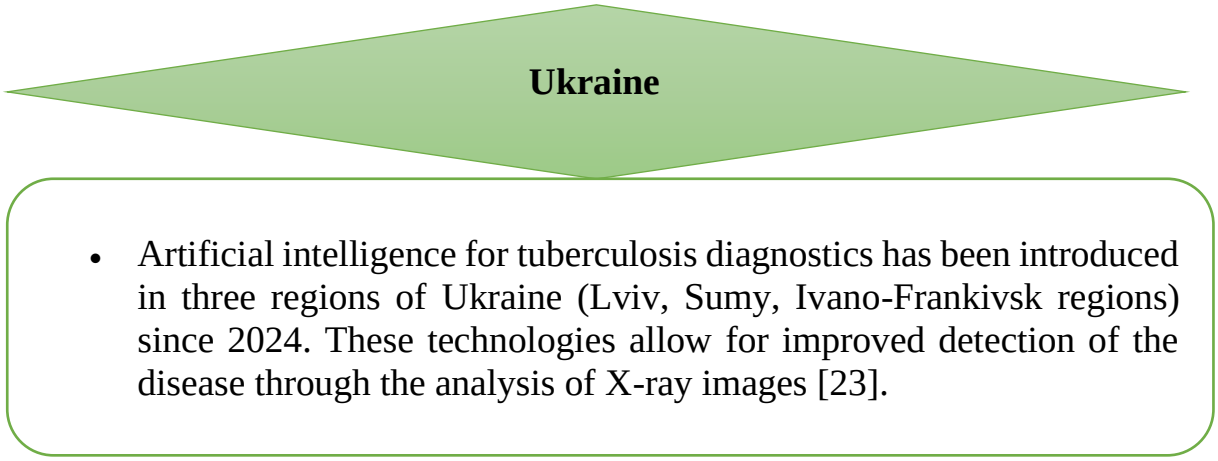

Fig. 7. Use of the latest diagnostic methods in Ukraine.

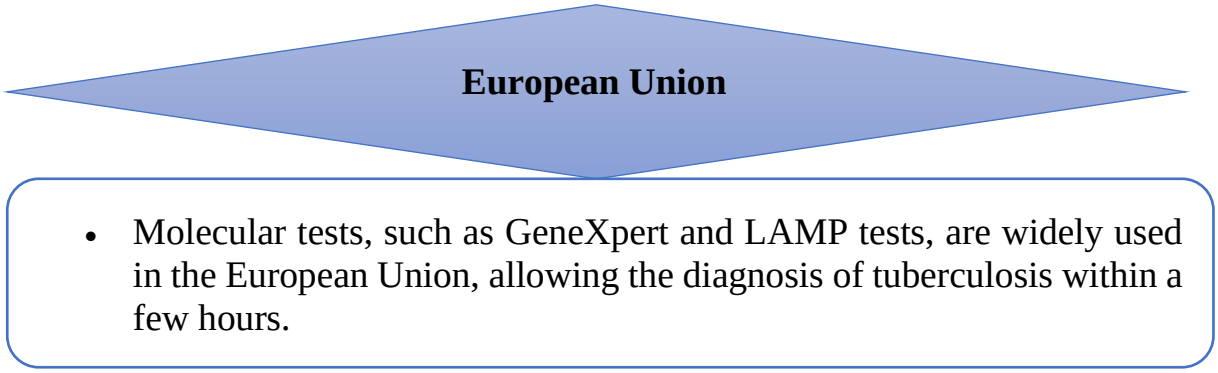

Fig. 8. Use of the latest diagnostic methods in the European Union.

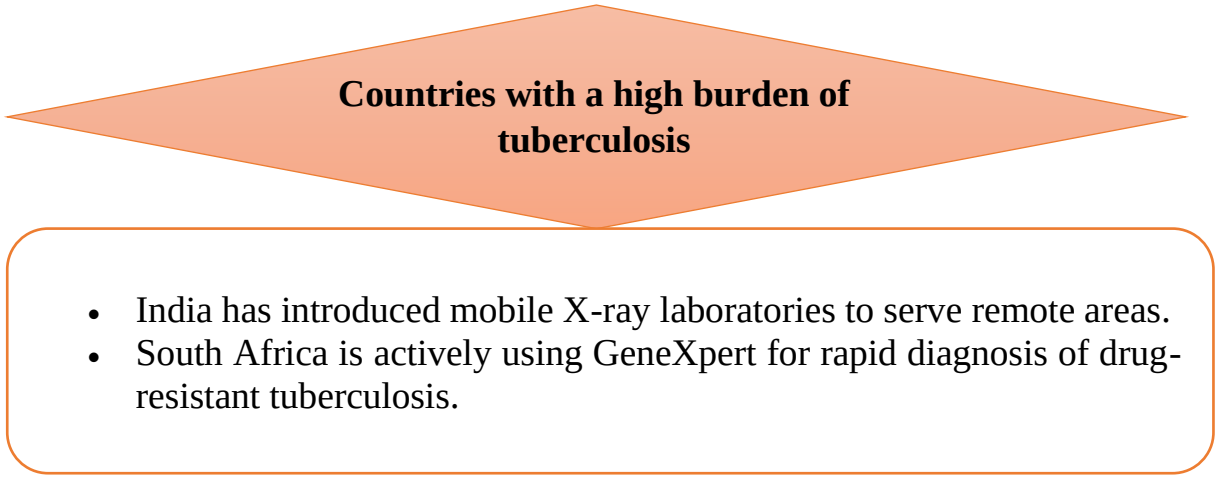

Fig. 9. Use of new diagnostic methods in countries with a high burden of tuberculosis.

From the above, we can conclude that:

✅ In Ukraine, there is a positive trend in the legislative regulation of the fight against tuberculosis, which provides free access to treatment and new diagnostic methods.

✅ In the countries of the European Union, there are more developed mechanisms for early detection and control of tuberculosis, including molecular tests and mobile clinics.

✅ In countries with a high burden of tuberculosis, such as India and South Africa, international donors play a significant role in financing, and diagnostics are based on simplified and cheaper methods.

✅ The main challenges for Ukraine: lack of funding, the need to expand the use of rapid tests and increase the coverage of prevention programs.

Analysis of regulatory acts and official reports of the World Health Organization on the fight against tuberculosis

To identify the main trends in the fight against tuberculosis, an analysis of regulatory acts of Ukraine and official reports of the World Health Organization was conducted. The analysis covers changes in legislation, treatment strategies, availability of medicines and the impact of the COVID-19 pandemic on the anti-TB care system.

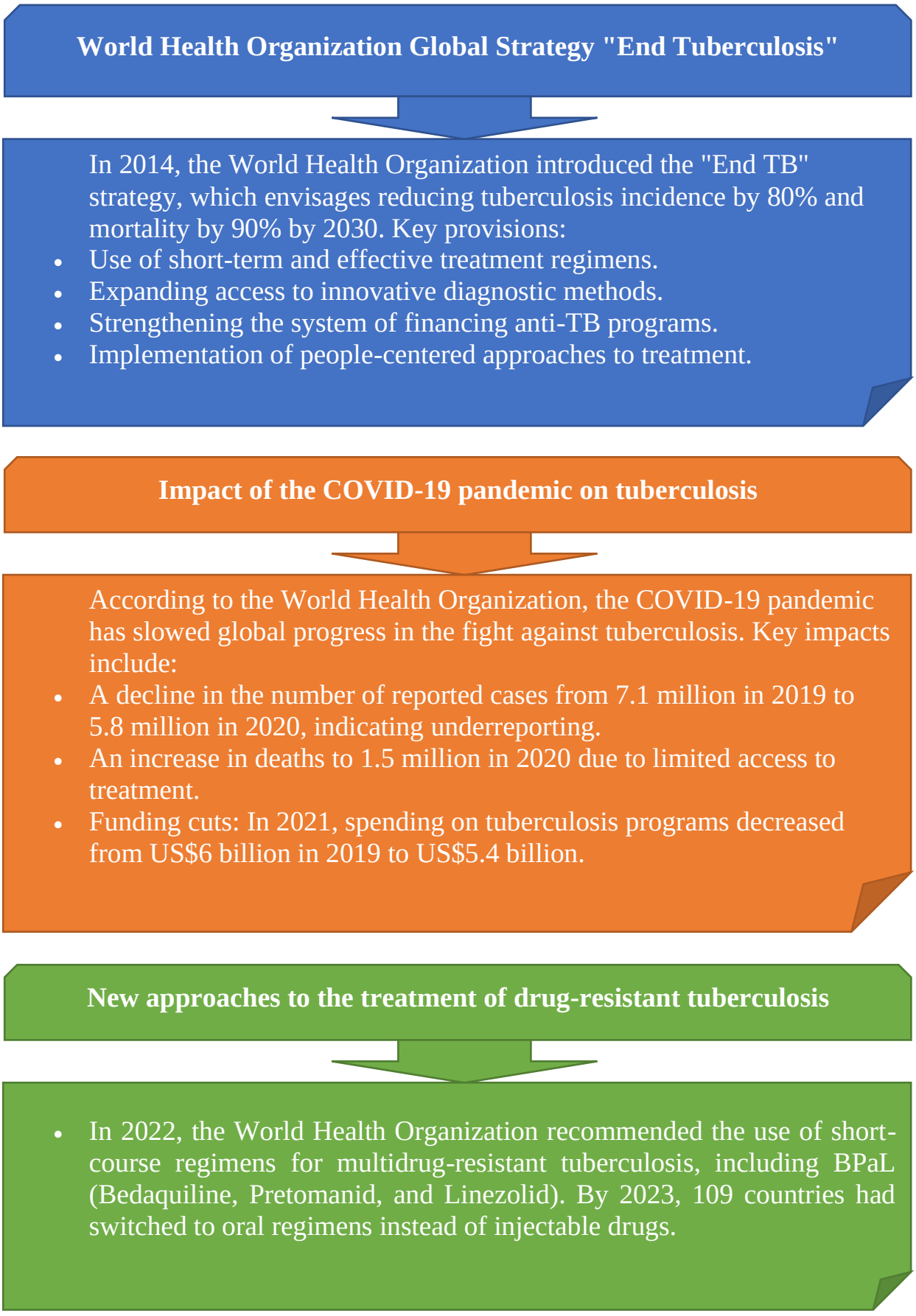

Fig. 10. International approaches to tuberculosis control: analysis of WHO reports.

◆ Law of Ukraine No. 9147 (2023)

The Verkhovna Rada adopted the Law of Ukraine "On Overcoming Tuberculosis" No. 9147, which harmonizes Ukrainian legislation with international standards [24]. Main innovations:

• Expansion of the laboratory network: a three-level system of microbiological laboratories has been created.

• Determination of the status of regional phthisiopulmonological centers that will provide services within the framework of the medical guarantees program.

• Free access to preventive treatment: patients with an increased risk of infection are provided with medicines.

• Social guarantees for medical workers: provision of additional paid leave to specialists working in the field of phthisiology.

◆ Implementation of modern diagnostic methods

In 2024, Ukraine began using artificial intelligence for tuberculosis diagnostics. Currently, these systems are installed in three regions – Lviv, Sumy, and Ivano-Frankivsk regions [23].

◆ Financing of anti-TB programs

According to the Ministry of Health of Ukraine, TB treatment remains free and financed by public funds. At the same time, Ukraine, like many countries with a high burden of TB, is largely dependent on international donors, in particular the Global Fund to Fight AIDS, Tuberculosis and Malaria [22].

Fig. 11. Legislative regulation of tuberculosis control in Ukraine.

Several important trends are observed in the fight against tuberculosis, which are aimed at improving the effectiveness of treatment, diagnosis and prevention of this disease. One of the main changes is the transition to short-term treatment regimens, in particular the use of new drugs, such as BPaL (Bedaquiline, Pretomanid, and Linezolid), and oral regimens for multidrug-resistant tuberculosis. In addition, the expansion of diagnostic capabilities, in particular through the introduction of artificial intelligence technologies, allows for faster and more accurate detection of the disease. An important aspect is the harmonization of national legislation with international standards, which contributes to the integration of Ukraine into international initiatives to combat tuberculosis. However, there is a dependence on international funding to ensure the availability of necessary medicines, which remains a significant challenge. In addition, there is a growing need to strengthen preventive measures and expand screening programs for the detection of tuberculosis at early stages (Fig. 12).

✅ **Switching to short-term treatment regimens**

BPaL (Bedaquiline, Pretomanid, and Linezolid), oral regimens for multidrug-resistant tuberculosis

✅ **Expanding diagnostic capabilities**

including the use of artificial intelligence

✅ **Harmonization of Ukrainian legislation**

with international standards

✅ **Dependence on international funding**

to ensure the availability of medicines

✅ **The need to strengthen preventive measures**

and screening programs

Fig. 12. Main trends in the fight against tuberculosis.

Given these trends, further steps should include increasing public funding, expanding coverage of prevention programs, and actively introducing new technologies in the diagnosis and treatment of tuberculosis.

Statistical analysis of the dynamics of morbidity and the effectiveness of the implementation of new treatment methods

The statistical analysis was conducted based on data from the World Health Organization, the Ministry of Health of Ukraine, and the Center for Public Health on the prevalence of tuberculosis, the dynamics of morbidity, mortality, and the effectiveness of new treatment regimens (Fig. 13, 14, 15. 16).

🔹 Global situation

According to the World Health Organization, 6.4 million new cases of tuberculosis were registered worldwide in 2022, slightly higher than the 2020 figure (5.8 million), but still below the pre-pandemic level (7.1 million in 2019). Key trends:

- Decrease in TB cases detected in 2020 due to the COVID-19 pandemic.
- Gradual recovery in the number of diagnosed patients in 2021–2022.
- The highest incidence rates were recorded in India, China, Indonesia and the Philippines.

🔹 Ukraine

Ukraine ranks 4th among the countries of the European Region of the World Health Organization in terms of the rate of spread of drug-resistant tuberculosis [22].

- 2022 – 18,510 cases of tuberculosis (+2.5% compared to 2021).
- 2023 – almost 20,000 cases, of which about 600 are among children.
- The main problem is the prevalence of multidrug-resistant tuberculosis – about 30% of new cases.

Fig. 13. Dynamics of tuberculosis incidence in the world and in Ukraine.

🔹 World trend

- 2020 – 1.5 million deaths (the highest figure in the last decade due to COVID-19).
- 2021 – a slight decrease in mortality, but the figures remain high (1.4 million).
- 2022 – an expected gradual restoration of the level of control over the incidence.

🔹 Ukraine

- In 2020–2021, TB mortality increased by 10% due to reduced access to treatment.
- In 2023, mortality among patients with multidrug-resistant tuberculosis decreased due to the introduction of new treatment regimens [22].

Fig. 14. Dynamics of mortality from tuberculosis.

🔹 Implementation of short-term therapy regimens

- Since 2022, WHO has been recommending shortened treatment regimens and pharmacotherapy for multidrug-resistant tuberculosis, in particular the BPaL regimen (Bedaquiline, Pretomanid, and Linezolid).

📌 **BPaL** (Bedaquiline, Pretomanid, and Linezolid) **– results in Ukraine:**

- Treatment is reduced from 18–24 months to 6–9 months.
- 2023: 1024 patients were screened with this regimen, of whom 358 started treatments.
- Efficacy: 80% of patients who completed the three-month course achieved cessation of bacterial shedding [22].

🔹 Use of artificial intelligence to diagnose tuberculosis

Since 2024, an artificial intelligence system for analyzing X-ray images has been operating in three regions of Ukraine (Lviv, Sumy, Ivano-Frankivsk regions). It is expected that it will:

- Increase tuberculosis detection by 20–30%.
- Reduce misdiagnosis and improve the quality of early diagnosis.

Fig. 15. Evaluation of the effectiveness of new treatment regimens and pharmacotherapy.

🔹 **Global situation**
• Expenditures on TB programs in 2021 amounted to US$5.4 billion, less than half of the required US$13 billion. • The main funding comes from national budgets (79%), but low-income countries depend on international donors.
🔹 **Ukraine**
• Treatment was financed by the state budget and international partners (Global Fund, USAID). • The medical guarantee program provides free provision of medicines to patients [22]. • At the same time, due to martial law, there are difficulties in supplying medicines to some regions.

Fig. 16. Financing and accessibility of treatment.

Thus, a statistical analysis of the dynamics of morbidity and the effectiveness of the implementation of new treatment methods showed that:

📌 Incidence dynamics: the number of new cases of tuberculosis in Ukraine is gradually increasing, which is associated with both improved diagnostics and the real spread of the disease.

📌 Mortality: an increase in 2020-2021 due to COVID-19, but since 2023 there has been a downward trend due to new treatment methods.

📌 Effectiveness of new treatment regimens: BPaL (Bedaquiline, Pretomanid, and Linezolid) demonstrates high effectiveness (80% successful treatment), which can significantly reduce the spread of drug-resistant tuberculosis.

📌 Diagnostics: the implementation of artificial intelligence has the potential to improve the detection of tuberculosis cases by 20–30%.

📌 Financing: remains a major challenge, as Ukraine depends on international assistance.

Further research should be aimed at expanding access to new treatment regimens, strengthening diagnostic capabilities, and ensuring stable financing of anti-TB programs.

Conclusions. The study of current trends in tuberculosis pharmacotherapy and access to essential medicines showed that:

1. Current trends in tuberculosis treatment and prevention. The introduction of short-term treatment regimens, in particular BPaL (Bedaquiline, Pretomanid, and Linezolid), allows to significantly reduce the duration of treatment for multidrug-resistant tuberculosis from 18–24 months to 6–9 months, which increases the effectiveness of treatment. In Ukraine, this regimen has shown 80% success among patients who completed a three-month course of therapy.

2. Expanding diagnostic capabilities. The introduction of artificial intelligence for the analysis of X-ray images in 2024 allows to improve the accuracy of tuberculosis detection and can increase the diagnostic rate by 20–30%.

3. Legislative initiatives and accessibility of treatment. The adoption of Law of Ukraine No. 9147 in 2023 contributes to improving access to treatment, developing a three-tiered diagnostic system, and providing social guarantees to medical workers. However, Ukraine's dependence on international donors remains a significant challenge in ensuring uninterrupted financing of anti-TB programs.

4. Morbidity and mortality dynamics.

- In 2023, almost 20,000 cases of tuberculosis were registered in Ukraine, which is 7.3% more than in 2022.
- Due to the COVID-19 pandemic, global mortality from tuberculosis increased to 1.5 million cases in 2020, but the latest data from the World Health Organization indicate a gradual restoration of control over the disease [26].

5. Financing and availability of medicines. Global funding for TB remains inadequate: in 2021, TB programs spent $5.4 billion, less than half of what is needed. Treatment is free in Ukraine, but martial law is making it difficult to deliver drugs to some regions.

Prospects for further research and action:

📌 It is necessary to expand the use of short-term treatment regimens that have shown high efficacy.

📌 Artificial intelligence in diagnostics should be scaled up to all regions of Ukraine.

📌 Increasing public funding will reduce dependence on international donors.

📌 It is important to strengthen preventive measures and coverage of screening programs for early detection of the disease.

Tuberculosis remains a global challenge, but modern pharmacotherapeutic and technological solutions create the prerequisites for effective control and gradual overcoming of the disease [27-35].

Declaration of conflict interest. The author declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article. The author confirms that they are the authors of this work and have approved it for publication. The author also certify that the obtained clinical data and research were conducted in compliance with the requirements of moral and ethical principles based on medical and pharmaceutical law, and in the absence of any commercial or financial relationships that could be interpreted as potential conflict of interest.

Funding. The non-for-profit organization Private Scientific Institution "Scientific and Research University of Medical and Pharmaceutical Law" (Ukraine, Kyiv) partially funded this research.

Data availability statement. The datasets analyzed during the current study are available from the corresponding author on reasonable request.

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