

Prevalence of alcohol use and depressive/anxiety symptoms among patients of opioid agonist treatment programs in Ukraine

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Abstract

This cross-sectional study explores the prevalence of alcohol use problems, depression/anxiety symptoms, and suicidal ideations among patients of the opioid agonist treatment (OAT) programs in Ukraine and their co-occurrence. AUDIT, Generalized Anxiety Disorder-7 (GAD-7), and Patient Health Questionnaire-9 (PHQ-9) were used to measure mental health conditions. In addition, the number of missed visits on site for substitute medication for the last month was counted, and blood alcohol levels were recorded (Drager Alcotest 6820, Draeger, Lübeck, Germany). Data were collected from October 2021 to January 2022 (before the full-scale Russian invasion) based on OAT centers in Kyiv, Sumy, and Lviv. The sample size was 999 patients. The overall rate of signs of alcohol-related problems (AUDIT), depression symptoms (PHQ-9), and anxiety symptoms (GAD-7) in the sample was 3.8 (SD 5.424), –7.42 (SD 5.336), and 5.058 (SD 4.264), respectively. For alcohol-related problems, 16.4% of the participants reported harmful drinking (one-month prevalence). Depression symptoms from moderate to severe were found in 26.73% of cases, and generalized anxiety symptoms from moderate to severe levels were found in 14.71% of patients (2-week prevalence). The 2-week suicide ideation prevalence was 24.9% (a quarter of all OAT patients). General co-occurrence of depression and anxiety symptoms was equal to 13.31% of all patients who participated in the study (32.13% of all patients having depression or anxiety symptoms). There was an increase in the general co-occurrence ratio with an increase in the severity of alcohol-related problems from 10.66% to 54.55%.

Keywords: *opioid agonist treatment (OAT), opioid agonist therapy, mental health, depression, anxiety, suicidal ideation*

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1. Introduction

The number of nonmedical opioid users worldwide has almost doubled in the recent decade. The latest estimation from the World Drug Report, 2022, states that 61 million people, representing 1.2% of the global population, used opioids in 2020 [1].

Opioid use is frequently associated with multiple health and social problems, which are the most significant risk factors for widespread mental disorders. In the comorbidity sections of Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition, Text revision (DSM-5-TR) and Eleventh Revision of the International Classification of Diseases (ICD-11) for opioid-related disorders, other substance use disorders are listed as the most frequent comorbidities, together with depression and anxiety [2, 3]. Other substances, especially tobacco, alcohol, cannabis, stimulants, and benzodiazepines, are mainly used to

reduce withdrawal or craving symptoms or to enhance the effects of opioids themselves. Periods of depression and anxiety are common during intoxication and withdrawal.

In the last two decades, statistics for the intertwined use of alcohol and opioids show relatively high numbers for different age and health condition groups in the United States, where the majority of such prevalence studies were conducted. Thus, in 2001–2002, opioid use disorder (OUD) with any comorbid alcohol-related disorder was diagnosed in 57.53% of adults who were mainly between 18 and 29 years (65%), male (73.9%), never married (63.2%), lived in an urban area (78.4%), and had insufficient personal income (65.4%) [4]. Opioid treatment seekers in 38% of cases had a comorbid alcohol use disorder (AUD) diagnosis in 2001–2006 [5]. Among adults with chronic

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pain and OUD diagnosis, 33.4–20.3% also had a diagnosis of AUD in 2006–2015 [6]. Comorbid diagnosis of OUD and AUD was reported in 42.3% of adolescents and young adults in 2015 [7]. Also, it is essential to mention that alcohol is often involved in opioid-related overdose deaths and is a risk factor for all-cause mortality among opioid users [8–11].

Researchers of the COMBINE (Combining Medication and Behavioral Intervention in Treating Alcohol Dependence) study in 2001–2004 discovered that participants with opioid misuse presented with not only more severe alcohol dependence but also more extensive psychiatric distress in scores of Brief Symptom Inventory (BSI) [12]. Also, data show that individuals with substance use disorders have a high prevalence of comorbid psychiatric disorders, including substance-induced and independent depression and anxiety [13–16]. Data from 2001 to 2006 display the co-occurrence of OUD with anxiety and depression among people who are in search of opioid treatment in 35.8% and 44.7% cases, respectively. For persons with a combined opioid and alcohol use, these numbers increased to 43.8% and 53.5%, respectively [5]. High number of depression (51.2%/63.5%) and anxiety (39%/53.9%) disorders also was found in 2006–2015 for opioid users with/without chronic pain [6]. One of the last systematic reviews on the association of opioid misuse with anxiety and depression shows that persons diagnosed with OUD based on DSM-IV and DSM-5 (studies starting from 2002) met the criteria for a depressive disorder in 27–61% of cases and anxiety disorder in 14–43% of cases based on a structured clinical interview. Also, it was reported that polysubstance use relates to higher rates of anxiety and depression symptoms [17].

As for persons who are in the process of medication-assisted treatment with methadone or buprenorphine, data reveal 24–50% of problematic alcohol consumption depending on the year, country, and severity of alcohol use with the tendency for associated high morbidity and mortality [5, 18–22]. At the same time, patients with alcohol misuse (AUDIT score ≥ 8) are less satisfied with their methadone dose and have more physical and mental health problems and poorer social functioning compared to AUDIT-negative patients [23]. One of the most considerable numbers for depression (82%) and anxiety (56%), starting from the mild level of severity according to Hamilton Rating Scales (HRS), was found among patients of opioid treatment centers in India [24]. Other studies reported numbers starting from around 50% comorbidity for both depression and anxiety and ending near 10% [22, 25–30]. There are data that patients on opioid agonist treatment (OAT) with a comorbid psychiatric diagnosis have a significantly lower quality of life than patients with only OUD [29]. Also, these mental health comorbidities are associated with worse treatment retention, treatment outcomes, severe opioid use, and higher mortality rates for patients treated with substituted medication [22, 28, 31, 32]. Nevertheless, opioid users receiving OAT (in comparison with those who do not) have lesser physical and mental health problems as well as better situations in occupational, financial, family, social, and other areas related to the quality of life [23, 27, 29, 33].

The OAT was introduced in Ukraine in 2004 through research projects and clinical studies [34]. Since 2017, it has been financed by the Government of Ukraine and fully integrated into the healthcare system in the form of OAT centers. As of 2024, 21,202 persons are receiving OAT [35] via 218 OAT centers all over Ukraine [36].

Despite differences in numbers (explained by the variability of studies' design, measuring methods, duration of prevalence, etc.), alcohol use, depression, and anxiety among participants of medication-assisted treatment programs are not only widespread but impact mortality, the severity of opioid use, and the efficacy of OAT itself. Understanding such a prevalence is essential for targeting comorbid patients and improving decision-making and care approaches to enhance the treatment results. In the Ukrainian case, when no sufficient data on the mental health of the OAT patients are available, mental health screening has additional value in attempts to convince decision-makers of the necessity of fulfilling patients' mental health needs.

2. Materials and methods

2.1. Methods and data collection

Prevalence data collection was organized based on three opioid-assisted treatment centers in Ukrainian cities such as Kyiv (Central Ukraine), Sumy (Eastern Ukraine), and Lviv (Western Ukraine), from October 1, 2021, to January 30, 2022 (before the full-scale Russian invasion).

The staff of OAT centers collected all the data (a convenient sampling method was utilized, covering all patients of three OAT centers). Doctors, psychologists, or social workers who previously obtained detailed instructions and training on the administration of the screening measures (AUDIT, Patient Health Questionnaire-9 (PHQ-9), and Generalized Anxiety Disorder-7 (GAD-7)) performed individual screenings during patients' appointments. All questionnaires (AUDIT for alcohol use patterns, PHQ-9 for depression symptoms, and GAD-7 for anxiety symptoms) were printed out and filled in together with each patient. In addition, the number of missed visits on site for substitute medication for the last month was counted, and blood alcohol levels were recorded with the breath-alcohol measuring instrument (Dräger Alcotest 6820, Draeger).

The Ukrainian versions of AUDIT, PHQ-9, and GAD-7, approved by the Ministry of Health of Ukraine for use in the OAT settings, were utilized [37]. The cut-off scores of 10 for depression (PHQ-9), 10 for anxiety symptoms (GAD-7), and 8 for hazardous alcohol consumption (AUDIT) were used [38, 39].

2.2. Data analysis

Data analysis and visualization were performed using JASP 0.14.3 (GNU Affero GPL v3, an open-source license). Descriptive statistics (mean, standard deviation, and frequency analysis) were used to describe the general results. The nonparametric Kruskal-Wallis one-way ANOVA (Analysis of Variance) was used to analyze multiple differences between independent samples. The Shapiro-Wilk test was used to analyze the normality of distributions. The contingency tables were used to analyze the co-occurrence of mental health conditions.

3. Results

3.1. Sample characteristics

Recruitment for the study was conducted from October 1, 2021 to January 30, 2022. The overall sample consisted of 999 persons who received buprenorphine or methadone as substitute medication at the OAT sites in Ukraine [Kyiv (354 patients; 35.4%), Lviv (337; 33.7%), and Sumy (308; 30.8%)]. No data regarding age, gender, occupation, or exact medication were collected.

The study samples of 999 patients (against 21,202 patients receiving the OAT) suggest high generalizability of the study results [35]; however, only 3 OAT centers of 218 participated in the study, and convenient sampling limits it to some extent.

3.2. Alcohol use, depression/anxiety symptoms, and suicide ideation prevalence

Cumulative averages for all measurements didn't show any significant extrema. The level of alcohol use within the AUDIT boundaries for low-risk consumption in the sample is 3.8 points;

the number of self-reported alcohol-free days—27.73 out of 31; the average GAD-7 score—5.06 (bottom line for mild anxiety); average PHQ-9 score—7.42 (mild depression); a mean number of missed visits for the last month—0.65; and the level of alcohol in blood within norm with no signs of intoxication—0.027 ppm (Table 1). None of the distributions comply with the normal distribution criteria (Shapiro–Wilk test).

The severity distribution (in percentages) varies on the estimated condition (Table 2). For alcohol-related problems, 16.4% of the participants show harmful drinking.

Table 1 • Descriptive statistics

				95% confidence interval mean						
	Valid	Missing	Mean	Upper	Lower	Std. deviation	Shapiro–Wilk	P-value of Shapiro–Wilk	Minimum	Maximum
AUDIT	999	0	3.801	4.137	3.464	5.423	0.715	<0.001	0.000	38.000
PHQ-9	999	0	7.418	7.749	7.088	5.336	0.922	<0.001	0.000	27.000
GAD-7	999	0	5.058	5.322	4.794	4.264	0.886	<0.001	0.000	21.000
Missed visits	998	1	0.645	0.809	0.481	2.644	0.256	<0.001	0.000	31.000
Alcohol level (promille)	999	0	0.027	0.034	0.020	0.116	0.249	<0.001	0.000	1.000

Table 2 • Levels of depression

Measures	N	%	% Summary
AUDIT scores			
Level 1 (0–7)	835	83.6	83.6
Level 2 (8–15)	127	12.7	16.4
Level 3 (16–19)	15	1.5	
Level 4 (20–40)	22	2.2	
PHQ-9 scores			
None-minimal (0–4)	302	30.23	73.27
Mild (5–9)	430	43.04	26.73
Moderate (10–14)	158	15.82	
Moderately severe (15–19)	73	7.31	
Severe (20–27)	36	3.60	
GAD-7 scores			
Minimal (0–4)	559	55.96	85.29
Mild (5–9)	293	29.33	14.71
Moderate (10–14)	101	10.11	
Severe (15–21)	46	4.60	
Suicide ideations			
Not at all	750	75.1	75.1
Several days	147	14.7	24.9
More than half the days	69	6.9	
Nearly every day	33	3.3	

Depression symptoms from moderate to severe levels were found in 26.73% of cases. Nearly three-quarters of respondents (73.27%) had no or mild occurrence of depressive symptoms.

Around half of the screened patients (55.96%) had minimal levels of generalized anxiety, and 29.33% of them had mild levels of it. Anxiety symptoms from moderate to severe levels were reported by 14.71% of patients.

We analyzed separately the answers to the last suicide-related question of PHQ-9 to understand the prevalence of suicide ideation among OAT patients in Ukraine. According to the data received, the 2-week suicide ideation prevalence is 24.9%. Nearly every day, 3.3% of patients had suicide ideations.

3.3. Alcohol use, depression, and anxiety co-occurrence

To analyze the co-occurrence of all three mental health conditions, contingency tables were calculated using the same cut-off score as in the previous calculations (Table 3).

General co-occurrence was calculated as a percentage of people with both conditions among all patients who participated in the study. General co-occurrence of depression and anxiety was observed in 13.31% of patients. That is equal to 32.13% of partial co-occurrence (percentage of all patients having depression or anxiety symptoms) (Figure 1).

However, the co-occurrence of depression and anxiety symptoms changes from 10.66% in those reporting the lowest levels of alcohol use to 54.55% in those with the highest level of alcohol use, suggesting that more severe alcohol-related problems correspond with higher levels of co-occurrence of depression and anxiety symptoms.

Table 3 • Contingency tables for AUDIT, PHQ-9, and GAD-7

AUDIT level	PHQ levels		GAD levels		Total	% (general co-occurrence)	% (partial co-occurrence)
			>10	<10			
Level 1	>10	Count	89.000	101.000	190.000	10.66%	30.48%
	<10	Count	13.000	632.000	645.000		
	Total	Count	102.000	733.000	835.000		
Level 2	>10	Count	28.000	23.000	51.000	22.05%	35.00%
	<10	Count	1.000	75.000	76.000		
	Total	Count	29.000	98.000	127.000		
Level 3	>10	Count	4.000	5.000	9.000	26.67%	30.78%
	<10	Count	0.000	6.000	6.000		
	Total	Count	4.000	11.000	15.000		
Level 4	>10	Count	12.000	5.000	17.000	54.55%	41.38%
	<10	Count	0.000	5.000	5.000		
	Total	Count	12.000	10.000	22.000		
Total	>10	Count	133.000	134.000	267.000	13.31%	32.13%
	<10	Count	14.000	718.000	732.000		
	Total	Count	147.000	852.000	999.000		

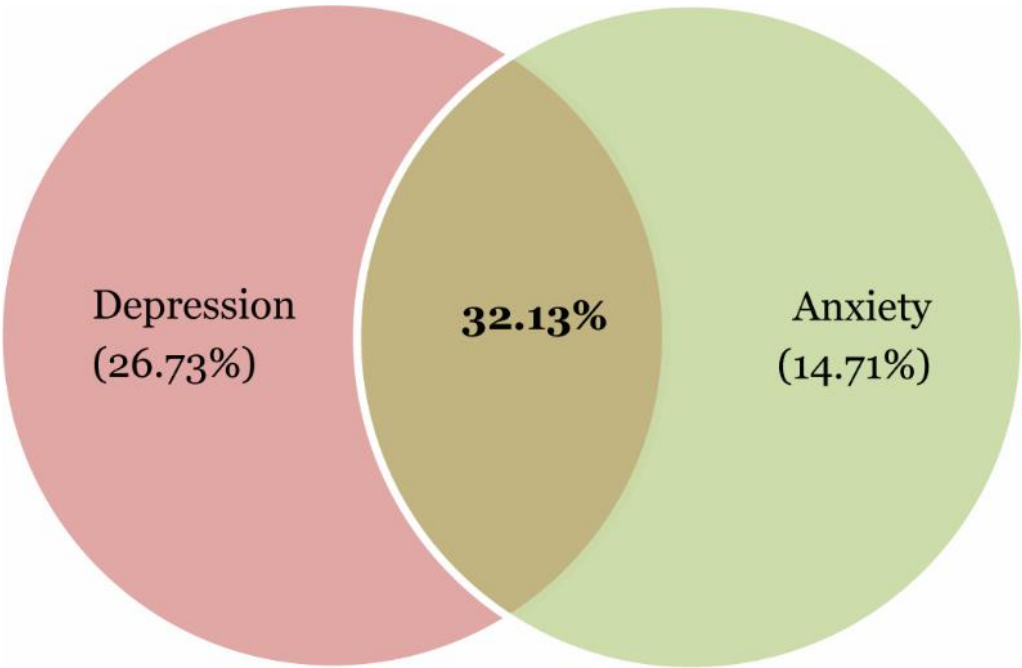


Figure 1 • Co-occurrence of depression and anxiety (partial).

3.4. Alcohol use problems and mental health of the OAT patients

To understand more about the connections between alcohol use and comorbid mental health conditions, four levels of AUDIT measure [Level 1 (0–7); Level 2 (8–15); Level 3 (16–19); Level 4 (20–40)] were used as the grouping variable (descriptive statistics in **Table 4**). An additional measure was considered—“Missed visits to the OAT site”.

To test between-subjects effects, nonparametric Kruskal-Wallis one-way ANOVA was performed for each dependent variable (depression, anxiety, and missed visits), with the AUDIT level as

an independent variable (missed visit: 48,958, df 3, $p < 0.001$; PHQ-9: 62,607, df 3, $p < 0.001$; GAD-7: 55,588, df 3, $p < 0.001$).

The depression level significantly elevates as the level of alcohol-related problems increases (**Figure 1**): 6.98 (SD 5.114) for the absence of problems in Level 1, 9.299 (SD 5.386) for Level 2, 11.467 (SD 4.853) for Level 3, and 13.864 (SD 6.081) for Level 4. The same situation is observed for anxiety [elevation of the means from 4.663 (SD 4.073) to 10.636 (SD 5.123)].

Missed visits do not change significantly for patients with different levels of alcohol-related problems (0.571–0.800). However, when the problems become severe (Level 4), the mean for the missed visits increases dramatically to 2.5 (SD 4.262).

Table 4 • Descriptive statistics (AUD as a grouping variable)

					95% confidence interval mean						
	AUDIT level	Valid	Missing	Mean	Upper	Lower	Std. deviation	Shapiro–Wilk	P-value of Shapiro–Wilk	Minimum	Maximum
PHQ-9	1	835	0	6.890	7.237	6.543	5.114	0.907	<0.001	0.000	27.000
	2	127	0	9.299	10.236	8.363	5.386	0.963	0.001	0.000	26.000
	3	15	0	11.467	13.923	9.011	4.853	0.878	0.045	4.000	17.000
	4	22	0	13.864	16.405	11.323	6.081	0.985	0.974	0.000	27.000
GAD-7	1	835	0	4.663	4.940	4.387	4.073	0.872	<0.001	0.000	21.000
	2	127	0	6.386	7.109	5.663	4.158	0.937	<0.001	0.000	18.000
	3	15	0	7.600	10.449	4.751	5.629	0.886	0.058	1.000	19.000
	4	22	0	10.636	12.777	8.496	5.123	0.990	0.997	0.000	21.000
Missed visits	1	834	1	0.571	0.754	0.387	2.707	0.213	<0.001	0.000	31.000
	2	127	0	0.795	1.098	0.493	1.738	0.524	<0.001	0.000	9.000
	3	15	0	0.800	1.380	0.220	1.146	0.718	<0.001	0.000	3.000
	4	22	0	2.500	4.281	0.719	4.262	0.661	<0.001	0.000	17.000

4. Discussion

The results of our study showed mild average levels of severity for all screened mental conditions; thus, the overall rate of signs of alcohol-related problems (AUDIT) in the sample was 3.8 (SD 5.424); general means for depression (PHQ-9) and anxiety (GAD-7) were 7.42 (SD 5.336) and 5.058 (SD 4.264), respectively. Altogether, 16.4% of respondents scored positively for unhealthy alcohol consumption (12.7% hazardous, 1.5% harmful, and 2.2% high-risk levels), 26.73% for signs of depression (3.6% severe, 7.31% moderately severe, and 15.82% moderate levels), and 14.71% for signs of anxiety symptoms (4.6% severe and

10.11% moderate levels). The 2-week prevalence of suicide ideation was high; 24.9% of study participants scored positively.

A comparison of obtained data with others collected in Ukraine before the full-scale Russian invasion is shown in **Table 5**. Several epidemiological mental health studies using the PHQ-9 and GAD-7 were conducted on Ukrainian samples. Comparisons of depression, anxiety, and suicide ideation prevalence among internally displaced persons (IDP) due to the first wave of Russian invasion [40], internally displaced people and the general population [41], and the Romani population of Ukraine [42] allow to observe some differences and speculate about their causes.

Table 5 • Data on depression, anxiety, and suicide ideation among different populations in Ukraine (2-week prevalence, data before February 2022)

Mental health conditions	OAT patients			Romani population	Internally displaced people		General population
	(current study)	[43]	[44]	[42]	[40]	[41]	
PHQ-9, depression	26.73%	43.5%	39.4%	32.7%	22%	25%	14%
GAD-7, anxiety	14.71%	X	18.2%	29.6%	17%	20.2%	12.2%
Suicide ideation	24.9%	X	X	26.9%	X		X

The levels of depression prevalence among OAT patients found by Machavariani et al. [43], as well as by Dumchev et al. [44], are higher than those from the current study; however, all of them were in the worldwide statistics window for people with OUD of 27–61% [17]. Ukrainian OAT patients’ depression is more prevalent than in the general Ukrainian population but comparable with ones among vulnerable samples, such as Romani people [42] and IDPs [40, 41].

At the same time, OAT patients’ generalized anxiety prevalence is 2–1.6-fold lower than in the Romani population (14.71–18.2% vs.

29.6%) and around 2–5% lower than in IDPs (14.71–18.2% vs. 17–20.2%).Data on the Ukrainian sample are under or comparable only with a lower threshold for the worldwide prevalence of anxiety disorders among opioid users based on a recent systematic review of 14–43% [17] and a meta-analysis of 24.0–33.3% [45].

As for suicide ideation, there is only one source for intra-country comparison, however, with different methodologies based on the World Health Organization (WHO) Composite International Diagnostic Interview (CIDI) [46]. Data collected in 2002 show 8.2% of lifetime and 1.8% of 12-month prevalence for suicide

ideation [46]. Our data demonstrate a drastically higher level of 2-week suicidal ideation prevalence (24.9%) in comparison to those data for the general population. Ukrainian data are consistent (although it is essential to mention the difference in data gathering methodology and time frame of prevalence) with those recently found across the globe. Thus, US adults with OUD self-reported past 12-month thoughts of killing oneself in 29.8% of cases in 2020 [47]; among OAT centers' participants interviewed in 2021 in Nepal, lifetime suicidality was observed in 26.0% of cases [48]; 41% of the OAT patients in Norway surveyed during 2016–2020 had attempted to die by suicide at least once during their lifetime [49].

Alcohol-related problems in Ukraine for the first time were screened with CIDI in 2002, providing the general population data for the lifetime (13.49%), 12-month (5.84%), and 1-month (2.83%) prevalence [50]. The new study utilizing AUDIC-C (abbreviated form of the AUDIT) revealed 13.3% of alcohol-related problems prevalence among OAT patients in Ukraine, which is close to our data (16.4%) [43]. It can be considered as a sign of elevated risk to have alcohol-related problems in comparison with the general population.

High numbers of harmful alcohol consumption by opioid users are the key finding in the majority of studies exploring the question of substances intertwined use [4, 5, 7, 18].

4.1. Limitations of the study

The study has limitations. Data were gathered from October 2021 to January 2022, and since then, the situation in Ukraine has drastically changed due to the full-scale Russian invasion. Therefore, our data and conclusions might serve as a baseline for further research, but they do not represent the real-time situation. No data regarding age, gender, occupation, exact medication, etc., were collected. Therefore, concluding about social or other determinants is impossible. The stage of the OAT treatment was not recorded for each patient; therefore, it is impossible to conclude the impact of the OAT lengths and stages on the patient's mental health condition. In the study, only screening instruments were used, without the confirmation of the diagnosis via clinical interviews or other means; therefore, it is impossible to make conclusions about the prevalence of mental health disorders based on the self-reported measures, and we prefer to use the "mental health conditions" and "symptoms". Additionally, despite the extensive use of the AUDIT, PHQ-9, and GAD-7 in Ukraine and the approval of the Ministry of Health for use in the OAT settings, validation studies of those instruments are scarce.

5. Conclusions

The prevalence of mental health conditions among people with OUDs who are receiving opioid-assisted treatment is very high in comparison to the general population, as explored in other studies. Depression is almost 2-fold higher (26.73% vs. 14%), anxiety is comparable (14.71% vs. 12.2%), and suicide ideations are highly prevalent (24.9%, each 4th of the patients). The same is valid for alcohol use problems, and their prevalence is very high (16.4%).

As for the comorbidities between all screened conditions, 13.31% of all patients who participated in the study had co-occurrence of depression and anxiety symptoms (32.13% of all screened positive for depression/anxiety). The depression and anxiety co-

occurrence shows a tendency to grow with increasing severity of alcohol use-connected problems (from 10.66% to 54.55%).

The severity of depression and anxiety symptoms is connected to the seriousness of alcohol use problems. The more severe the alcohol-related problems of the OAT patients, the higher the scores for depression (the mean PHQ-9 score changes from 6.89 for the patients with an absence of alcohol-related problems to 13.86 for those with the largest AUDIT scores). The same tendency is for generalized anxiety scores (changing from 4.66 GAD-7 mean scores to 10.64). The additional interconnection was found for the number of missed visits to the OAT sites, with most of the weight falling to the last level of AUDIT scores, indicating possible moderate or severe AUD—2.5 missed days during the month.

The data received corresponded with those obtained in a few similar studies conducted in Ukraine.

The results of this study point out critical next steps regarding the support of people receiving OAT in Ukraine. Their mental health needs must be taken into account, as it impacts not just the patient's well-being but adherence to OAT itself. There must be a proposal for additional mental health support (psychological, social, and pharmacological) for OAT patients. During the support, complex needs must be addressed simultaneously—alcohol use-related problems, depression, anxiety, and other possible mental conditions.

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Author contributions

Conceptualization, V.K. and I.I.; methodology, V.K.; formal analysis, V.K.; investigation, V.K. and V.G.; resources, I.I.; data curation, V.K.; writing—original draft preparation, V.K. and V.G.; writing—review and editing, I.I.; visualization, V.K.; supervision, I.I.; project administration, I.I.; funding acquisition, I.I. All authors have read and agreed to the published version of the manuscript.

Conflict of interest

The authors declare no conflict of interest.

Data availability statement

Data are available under the Creative Commons Zero "No rights reserved" data waiver (CC0 1.0 Public domain dedication) on Zenodo: Prevalence of alcohol use, depressive and anxiety disorders among patients of opioid agonist treatment programs

in Ukraine [Data set]. <https://doi.org/10.5281/zenodo.10256403> [51].

Institutional review board statement

The study protocol was developed in close collaboration with representatives of the OAT sites. Experts from the OAT sites evaluated all research tools. The study followed the Declaration of Helsinki and the National Psychological Association of Ukraine Ethical Regulation. All the research stages were developed according to the requirements of international guidelines for the ethical review of epidemiological studies [52, 53]. The Zhytomyr State University Ethics Review Board approved the ethics protocol, approval number 05-2208/2021 from 10.07.2021.

Informed consent statement

Informed consent was obtained from all the patients involved in the study.

Sample availability

The authors declare no physical samples were used in the study.

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