Innovative Approaches to Medical and Pharmaceutical Care, Pharmacotherapy, and Availability of Pharmaceutical Supplies for Tuberculosis Patients in Wartime

Viktoriia Shapovalova (Doctor of Pharmaceutical Sciences, Professor, Lviv Medical University, Public Organization "Association of Medical and Pharmaceutical Law", Ukraine)
Corresponding author: Viktoriia Shapovalova

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Abstract. This article explores advanced methodologies for delivering medical and pharmaceutical care to tuberculosis patients under regional wartime conditions. Emphasizing organizational, legal, clinical, and pharmacological considerations, the discussion highlights the critical role of robust pharmaceutical management, enhanced access to anti-tuberculosis medications, and socially oriented logistical protocols for pharmaceutical provisioning and pharmacotherapy. The authors investigate how new pharmacotherapy models can be economically effective, and they propose a series of legal and managerial adaptations tailored to the realities of wartime. By focusing on strategies to secure reliable medication access and implement efficient clinical pathways, this study underscores the importance of a coordinated, multidisciplinary response. Particular attention is paid to the issues of organizational and legal, clinical and pharmacological, pharmaceutical management, increasing the availability of anti-tuberculosis drugs, socially oriented and accessible logistical algorithms for pharmaceutical provision and pharmacotherapy. Moreover, it offers insights into how healthcare systems can remain resilient in crisis situations, ensuring that individuals with tuberculosis continue to receive necessary interventions despite the challenges posed by conflict conditions. Recommendations include revising regulatory frameworks and optimizing pharmaceutical management to meet the specific demands of wartime environments.

Keywords: tuberculosis, pharmacotherapy, wartime, organizational and legal management, clinical and pharmacological management, patient-oriented therapy, accessibility.

Introduction. The World Health Organization (WHO) has said that deaths from tuberculosis in Europe are rising again after a decline of almost 20 years. WHO attributes the COVID-19 pandemic and its associated restrictions, diversion of medical resources, delayed diagnosis, and the spread of drug-resistant tuberculosis to the cause [1]. According to WHO, tuberculosis is one of the ten deadliest infectious diseases in the world. The number of people with tuberculosis and its drug-resistant forms is increasing for the first time in many years. In 2021, 10.6 million people fell ill with tuberculosis, which is 4.5% more than in 2020, and 1.6 million people died from tuberculosis (including 187,000 HIV-positive people). In addition, the burden of drug-resistant tuberculosis increased by 3% from 2020 to 2021. There were 450,000 new cases of rifampicin-resistant tuberculosis. Seven countries in the region with a high burden of tuberculosis – Ethiopia, Kenya, Lesotho, Namibia, South Africa, the United Republic of Tanzania, and Zambia – met or exceeded the 2020 benchmark of a 20% reduction in tuberculosis incidence compared to 2015 [2].

Prior to the full-scale invasion, Ukraine had been implementing innovative solutions to combat tuberculosis. It was a leader in this area among the countries of Eastern Europe and Central Asia. Due to active hostilities, targeted attacks by the enemy on the medical system, and large-scale migration, the risks of the spread of infectious diseases, including tuberculosis, are increasing [3].

In wartime, the risk of contracting tuberculosis has increased not only for risk groups, including drug addicts, sex workers, the homeless, and people living below the poverty line, but also for the rest of the population [4].

The outpatient treatment model allowed tuberculosis patients to adapt more quickly to their new places of residence. Many people left their homes and found shelter in safer regions. Tuberculosis patients were able to call the phthisiatric or pulmonological institution of the region in which they found themselves and find out all the details of further support [5].

Innovative research on the features of medical care, pharmacotherapy, availability of pharmaceutical supplies, and tuberculosis prevention and rehabilitation measures in wartime at the regional level has not yet been conducted in the world or in Ukraine. Pharmacoeconomic and organizational-legal models of medical and pharmaceutical care, their pharmaceutical correction, justification for the development of formulations for the introduction of new anti-tuberculosis drugs into medical practice are absent. This is the range of issues that the research is aimed at solving.

The purpose of the study was to introduce innovative approaches to medical care, establish a diagnosis of tuberculosis among all population groups, patients; develop pharmacoeconomic models of pharmacotherapy that act on Mycobacterium tuberculosis cells; study the social mechanisms of the spread of tuberculosis in war conditions; develop ways to increase pharmaceutical support for patients with tuberculosis; search for and justify the composition of new drugs for pharmaceutical care of the disease at the regional level.

Tasks:

1. Based on the methods of research of different population groups, patients who have contracted tuberculosis, to establish innovative approaches to medical care, pharmacotherapy, and availability of pharmaceutical support for patients with tuberculosis in wartime conditions (regional level).
2. To substantiate pharmaceutical agents for the prevention and correction of disorders of organs and systems caused by the action of Mycobacterium tuberculosis.
3. To develop a medical and pharmaceutical algorithm for detecting changes in organs and systems in different population groups, patients under the influence of Mycobacterium tuberculosis, which was infected in wartime conditions, and means of its pharmacotherapeutic correction.
4. To conduct clinical and pharmacological, classification and legal, nomenclature and legal studies to develop new strategies for diagnostics, pharmacotherapy, availability, prevention, and rehabilitation measures among different age groups of the population with tuberculosis.
5. To develop organizational and legal studies for expert assessment of the regulatory framework for the circulation of anti-tuberculosis drugs, to propose regulatory initiatives in the system of legal relations "doctor-patient-pharmacist-lawyer".

Expected novelty of the study.

Innovative studies on the features of medical and pharmaceutical care, pharmacotherapy, availability of pharmaceutical support, measures for the prevention and rehabilitation of tuberculosis in war conditions in the world and in Ukraine have not been conducted so far. Pharmacoeconomic and organizational and legal models of medical and pharmaceutical care, their pharmaceutical correction, development of formulations for the introduction of new anti-tuberculosis drugs into medical practice are absent. The above formulated the purpose of the work.

Materials and methods. The work reviewed scientific sources of leading scientists in the world on tuberculosis. The following were studied: regulatory and legal framework, clinical protocols, guidelines, standards for the treatment of tuberculosis, "Tuberculosis. Evidence-based clinical guidelines", "Standards of medical care. Tuberculosis", patient clinical routes, medical records, medical histories, medications, instructions for medical use, questionnaires (of doctors, patients, different age groups of the population) and other local documents.

Methods of the research. Clinical and instrumental, pharmacoeconomic, experimental, clinical and pharmacological, classification and legal, nomenclature and legal, marketing, social, epidemiological, technological, analytical, organizational and legal studies were used.

The study will adhere to the basic concepts of evidence-based medicine and evidence-based pharmacy. Researchers: study the methods and routes of spread of Mycobacterium tuberculosis, work out the mechanisms by which tuberculosis spreads among the population, patients; develop pharmacoeconomic analysis methods that will allow for the implementation of patient-centered pharmacotherapy and increase the availability of pharmaceutical care for patients with tuberculosis, taking into account the principles of evidence-based medicine, evidence-based pharmacy, academic integrity, and pharmaceutical ethics; conduct clinical-pharmacological, classification-legal,

marketing, nomenclature-legal research and work on the justification and development of new formulations of medicinal products based on known active pharmaceutical ingredients that would be more effective, safe, high-quality, and affordable; help identify populations at increased risk, identify new cases of tuberculosis, and study the ways in which the infection spreads; conduct an expert assessment of the regulatory framework for the circulation of anti-tuberculosis drugs, and develop regulatory initiatives in the system of legal relations "doctor-patient-pharmacist-lawyer" [6].

Level of evidence for the expected results: grade B, level 3 (evidence based on data from at least one study with a high degree of quality, in which there was a control group). The evidence will be based on data from pharmacoeconomic, experimental, clinical and pharmacological, classification and legal, nomenclature and legal, marketing, social, epidemiological, technological, analytical, organizational and legal studies.

The degree of proven effectiveness and expediency of conducting the research: class I, level C (consensus of the beliefs of experts based on the results of research and practice). The results of the research will be analyzed and compared with the data of other authors. It is planned to develop integrated approaches to pharmacotherapy, increase the level of availability of drugs, preventive, and rehabilitation measures for patients with tuberculosis who are undergoing treatment and rehabilitation in health care institutions.

The research of the article is a fragment of research works of Private Scientific Institution "Scientific and Research University of Medical and Pharmaceutical Law" on the topic "Multidisciplinary research of post-traumatic stress disorders during war among patients (primarily combatants)" (state registration number 0124U002540, implementation period 2024-2029); 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); Kharkiv Medical Academy of Postgraduate Education on the topic "Pharmaceutical and medical law: integrated approaches to the system of drug circulation from the standpoint of forensic pharmacy and organization of pharmaceutical business" (state registration number 0121U000031, terms 2021-2026); Luhansk State Medical University "Conceptual interdisciplinary approaches to pharmaceutical provision and availability of drugs, taking into account organizational and legal, technological, analytical, pharmacognostic, forensic and pharmaceutical, clinical and pharmacological, pharmacoeconomic, marketing, social and economic competencies" (state registration number 0123U101632, terms 2023-2027); Petro Mohyla Black Sea National University on the topic "Conceptual interdisciplinary approaches to the drug circulation system, taking into account organizational and legal, technological, biopharmaceutical, analytical, pharmacognostic, forensic and pharmaceutical, clinical and pharmacological, pharmacoeconomic, pharmacotherapeutic aspects" (state registration number 0123U100468, implementation period 2023-2028).

Results and discussion. In a situation of armed conflict or military operation, there are risks that cause an increase in the incidence of tuberculosis among all population groups and patients. These risks include: overcrowding, poor hygiene, stress, impaired immune system, lack or limited medical and pharmaceutical care [7].

It is important to note that the specific incidence of tuberculosis among different age groups of the population may vary depending on the context and specific conditions. The level of tuberculosis incidence among patient groups can be carefully studied and monitored by medical and pharmaceutical services involved in health and pharmaceutical provision, to act appropriately to control and prevent tuberculosis.

Due to the war in Ukraine, all population groups found themselves in the risk zone, which causes an increase in the incidence of tuberculosis. These risks include: overcrowding, poor hygiene, stress, impaired immune system, lack or limited medical and pharmaceutical care.

Based on the processed data, studies were conducted in the following areas.

Medical

Researchers are studying the ways and means of spreading Mycobacterium tuberculosis, working out the mechanisms by which tuberculosis spreads among the population and patients [8].

Pharmacoeconomic

Researchers are working out pharmacoeconomic analysis methods that will allow for the implementation of patient-centered pharmacotherapy and increase the availability of pharmaceutical care for patients with tuberculosis, considering the principles of evidence-based medicine, evidence-based pharmacy, academic integrity, and pharmaceutical ethics.

The Ministry of Health of Ukraine announced the registration in Ukraine of “Pretomanid”, a drug that is considered innovative in the pharmacotherapy of severe forms of tuberculosis [6].

Pharmaceutical development of new drugs

Mycobacterium tuberculosis can be drug-resistant, which complicates the pharmacotherapy of tuberculosis. Researchers conduct clinical-pharmacological, classification-legal, marketing, nomenclature-legal studies and work on the justification and development of new formulations of drugs based on known active pharmaceutical ingredients that would be more effective, safe, high-quality, and affordable.

Social and epidemiological studies

Studies of the spread of tuberculosis and risk factors are important for disease control. They help identify populations at increased risk, detect new cases of tuberculosis and study the ways in which the infection spreads.

Organizational and legal research

Researchers carry out an expert assessment of the regulatory framework for the circulation of anti-tuberculosis drugs, develop regulatory initiatives in the system of legal relations "doctor - patient - pharmacist - lawyer" [9].

These areas of research contribute to understanding the risks, mechanisms, and ways of spreading Mycobacterium tuberculosis for the development of new strategies for diagnostics, pharmacotherapy, accessibility, prevention and rehabilitation measures among different population groups, patients suffering from tuberculosis in wartime.

Therefore, the expected scientific and scientific and technical products of this research are unique and have no analogues in the world.

Description of scientific and technical products:

- establishment of innovative approaches to medical and pharmaceutical care, pharmacotherapy, and accessibility of pharmaceutical support for patients with tuberculosis in wartime
- development of pharmaceuticals for the prevention and correction of lung and lymph node disorders caused by the action of Mycobacterium tuberculosis.

Medical effectiveness of the study

Establishment of mechanisms of influence of Mycobacterium tuberculosis on bronchopulmonary system in different population groups, development of pharmacotherapy regimens for patients with tuberculosis in wartime conditions [10].

Social effectiveness of the study

Study of features of occurrence, clinical picture, diagnostics, and pharmacotherapy of tuberculosis in different population groups and patients in wartime. A new approach to the problem of spread of tuberculosis in wartime conditions will contribute to accumulation of knowledge about innovative approaches to medical and pharmaceutical care, pharmacotherapy, and availability of pharmaceutical support for patients with tuberculosis in wartime conditions [11].

Economic effectiveness of the study

Determination of tuberculosis disease in the structure of sanitary losses occupies a prominent place. Represents a certain problem for organization of medical and pharmaceutical care and pharmacotherapy at the stages of medical evacuation. Entails numerous material costs. The development of an algorithm for detecting tuberculosis in different population groups and patients exposed to Mycobacterium tuberculosis, which was infected in wartime conditions, and its pharmacotherapy will significantly reduce the economic costs of treatment and rehabilitation of patients of different age groups [12, 13].

Organizational and legal management

Considering the peculiarities of wartime, the organizational and legal management of medical and pharmaceutical care for patients with tuberculosis involves the creation of a flexible regulatory support system. This system should facilitate the operational distribution of anti-tuberculosis drugs, adapt the legal framework to the conditions of crisis times, and improve interaction between healthcare institutions, patients, and pharmacists. In addition, the development of regulatory initiatives is important for strengthening the continuous provision of medicines that meet the specific needs of tuberculosis treatment in conditions of limited access to resources [14].

Clinical and pharmacological management

Clinical-pharmacological management involves adapting treatment protocols to regional needs and wartime conditions, as well as incorporating innovative pharmacotherapeutic approaches. An important aspect is the selection of drugs for the treatment of drug-resistant forms of tuberculosis. With the use of new drugs registered in Ukraine, such as pretomanid [6]. In addition, it is necessary to develop algorithms for supporting patients with a weakened immune system, as well as ensuring the availability of medical and pharmaceutical services at all stages of treatment [15].

Pharmaceutical management

Pharmaceutical management in wartime is focused on increasing the availability of anti-tuberculosis drugs by optimizing the coordination of supplies and ensuring pharmaceutical supervision over their circulation. Interaction with local institutions is important, which must comply with the norms governing the storage, transportation and dispensing of drugs. The use of alternative logistical approaches for delivering drugs to remote or dangerous regions is also proposed [15, 16].

Patient-centered pharmacotherapy

Patient-centered pharmacotherapy aims to create conditions for ensuring effective, accessible, continuous treatment of patients with tuberculosis. Those who are displaced or in hard-to-reach places. It is important to implement an outpatient treatment model and provide consultations for patients via telemedicine or hotlines. In addition, social support programs are important to increase the adherence of vulnerable groups of patients to treatment and reduce the risks of its interruption [17, 18].

Socio-economic accessibility of pharmaceutical provision

Analysis of the socio-economic accessibility of pharmaceutical provision involves substantiating the costs of tuberculosis pharmacotherapy for privileged categories of patients in war conditions. Determining the optimal ways to reduce costs associated with medical and pharmaceutical care and patient rehabilitation is socially relevant for the economy. The proposed measures include the development of cost-effective logistical algorithms for pharmaceutical provision, pharmacotherapy and diagnostic regimens based on evidence-based standards [19-21].

Conclusions. In conclusion, the study emphasizes the need to develop innovative approaches in all aspects of the provision of medical and pharmaceutical care, pharmacotherapy, and the availability of pharmaceutical support to patients with tuberculosis in wartime. Organizational, legal,

clinical, pharmacological, pharmaceutical, and socially oriented measures contribute to increasing the effectiveness of treatment, reducing the risks of infection spread and economic costs.

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