Post-Traumatic Stress Disorder: Administration, Clinical and Pharmacological, Organizational and Legal, Pharmaceutical Management, Recent Case Studies

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Abstract. Administered post-traumatic stress disorder based on ICD-11. The organizational and legal management of post-traumatic stress disorder's pharmacotherapy based on evidence-based medicine and evidence-based pharmacy was studied. The use of medications to reduce post-traumatic stress disorder's symptoms is indicated. Analgesics, anxiolytics, antidepressants, anticonvulsants, and drugs from other clinical-pharmacological groups can be used for analgesia, mood improvement, anxiety reduction, and control of hypergaining. Areas of professional reintegration (support in job search, skills training, education, employment, and adaptation to civilian life) have been determined. Legal support in the system of legal relations "doctor-patient-pharmacist-lawyer" indicated in order to achieve a comprehensive and multidimensional approach to the medical and pharmaceutical care of patients with post-traumatic stress disorder. Clinical and pharmacological management in the pharmacotherapy of post-traumatic stress disorder was studied. The further pharmaceutical development of the composition of the new drug based on the known active pharmaceutical ingredients of an analgesic and an antipsychotic is substantiated. Mentioned about the organizational and legal management of social patient-oriented pharmacotherapy, recent case studies of post-traumatic stress disorder in conflict conditions.
Keywords: ICD-11, PTSD, administration, management, pharmacotherapy.

Introduction. On January 1, 2022, the eleventh edition of the International Classification of Diseases of the Eleventh Edition (ICD-11) began to operate in the world. ICD-11 was developed by the World Health Organization. The development of ICD-11 took more than ten years. More than 300 experts from 55 countries participated in it, who also considered 10,000 additional proposals from people from all over the world. The classification was updated in accordance with advances in science and medical practice [1, 2].

The world's leading scientists have established that post-traumatic stress disorder (PTSD) is the only serious mental disorder whose cause is considered known. PTSD is a disorder that involves a threat to a person's physical integrity, causing a response of intense fear, helplessness, or terror. Although PTSD is still largely viewed as a psychological phenomenon, over the past three decades the growth of the literature on biological PTSD has been explosive, and there are now thousands of references. Ultimately, the impact of a military conflict, an environmental event, such as psychological trauma, must be understood at the organic, cellular, and molecular levels [3].

It has been determined that PTSD was formerly known as combat fatigue syndrome or post-traumatic stress disorder. A severe mental disorder, which is usually caused by experiencing some frightening, frightening events, or trauma. The person suffers serious physical or mental harm. PTSD is a long-term effect of the continuous occurrence of traumatic conditions, which leads to a person's feelings of helplessness, intense fear, and terror. There are various examples of events that can cause PTSD. For example, physical, mental, or sexual violence at home, at work, by other people, unexpected death of a loved one, accidental event, war, natural disaster, state of emergency, conditions of force majeure [4].

Because of the war in Ukraine, all contingents of the population found themselves in the risk zone, which causes an increase in the incidence of PTSD. Such risks include: severity of trauma, personality, long-term experience of traumatic events, lack of social support, intense negative

emotions, unhealthy coping strategies for PTSD associated with drug addiction (alcohol and drug addiction).

Until now, comprehensive studies of administration, management, organizational and legal, clinical and pharmacological, social patient-oriented pharmacotherapy of PTSD in the conditions of conflicts in the world and in Ukraine have not been conducted, which constitutes the relevance, scientific value and practical significance of the work. Therefore, the expected scientific goal of the work is unique and has no analogues in the world.

The purpose of the study was to conduct administration, clinical and pharmacological, organizational and legal management of social patient-oriented pharmacotherapy, recent case studies of PTSD in conflict conditions; to analyze clinical-pharmacological therapy, psychosocial support and psychotherapy to improve PTSD symptoms, support victims and promote their recovery.

To achieve the purpose of the study, it was necessary to solve the following tasks:

- the first task was to administer PTSD based on ICD-11;
- the second task was to study the organizational and legal management of PTSD pharmacotherapy based on evidence-based medicine and evidence-based pharmacy. The use of medication may be helpful in reducing PTSD symptoms. Analgesics, anxiolytics, antidepressants, anticonvulsants, and drugs from other clinical-pharmacological groups can be used for analgesia, mood improvement, anxiety reduction, and control of hypergaining;
- the third task was to determine the direction of professional reintegration. Professional reintegration is an important task for patients. Support in finding work, skills training, education, employment, and adjustment to civilian life can all contribute to successful adaptation. Legal assistance in the system of legal relations "doctor - patient - pharmacist - lawyer" to achieve a comprehensive and multidimensional approach to the medical and pharmaceutical care of patients with PTSD;
- the fourth task was to research clinical and pharmacological management in pharmacotherapy. Rationale for new pharmacological agents for the treatment of PTSD. For example, some antidepressants, such as sertraline and paroxetine, have been shown to be effective in reducing PTSD symptoms. Other drugs, such as anti-anxiety drugs and mood stabilizers, may also be used to improve the mental state of victims;
- the fifth task was to substantiate the further pharmaceutical development of the composition of a new drug based on the known active pharmaceutical ingredients of an analgesic and an antipsychotic.

Materials and methods. The paper reviewed the scientific sources of the world's leading scientists on PTSD and related diagnoses. Studied: regulatory and legal framework, clinical protocols, guidelines, standards of treatment of PTSD associated with drug addiction, drugs, instructions for medical use, other local documents.

Methods of the research. Management, administration, organizational and legal, normative, documentary, clinical and pharmacological, comparative, graphic analysis were used in the study.

Performance indicators. The basic concepts of evidence-based medicine and evidence-based pharmacy will be observed in the study. Researchers: evaluate literature data, examine PTSD codes, determine clinical and pharmacological groups of drugs in the pharmacotherapy of PTSD, determine directions of professional reintegration, develop research design.

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 – evidence will be based on clinical and pharmacological, classification and legal, nomenclature data – legal, social, organizational and legal, forensic and pharmaceutical, technological research.

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.

The research of the article is a fragment of research works of 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); Kharkiv Medical Academy of Postgraduate Education on "Improving the organizational and legal procedure for providing patients with drugs from the standpoint of forensic pharmacy, organization and management of pharmacy" (state registration number 0116U003137, terms 2016-2020) and "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); 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. The following types of PTSD were established: asthenic, anxiety-phobic, hysteroform, depressive, associated with addictions. PTSD is a frequent, persistent, and disabling consequence of traumatic events. The onset of the disorder and early identifiable symptoms allow for early detection and prevention. Empirical findings and theoretical models have delineated specific risk factors and pathogenic processes leading to PTSD. Controlled studies have shown that theoretical preventive or pharmacological interventions target stress hormones. They are effective in survivors. However, the effectiveness of early interventions remains unknown. The results obtained in total (large groups) do not take into account individual heterogeneity in the pathogenesis of PTSD [5].

Administration of PTSD. Today, complex PTSD has been accepted as a new diagnosis in ICD-11. Individuals with complex PTSD have prolonged or repeated exposure to trauma (childhood abuse, domestic or community violence). Complex PTSD is common in 1-8% of the population and up to 50% in psychiatric institutions. Advances in the diagnosis, assessment, and differentiation of PTSD and borderline personality disorder, as well as the assessment and treatment of children and adolescents, are reported. Research recommends multicomponent therapies, beginning with an emphasis on safety, psychoeducation, patient-provider collaboration, and treatment components that include self-regulation strategies and trauma-focused interventions [6].

In the modern world, the diagnosis of PTSD has undergone significant development. With the changes in DSM-5 and the proposed changes in ICD-11, the two systems are moving in different directions. Treatments for PTSD are developing, but evidence of effectiveness is insufficient. Trauma-focused cognitive-behavioral therapy and eye movement desensitization and reprocessing remain the first choice. Pharmacotherapy is secondary. There is evidence of an effect for paroxetine, venlafaxine, and fluoxetine and less for sertraline [7].

In conflict settings, there are serious risks that can cause PTSD to increase. Stress is reflected in the mental and psychological state of eyewitnesses who are in the conflict zone, including civilians, internally displaced persons, veterans of military events, volunteers, journalists, and humanitarian workers. Untimely diagnosis causes deepening of psycho-emotional complications from the experience of conflict, stress, and the occurrence of PTSD. Often associated addiction complicates the course of PTSD. Affective and behavioral reactions and changes associated with a traumatic experience, psycho-emotional distress, may have long-term adverse consequences for a person's functioning, mental, physical, social, emotional, or spiritual well-being. Consequences of stress in the area of arrivals, injuries sustained, concomitant somatic diseases (bronchopulmonary system, gastrointestinal tract, development of polyradiculoneuritis caused by difficult conditions of being in the conflict zone), impressive force of explosion energy cause damage to the middle and inner ear, bone tissues, cardiovascular organs -pulmonary system, abdominal cavity, and chronic pain syndrome. Providing patient-oriented clinical and pharmacological, psychological, social care, pharmacotherapy and rehabilitation can help reduce the risk of developing PTSD and improve the psychological well-being of victims.

A high level of comorbidity of PTSD against the background of major somatic diseases is accompanied by symptoms of depression, anxiety, acute reaction to stress, depressive reactions, and

generalized anxiety disorder. Many of them need the help of specialists - narcologists, psychiatrists, somatologists, neurologists, pharmacologists, psychotherapists, psychologists. They have a higher risk of developing critical PTSD conditions (severe post-intoxication somatic, neurological, psychopathological complications, psychotic disorders, paroxysmal states, suicidal actions, traumatism, aggressive tendencies, etc.). From 20% to 40% of eyewitnesses to conflicts need psychological help. Symptoms of acute trauma are found in 60-80% of internally displaced persons who witnessed the death of civilians or saw the bodies of the dead. Patients aged 18-24 years who have symptoms of depression or who have had problems with alcohol are at greater risk of developing psychiatric symptoms. Symptoms of PTSD develop in approximately 12-20% of eyewitnesses of conflicts who have suffered trauma or damage, but did not seek medical, pharmaceutical, and psychological help [8].

The majority (85%) of PTSD pathologies are accompanied by a pain syndrome. Individual features of response to pain affect the experience of pain. They are determined by the situational psychological state, the nature of somatic disorders and their localization, the nature of pathogenic factors, the individual life experience of the individual, and cultural features. The pathological effect of chronic pain is caused by the lack of a protective and signaling function, i.e., the lost positive therapeutic activation of the patient, which contributes to the healing of the resulting damage [9].

Individuals with PTSD need systematic, consistent curation, including psychopharmacological therapy, psychotherapy, and rehabilitation measures. This system should be implemented comprehensively and in stages [10].

The course of the disease in PTSD is wave-like. Most often, recovery occurs. Sometimes the disease can have a chronic course for years, which leads to a change in personality [11].

In ICD-11, PTSD is included in section 06 – Mental, behavioral, and neuropsychological developmental disorders. Mental, behavioral, and neurodevelopmental disorders are syndromes that are characterized by a clinically significant disorder of a person's cognitive function, emotional self-regulation, or behavior. Reflect dysfunction in psychological, biological, or developmental processes underlying mental and behavioral functioning. These disorders or impairments are typically associated with distress or impairment in personal, family, social, educational, occupational, or other important areas of functioning.

Exceptions include acute stress reaction (code QE84), uncomplicated bereavement (code QE62). Classified in other headings:

- sleep-wake cycle disorders (code 7A00-7B2Z);
- sexual dysfunctions (code HA00-HA0Z);
- gender non-conformity (code HA60-HA6Z).

PTSD, a disorder specifically related to stress, is directly related to exposure to a stressful or traumatic event. For each disorder in this group, the presence of an identified stressor is a necessary but not sufficient causative factor.

PTSD, stressful events do not go beyond ordinary life situations (divorce, socio-economic problems, bereavement). Other disorders require exposure to a stressor of an extremely threatening or terrifying nature (a known traumatic event). PTSD is distinguished by the fact that symptoms, in their origin, manifestation and duration, occur only in response to stressful events. Exceptions include burnout syndrome (code QD85); acute stress reaction (code QE84).

A study was carried out concerning the comparison of chapters related to PTSD in ICD-10 and ICD-11. The results of the work are presented in the Table 1.

Table 1. Comparison of PTSD sections of ICD-10 and ICD-11.

ICD-10		ICD-11	
F00-F99	Mental and behavioral disorders	06	Mental, behavioral, and neurodevelopmental disorders
F40-F48	Neurotic, stress-related and somatoform disorders		

F43	Reactions to severe stress and adaptation disorders		Disorders directly related to stress
F43.10	Post-traumatic stress disorder	6B40	Post traumatic stress disorder
		6B41	Complex post-traumatic stress disorder

Changes in ICD-11 were manifested in the change of code F43.10 from ICD-10 to two different codes: 6B40 – post-traumatic stress disorder; 6B41 – complex post-traumatic stress disorder.

The differences between PTSD and complex PTSD are shown in the Table 2.

Table 2. Differences between PTSD and complex PTSD.

PTSD	Complex PTSD
PTSD may develop after exposure to an event or series of events of an extremely threatening or terrifying nature. Characterized by the presence of all the following characteristics:	Complex post-traumatic stress disorder (complex PTSD) is a disorder that can develop after exposure to an event or series of events of an extremely threatening or terrifying nature. Most often these are long-term or repeated events that are difficult or impossible to avoid (torture, slavery, genocidal campaigns, long-term domestic violence, repeated sexual or physical abuse in childhood). All diagnostic criteria for PTSD are present. In addition, complex PTSD is characterized by severe and persistent symptoms such as:
1) re-experiencing in the present time a traumatic event or several events in the form of vivid intrusive memories, flashbacks, or nightmares. Re-experiencing may be represented in one or more sensory modalities and is usually accompanied by strong or overwhelming emotions, such as fear or horror, and pronounced physical sensations;	1) problems in affect regulation;
2) avoidance of thoughts and memories about an event or events, or avoidance of activities of situations or people reminiscent of the event(s);	2) stress-related persistent ideas about oneself as humiliated, crushed, or worthless, accompanied by feelings of shame, guilt or failure;
3) a persistent sense of current heightened threat, which may be indicated, for example, by hypervigilance or an increased startle response to stimuli such as sudden loud noises. Symptoms persist for at least several weeks and cause significant impairment in personal, family, social, academic, occupational, or other important areas of functioning.	3) difficulties in maintaining relationships and experiencing a feeling of closeness to other people. These symptoms cause significant impairment in personal, family, social, academic, occupational, or other important areas of functioning.
ICD-10 inclusions Traumatic neurosis	
ICD-10 Exceptions Acute stress reaction (QE84)	*ICD-11 exceptions* Post-traumatic stress disorder (6B40)

Organizational and legal management of PTSD.

International treatment protocols, guidelines based on evidence-based medicine created by DUODECIM Medical Publications, Ltd. suggest using Guideline 00734 "Acute reaction to stress and

post-traumatic stress disorder". Author: Matti Ponteva, original text editor: Sari Atula, date last updated: 2018-08-21. https://guidelines.moz.gov.ua/documents/3525

Medical and technological documents on the subject of PTSD are available in Ukraine (https://www.dec.gov.ua/mtd/posttravmatychnyj-stresovyj-rozlad/):

- post-traumatic stress disorder; adapted evidence-based clinical guideline (https://www.dec.gov.ua/wp-content/uploads/2019/11/2016_121_akn_ptsr.pdf);
- unified clinical protocol of primary, secondary (specialized) and tertiary (highly specialized) medical care "reaction to severe stress and adaptation disorders. post-traumatic stress disorder" approved by Order of the Ministry of Health of Ukraine dated February 23, 2016 No. 121 (https://www.dec.gov.ua/wp-content/uploads/2019/11/2016_121_ykpmd_ptsr.pdf);
- adapted clinical guideline "Post-traumatic stress disorder" aims to help the doctor and the patient in making a rational decision in various clinical situations. It serves as informational support regarding the best clinical practice based on evidence of the effectiveness of the use of certain medical technologies, drugs, and organizational principles of medical and pharmaceutical care [12].
- at the moment, there are no international and national protocols for the treatment and pharmacotherapy of complex PTSD.

PTSD treatment and pharmacotherapy involves eliminating or reducing emotional feelings or symptoms in order to improve the person's daily functioning. Issues to consider in the case of PTSD include ongoing trauma, abuse, or a bad relationship. Various drugs used to treat PTSD include selective serotonin reuptake inhibitors (citalopram, fluvoxamine, fluoxetine); tricyclic antidepressants (amitriptyline, isocarboxazid); mood stabilizers (divalproex, lamotrigine); atypical antipsychotics (aripiprazole, quetiapine).

Clinical and pharmacological management.

Establishing the pathogenetic mechanisms of PTSD influence on the formation of addictive states in different contingents of the population. Studying the nature of changes in the emotional state will allow to develop effective means of pharmacological and psychosocial therapy, psychotherapeutic treatment of PTSD in conflict conditions.

Pharmaceutical management.

Organizational and legal, marketing, pharmacoeconomic studies. Pharmaceutical development of a new drug based on known active pharmaceutical components of an analgesic and an antipsychotic. Interdisciplinary approach: a combination of clinical narcology, clinical pharmacy, clinical pharmacology, pharmacotherapy, drug technology, forensic pharmacy, pharmaceutical case management, pharmaceutical development of new drugs, medical and pharmaceutical law, psychotherapy, as well as the inclusion of various support and rehabilitation methods, such as social support , education and employment, legal support in the system of legal relations "doctor-patient-pharmacist-lawyer" to achieve a comprehensive and multidimensional approach to medical and pharmaceutical care for patients with various types of PTSD [13].

Social patient-oriented pharmacotherapy.

Studying the peculiarities of pharmaceutical supply, clinical picture, types, diagnosis, and pharmacotherapy of PTSD in different contingents of the population and patients in the conditions of military conflicts is one of the urgent tasks of social pharmacy and medicine. A new approach to the problem of PTSD in wartime conditions will contribute to the accumulation of knowledge about a multimodal approach to pharmacological and psychosocial therapy, psychotherapeutic treatment of PTSD

Economic efficiency of pharmacotherapy.

The cost-effectiveness of PTSD pharmacotherapy can be difficult to evaluate due to various factors affecting the economy and access to resources in the context of covid, post-covid, long-covid disorders, and in conflict settings [14]. However, treating PTSD can have a significant positive impact on individuals, society, and the economy as a whole. Some aspects that can be taken into account when evaluating economic efficiency: increase in working capacity; reduction of medical expenses; social stability; improving the quality of life. Given these factors, effective treatment of PTSD can

have a positive impact on the economy by providing increased work capacity, reduced medical costs, and improved social stability. However, it is important to remember that evaluating the cost-effectiveness of PTSD treatment requires consideration of the war context, available resources, and individual patient needs.

Conclusion. Post-traumatic stress disorder against the background of the main somatic diseases in the context of accompanying comorbid addictive conditions in conflict conditions has features: a wide range of traumatic events, abuse of psychoactive substances, the presence of addictive dependencies, duration of traumatic experience, loss and separation, social environment, cultural and mental characteristics. In this regard, the scientific hypothesis of the study is that the treatment of post-traumatic stress disorder associated with addictions in the conditions of war should be specialized, taking into account all these features. A multimodal approach combining clinical-pharmacological therapy, psychosocial support, and psychotherapy may be effective in the understanding, diagnosis, and pharmacotherapy of conflict-related post-traumatic stress disorder. Post-traumatic stress disorder and related diagnoses were studied. Determined that the new diagnosis 6B41 – complex post-traumatic stress disorder is included in ICD-11. Differences between post-traumatic stress disorder and complex post-traumatic stress disorder were given. Established that there are no international and national protocols for the treatment and pharmacotherapy of complicated PTSD. Administration, organizational and legal, clinical and pharmacological, pharmaceutical management, social patient-oriented pharmacotherapy, cost-effectiveness of post-traumatic stress disorder's pharmacotherapy was systematized.

Conflict of interest. The author has approved the article for publication and declare that the research was conducted in the absence of any conflict or potential conflict of interest.

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