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SURVEY OF CLIENT SATISFACTION WITH OPIOID MAINTENANCE THERAPY (OMT) SERVICES AMONG PARTICIPANTS IN KYIV AND THE KYIV OBLAST REGION: A PILOT STUDY REPORT

The Eurasian Harm Reduction Association (EHRA) is a non-profit public organisation, uniting 267 organizational and individual members from 29 countries of the Central and Eastern Europe and Central Asia region (CEECA). EHRA's mission in the CEECA region is the creation of a favourable environment for sustainable harm reduction programmes and decent lives for people who use drugs.

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A note about language

The following report was originally produced in Russian. It has been translated from the original, as have the responses of study participants and some of the sources.

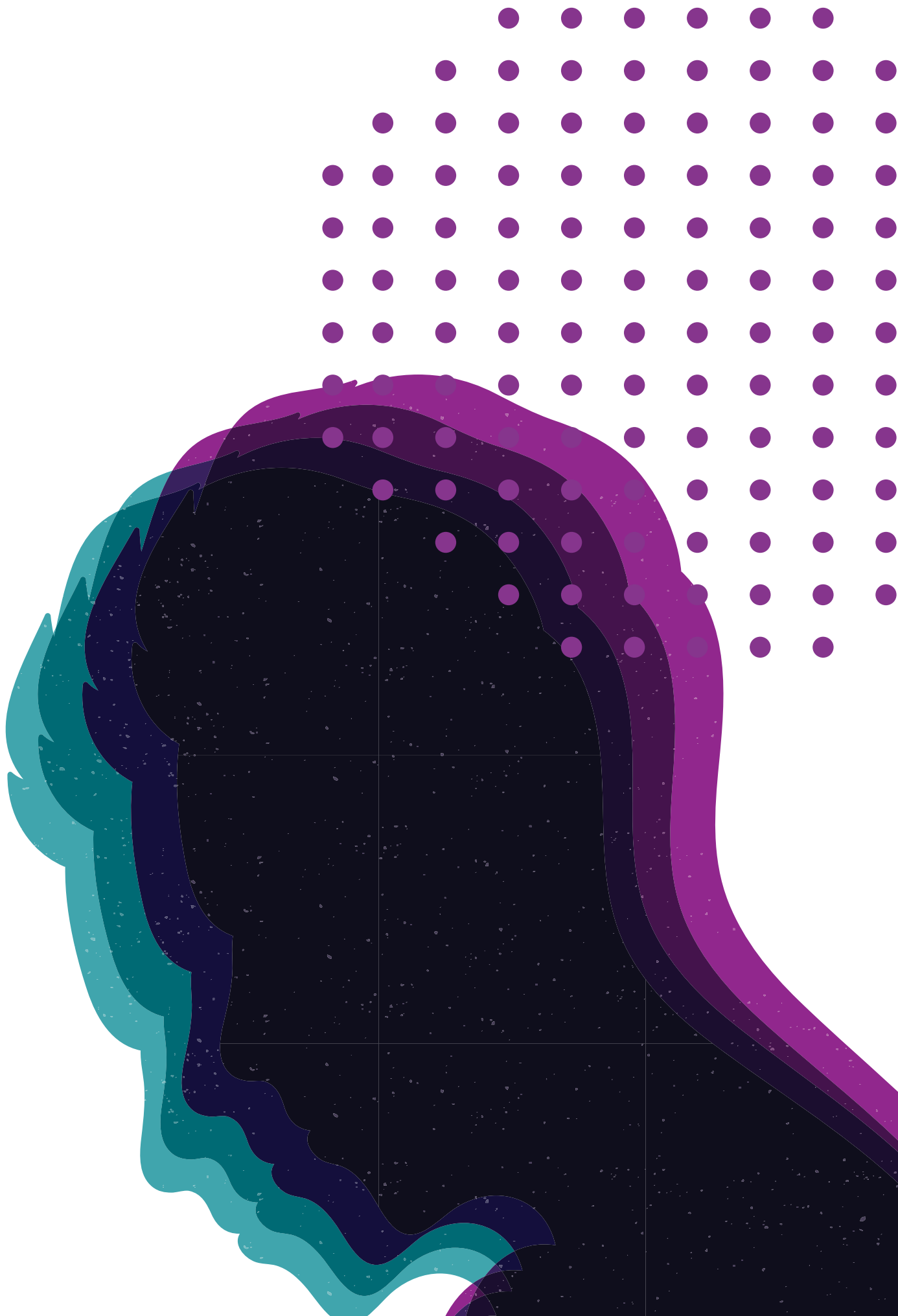
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ABBREVIATIONS AND ACRONYMS

CSQ-8	Client Satisfaction Questionnaire
EHRA	Eurasian Harm Reduction Association
Global Fund	The Global Fund to Fight AIDS, Tuberculosis and Malaria
IRB	Institutional review board
HIV	Human immunodeficiency virus
HRQL	health-related quality of life
OMT	opioid maintenance therapy
PEQ-ITSD	Patient Experiences Questionnaire for Interdisciplinary Treatment for Substance Dependence
PEPFAR	United States President's Emergency Plan for AIDS Relief
PWID	People who inject drugs
SSS-30	Service Satisfaction Scale
VSSS-32	Verona Service Satisfaction Scale
VOLNA	Ukrainian Network of People who use Drugs
WHO	World Health Organization



RESEARCH STRATEGIES: PARTNERSHIP APPROACHES TO COMMUNITY-BASED RESEARCH

Our approach to this study was based on the principles of equal partnership with the community of people who inject drugs and/or receive opioid maintenance therapy (OMT). This community was represented during this project by partners from four organizations: the Ukrainian Network of People who use Drugs (VOLNA), Drug-users Ukraine, the Drop-in Centre and the ENEY. Financial and organizational support for the research was provided by the Eurasian Harm Reduction Association (EHRA).

The main principles of equal partnership in community-based research were outlined in a paper entitled *The review of community-based research: assessing partnership approaches to improve public health* (59), which states that community-based research does the following:

- 1.** It recognizes community as a unit of identity. Traditional ways of identification—such as through membership in a family, friendship network, professional community or geographic neighbourhood—are socially constructed dimensions of identity created and recreated through social interactions. As a unit of identity, community is characterized by an emotional connection between its members, and by common symbol systems, shared values and norms, mutual (although not necessarily equal) influence, common interests and a mutual respect for each other's needs.
- 2.** It builds on strengths and resources within the community.
- 3.** It facilitates collaborative partnerships between researchers and community members in all phases of research.
- 4.** It integrates knowledge and action for the mutual benefit of all partners.
- 5.** It is a process of co-learning and mutual empowerment that facilitates the reciprocal transfer of knowledge, skills, capacity and power.
- 6.** It creates mechanisms to ensure the sustainability of partnerships.
- 7.** It addresses health from both positive and ecosystem model perspectives. The ecosystem model approach in health care emphasizes biomedical, social, economic, cultural, historical and political factors as determinants of health and disease.
- 8.** It involves ongoing feedback and the use of findings to inform the decision-making process and data-based actions.

INTRODUCTION

The first opioid maintenance therapy (OMT) programmes in Ukraine were officially launched in 2004 following the appeals of several international agencies to introduce OMT to tackle the spread of HIV among people who inject drugs (1). The first programmes used buprenorphine, but methadone was introduced in 2008, after the Ministry of Health approved the necessary regulations (2). Funding has been provided for OMT programmes since 2004, particularly through grants from the Global Fund to Fight AIDS, Tuberculosis and Malaria (the Global Fund).

In 2008, the Association of OMT Clients in Ukraine (zapitay.in.ua) was established in Kyiv to: (a) advocate for the human rights of people who inject drugs; (b) raise awareness about OMT; and (c) support people who inject drugs, people receiving OMT, their families, and other affected communities. In 2015, the National Hotline on Drug Addiction and OMT was established, aiming to do the following:

...reduce the negative effects of the HIV/AIDS epidemic and drug addiction, to improve the quality of life of people living with HIV, OMT clients and their families and affected people, to expand the access to OMT programmes, and to improve the quality of medical and psychological care through the provision of consulting services (over the phone and online) on OMT, injecting drug use, viral hepatitis and other related issues. (3)

By the end of 2016, the Ministry of Health had approved the allocation of 13 million UAH from the domestic budget for the procurement of medicines for OMT. In 2018, the procurement of medicines for OMT programmes was completely funded for the first time by the domestic budget (4). In the same year, the Ukrainian Network of People who use Drugs (VOLNA) was established to ensure the sustainable transition from Global Fund support to domestic funding.

In particular, VOLNA's goals involved the monitoring of government commitment to ensure that the provision of services and the scale-up of existing OMT programmes was uninterrupted. It was important that sites that received funding from the state and local budgets were also financially supported through the grants provided to the government by international donors, such as the Global Fund and the United States President's Emergency Plan for AIDS Relief (PEPFAR). According to the Centre for Public Health under the Ukraine Ministry of Health, 995 of the 11,853 patients in treatment as of 1 September 2019 were receiving treatment that was funded with the help of grants from the Global Fund and PEPFAR.

Definition of key terms, priorities and components of opioid maintenance therapy programmes in Ukraine

The implementation of OMT programmes in Ukraine is regulated by Decree No. 200, On the Approval of the Regulations for Opioid Maintenance Therapy for Patients with Opioid Addiction (the Decree) (5). Within the framework of the Decree, a person receiving OMT medication is referred to as “a patient who has been diagnosed with opioid addiction in compliance with the International Classification of Diseases (ICD–10) [code] F11: Mental and Behavioural Disorders due to use of Opioids” (5).

Decree No. 200 declares that OMT programmes are an integrated set of medical, social and (as applicable) psychological services and support. For programme admission, priority must be given (and medicines dispensed) to patients who, in addition to a drug addiction diagnosis, have any of the following diseases or conditions:

- HIV.
- Tuberculosis, particularly in the case of compulsory treatment (Article 11 of the Law of Ukraine “On Combating Tuberculosis”).

- Pregnancy.
- Hepatitis B or C.
- Septic conditions.
- Oncological diseases.

In compliance with the given priorities, the Decree guarantees access to medical care for OMT patients and further referral to health facilities according to their diagnoses.

In addition to general guidelines on the provision of OMT services, the Decree sets forth OMT priorities and programme contents in Ukraine as a whole. The priorities of OMT have been described as follows: (a) to ensure access to medical care and further referral of OMT patients to health facilities according to their diagnoses; and (b) (as the doctor's responsibility) to control compliance with OMT programme policies and the authorized use of OMT medicines. With regard to the contents of the programmes, the Decree mandates that the Ministry of Health and its subordinate facilities “ensure an integrated approach to the provision of medical, social, and (as required) psychological



care to patients with opioid addiction in accordance with the Ukrainian law,” and that “social and psychological support is provided to OMT patients involving social workers and psychologists—either staff members, if available from the primary health care facility, or specialists from other institutions and public organizations as applicable” (5).

In particular, an important programme priority is to control compliance with the authorized use of OMT medicines, whether they are self-administered or taken under direct observation at the facility:

- To monitor compliance with the authorized use of medicines received by patients for self-administration in out-patient settings (including at-home modes of care delivery), the doctor shall request on a regular basis (at least once within 30 days) that the patient or their caregiver (e.g., family member, custody holder or guardian) submit their unused medication to control the stock currently on hand.
- To control compliance in facility settings, the OMT physician or nurse asks the patient to take medication under direct observation, without turning away from the doctor. This is to ensure that the substance has been swallowed and that no portion of it is kept in the patient’s mouth. The individual is then asked to fill the disposable cup they used to take their medication with a fresh portion of drinking water and to drink it. Patients are also encouraged to say a couple of phrases afterwards to verify that the substance has been completely swallowed.

A decision to terminate OMT can be made by the doctor if: (1) the patient receiving therapy submits a written request to discontinue their enrolment in OMT programmes; or (2) the patient violates the OMT programme rules and policies, which are mandatory for everyone receiving OMT. The OMT programme rules and policies are set out in the informed consent form, which must be signed by everyone when they enter the programme. According to these rules, the patient receiving OMT is not allowed to do any of the following:

- Visit health facilities to receive OMT medication when under the influence of alcohol or illicit drugs.
- Take from the OMT facility medicines that were received for observed therapy unless they are authorized take-home doses that have been dispensed for self-administered therapy in out-patient settings, including at-home modes of delivery.
- Perform any unauthorized activities with psychoactive substances, illicit drugs or precursors on the health facility premises.
- Cause a nuisance in the health facility. Medical personnel may seek police assistance to deal with individuals who are causing a public nuisance.
- The doctor can make a decision to discontinue OMT enrolment if a patient who has been prescribed supervised or daily pick-up misses 10 or more consecutive doses within a month. Patients are supposed to inform their doctor if they need to travel to another region for a valid reason (such as hospitalization, relocation, business travel or vacation).

In addition to the OMT sites funded by the government and international donors, a network of OMT providers has been developed in Ukraine based on private health clinics and units that provide OMT services without receiving governmental funds or subsidies. De jure such sites are not considered as OMT program to assist patients with drug dependence, but de facto they perform this function. The activity of such sites is regulated by Order of the Ministry of Health of Ukraine No. 360 “On approval of the Rules for prescribing for medical products, the Procedure for the dispatch of medicinal products and medical products from pharmacies and their structural units, Instructions on the order of storage, registration and destruction of prescription forms” (120). Such sites provide detox services (short-term and long-term) and the opportunity to collect prescriptions for take-home medicines. All of these services are provided on a per fee basis.

According to the World Health Organization (WHO) guidelines for psychosocially-assisted pharmacological treatment of opioid dependence, this mode of OMT service delivery is referred to as “unsupervised treatment” (6). Such unsupervised treatment is cheaper to establish and easy to expand. The expansion of treatment programmes is a top priority for many countries that are experiencing both high rates of HIV incidence among people who inject drugs and low treatment rates, and some research indicates that the expansion of unsupervised treatment with buprenorphine is the most rapidly available and feasible intervention to meet existing treatment needs in the short term (7). Despite this, it is not completely clear whether unsupervised treatment using predominantly buprenorphine can be as efficient for reducing the spread of HIV as directly observed treatment with methadone (6).

The development of an infrastructure of private service providers in parallel to those funded by the government and international donors can be explained by the fact that it is possible within the existing legislation, and by a high demand for OMT services, which for a number of reasons cannot be entirely satisfied by the existing network of sites funded by the government and through donors. We will investigate these reasons later in this report.

It is important to note that although Order No. 360 does not define OMT prescription as an integrated package of services, according to our data, in practice these sites operate under the same principles as sites subsidized by the state. In particular, due to the fact that the technical requirements for the implementation of these activities are general and are formulated in the regulatory documents presented below. In addition, as indicated by employees of partner organizations with which this study was conducted, the activities of counseling and testing for HIV are also carried out on private OMT sites. In general, compliance with the technical requirements defined in regulatory documents guarantees the private OMT sites the opportunity to carry out their activities under the Law. Non-compliance with these requirements leads to the forced closure of such sites by regulatory authorities.

Unfortunately, no information is publicly available on the number of unsupervised sites or the patients who use them.

In addition to the above mentioned Orders No. 200 and No. 360, there are a number of other documents in accordance with which the provision of OMT services in Ukraine is regulated, the main of which are:

- Decree of the Cabinet of Ministers of Ukraine No. 333 “On approval of the Procedure for acquisition, transportation, storage, delivery, use and destruction of drugs, psychotropic substances and precursors in health care facilities” (121).
- Order of the Ministry of Internal Affairs of Ukraine No. 52 “Requirements for sites and premises intended for implementation of activities on circulation of narcotic substances, psychotropic substances, precursors and storage of such substances removed from illegal circulation” (122).
- Order of the Ministry of Health of Ukraine No. 590 “On approval of officially recommended equipment lists covering medical items for specialized health care facilities and structural divisions of health care facilities providing clinical and diagnostic assessment and care to people with HIV/AIDS” (123).

A note on terminology

In this report, we will use the term “OMT patients” to refer to participants in any OMT programme. “Respondents” will be used to refer to study participants who are OMT patients. Keeping with the provisions of Decree No. 200, we understand that OMT is an integrated set of medical, social and (as applicable) psychological services and supports; as such, we will refer to it as “OMT service” (or “OMT services”). OMT sites funded by the government and international donors will be referred to as “funded sites,” while sites based on private clinics and offices will be referred to as “private sites.”

STUDY BACKGROUND

Study rationale

The lack of attention paid to treatment satisfaction in Ukraine can probably be attributed to a shift in emphasis towards the needs of increasing service coverage, even while the quality of service is seldom included in ongoing discussions. Moreover, OMT programmes in Ukraine—which were originally introduced to respond to the rapidly increasing rates of HIV infection rather than rates of injecting drug use—have become a key pillar in the prevention of tuberculosis and viral hepatitis B and C. As such, the main performance indicators in OMT programmes involve the number of new patients receiving treatment, patient retention (adherence) rates, the number of patients living with HIV who are on treatment, and other similar indicators. Since OMT programmes have been operating in Ukraine for more than 10 years, however, the study of patient satisfaction with treatment offers opportunities for a better understanding of OMT service development prospects in the long run and of treatment trajectories and changing needs at the patient level.

Since 2000, WHO has been calling for studies of client satisfaction with treatment among patients attending OMT and other addiction treatment programmes in order to provide a better understanding of the current situation and to leverage the programme development efforts in the field (42). A key feature in the study of patient satisfaction with treatment is to shift the focus from treatment outcomes to patient needs and expectations (43). The study of satisfaction with treatment helps deepen our understanding of the views of patients about: (a) the programme environment; (b) the interactions between patients and treatment service providers; (c) the client experience and treatment dynamics; (d) and the possible (and desirable) treatment prospects or outcomes (36–41).

The main limitation for the assessment of patient satisfaction among OMT programme participants is the relatively small number of verified tools available to measure their satisfaction with treatment. Prior to the introduction of specific tools, patient satisfaction in OMT programmes was assessed using tools designed to measure satisfaction in the wider patient population. This included the Client Satisfaction Questionnaire (CSQ-8) (44), the Service Satisfaction Scale (SSS-30) (45), and the Verona Service Satisfaction Scale (VSSS-32) (46). In 2002, J. de los Cobos et al. introduced a VSSS-32 for methadone-treated opioid-dependent patients—the VSSS-MT—that was specifically adapted for use in substitution (methadone) therapy programmes (46). The VSSS-MT consists of 27 questions on a 5-point Likert scale that address specific aspects of service delivery and the overall quality of services. The authors report that the VSSS-MT demonstrates good-to-excellent internal reliability and a satisfactory reliability level at test–retest.

Other tools have been developed. In 2004, Australian researchers who believed that the VSSS-MT was too long and complicated for most OMT patients developed a shorter version that consists of 11 questions (47). In 2013, Norwegian researchers developed a new questionnaire (consisting of 33 questions) to assess treatment satisfaction among people with drug addictions: the Patient Experiences Questionnaire for Interdisciplinary Treatment for Substance Dependence (PEQ-ITSD) (48). Despite these attempts to develop an improved assessment tool to measure treatment satisfaction in OMT patients, VSSS-MT remains the most widely used tool in published studies (36, 38, 49, 50).

Since none of the previously developed tools for assessing treatment satisfaction among OMT patients were tested in post-Soviet countries, it was reasonable to fill that gap by conducting a

short qualitative survey to form a set of questions to measure satisfaction with OMT services using data collected in Ukraine. We assumed that for a quantitative study of satisfaction with OMT services in Ukraine, we would need a carefully developed tool that had been tested on a sample with the highest variability of all available types of OMT patients. Moreover, as far as we know, none of the studies previously conducted in Ukraine have involved patients of private OMT sites, even though such sites might be available in Ukraine in even greater numbers than funded ones. We assumed that studying and understanding patient experiences at these private OMT sites would be equally important for developing a better understanding of patient satisfaction with treatment, which in turn can

establish a framework for the development of good practice guidelines for the provision of OMT service in Ukraine.

With that rationale in mind, the goal of this study was set as follows: to measure client satisfaction with OMT services among patients of OMT sites funded by the government and international donors and private ones in Kyiv and the Kyiv Oblast region.

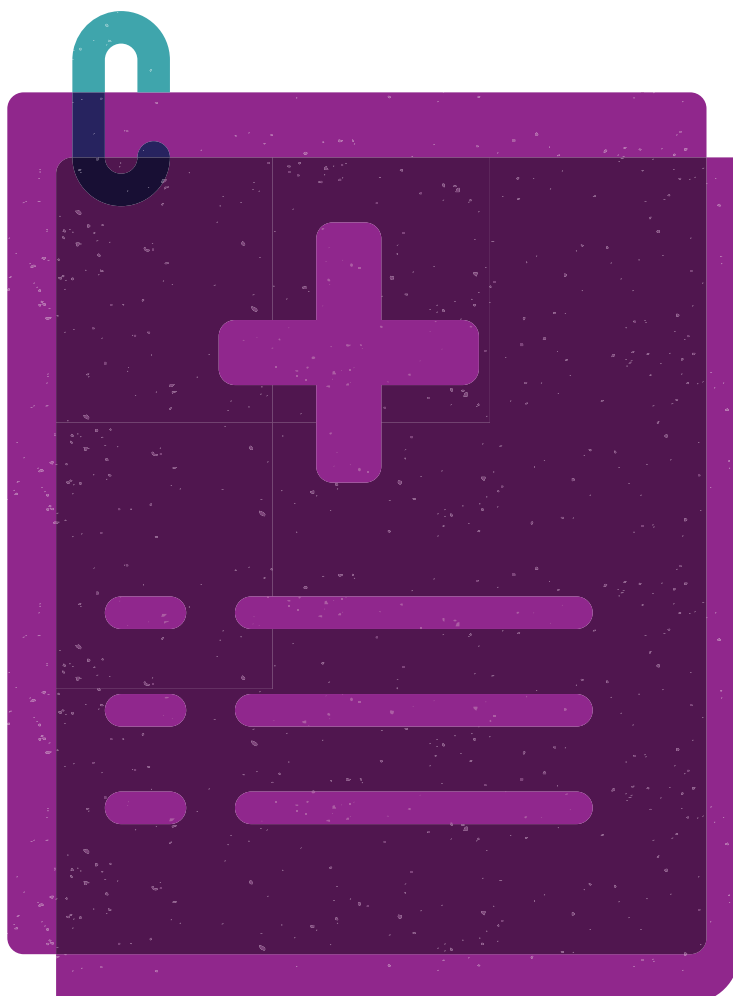


Context

This section provides information that is publicly available on the website of the Ukraine Centre for Public Health (phc.org.ua). We considered it important to study two data sets: data presented at the time of writing of the protocol of this study (March–April 2019), and data presented at the time of the end of this study (October 2019) from 01/02/2019 and from 01/09/2019. In fact, the field data collection ended on October 20, but at the time of writing this report (November 2019), the data from October 2019 have not yet been made publicly available. Regardless, we value this opportunity and thank the Centre for Public Health for providing to the public monthly data on patients of OMT sites in Ukraine. We consider these data to be informative, and using them to analyze the treatment provision situation in Ukraine may well be an important monitoring tool for both patient and community organizations. Analysis of these data also can be used as a source for formulating research questions and building a research design.

As of 1 February 2019 (when the study protocol was written), data from the Centre for Public Health indicated that funded OMT sites ($n = 211$) in 25 regions of Ukraine involved 11,439 patients (see Table 1). A total of 9,425 (82.2%) patients were men, and 2,014 (17.8%) were women. Methadone in tablet form was provided to 10,180 patients (89%); methadone in liquid form was provided to 174 patients (1.5%). A further 1,084 patients (9.5%) were treated with buprenorphine.

For self-administered therapy, medicines were dispensed to 3,780 OMT patients (33% of total participants), who received take-home doses of medication for a certain period of time (e.g., seven to 10 days). In addition, 887 patients (8%) received a prescription to purchase medication at their own expense, and 547 patients (5%) received OMT medicines in hospital settings (i.e., at in-hospital facilities or—in the case of patients with a confirmed disability status—at home). The number of HIV-positive OMT patients was 4,657 (40.7%) (8). In 2018, OMT sites were opened at primary health-care facilities: during the year, 33 new OMT sites were opened in the regions and nine sites were opened in Kyiv. By the end of the year 643 (6%) patients were receiving OMT at those newly opened sites.



As of October 2019 (the completion of the study), the most recent data available from the Centre for Public Health indicated that funded OMT sites (n = 204) in 25 regions of Ukraine involved 11,853 patients (see Table 1). There were 9,808 (88.6%) men and 2,045 (17.2%) women. Methadone in tablet form was dispensed to 10,506 patients (89%); methadone in liquid form was provided to 258 patients (2.1%). Buprenorphine was provided to a further 1,089 patients (9.1%).

For self-administered therapy, medicines were dispensed to 4,551 OMT patients (38.4% of total patients), who received take-home doses of medication for a certain period of time (e.g., for seven to 10 days). In addition, 904 patients (7.6%) received prescriptions to purchase medication at their own expense, and 606 patients (5.1%) received medicines in hospital settings (i.e., in-hospital facilities or—in the case of patients with a confirmed disability status—at home). The number of HIV-positive OMT patients was 4,747 (40%).

TABLE 1. NUMBER OF PATIENTS RECEIVING SERVICES FROM FUNDED OPIOID MAINTENANCE THERAPY SITES IN UKRAINE, BY SERVICE TYPE, BEGINNING OF THE STUDY AND ITS COMPLETION*

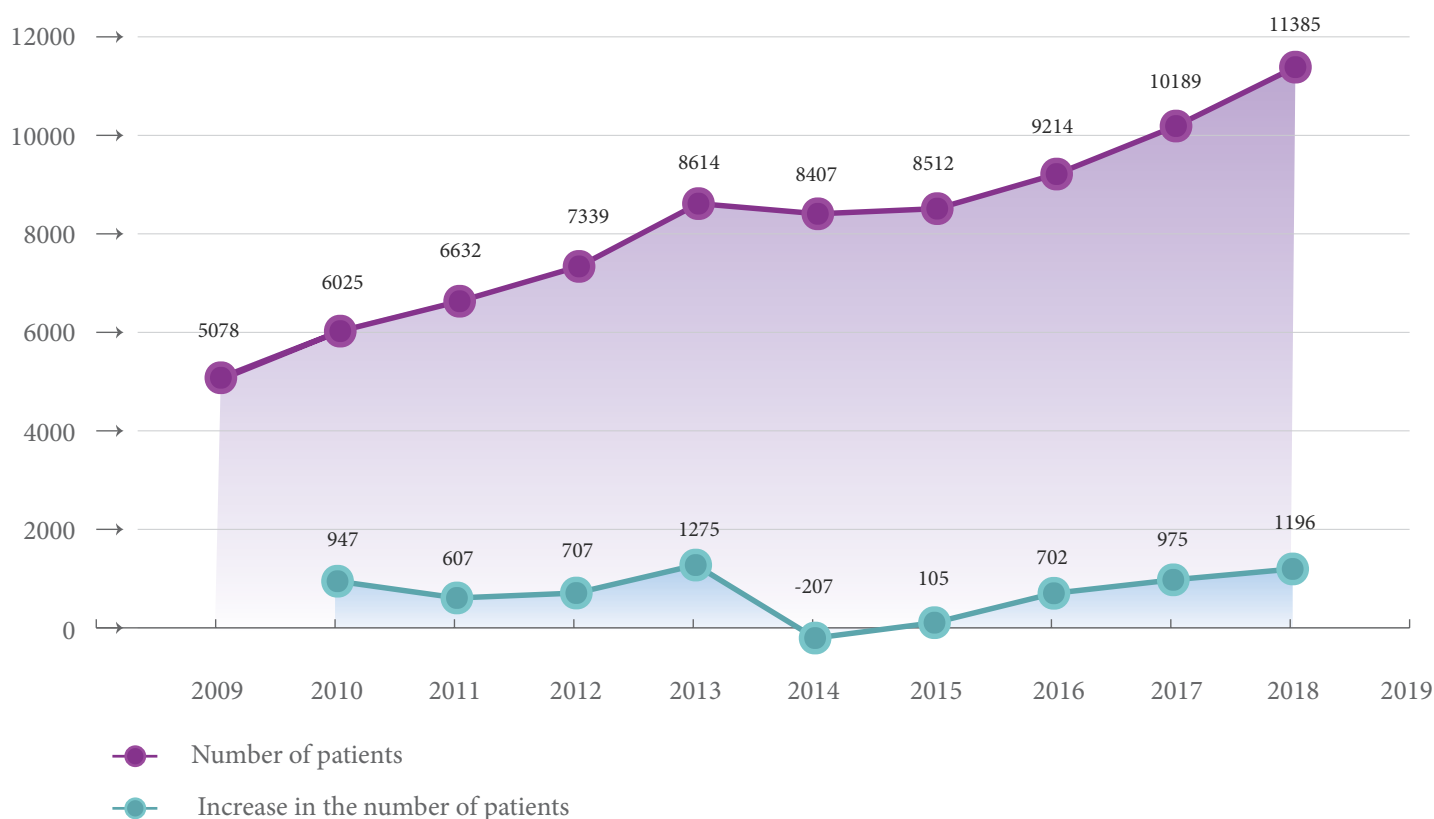
	Opioid maintenance therapy medicines	Total number of patients	Those receiving medication for self-administered therapy	Those receiving a prescription	Those receiving medication in hospital or at home	Number of male patients	Number of female patients	Number of patients with HIV	Number of patients with HCV	Number of patients with TB	Number of patients receiving ART	Median age	Average length of drug use
1 September 2019	Buprenorphine	1089	569	232	31	879	210	447	650	213	431	41	18
	Methadone (liquid)	258	0	0	0	225	33	96	110	29	92	35	17
	Methadone (tablet)	10506	3982	672	575	8704	1802	4204	6114	1557	3840	38	16
	Subtotal	11853	4551	904	606	9808	2045	4747	6874	1799	4363		
1 February 2019	Buprenorphine	1085	488	261	26	878	207	449	668	206	421	40	18
	Methadone (tablet)*	174	0	0	0	149	25	69	57	15	67	36	16
	Subtotal	10180	3292	626	521	8398	1782	4139	6049	1563	3640	38,1	17,8
	Total	11439	3780	887	547	9425	2014	4657	6774	1784	4128		

*The study was completed in October 2019, but the most current data at that time were from 1 September.

Based on the characteristics of both patients and OMT services in Ukraine that we documented over the seven months of this study, we can highlight a number of features:

- Although the number of OMT sites in Ukraine decreased from 211 to 204 (a change that the Centre for Public Health has not commented on in any way), the general number of patients using funded OMT sites still increased by 414 over this period. Based on the trends over the first seven months of 2019, we can suggest that by the end of the 2019, the number of new patients may exceed that of 2016 (when 702 new patients were enrolled). It is unlikely, however, that it will reach the total of 2018 (when there were 1,196 new patients) or even 2017 (with 975 new patients).
- Regarding the proportion of medicines used, the total share of patients receiving methadone in liquid form increased, up from 1.5% to 2.1% (or from 174 to 258 patients). Over the same period, the total share of patients receiving buprenorphine decreased from 9.1% to 2.5%, even though the actual number of patients receiving buprenorphine increased by five (from 1,084 to 1,089).
- There was an increased proportion and number of patients receiving take-home doses of medication (covering a period of between seven and 10 days) for self-administered therapy: it rose from 33% to 38.4% (from 3,780 patients to 4,551). Given that the most recent data updates available from the Centre for Public Health website date back to 1 September 2019, this likely can be explained by the lack of newly updated data on the number and proportion of patients receiving directly observed therapy with daily pick-up compared to those receiving take-home doses of medication for self-administered therapy for several days at a time.

FIGURE 1. ANNUAL INCREASE IN THE NUMBER OF PATIENTS ENROLLED WITH FUNDED OPIOID MAINTENANCE THERAPY SITES



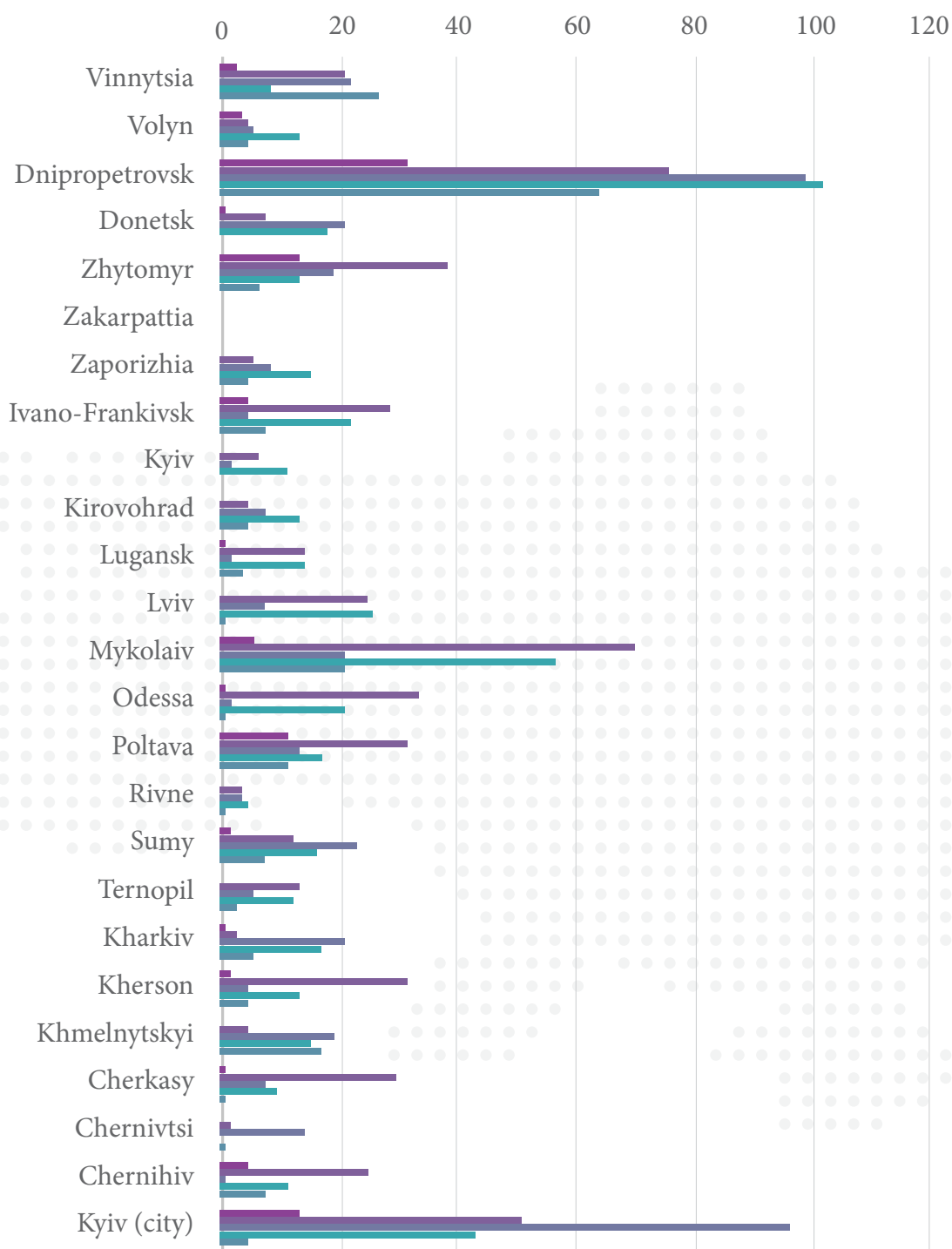
According to the Centre for Public Health's report on the outcomes of the OMT programme in 2018, a total of 1,903 patients terminated OMT in 2018. This amounts to 16.7% of the total number of OMT patients in Ukraine. Reported reasons for these terminations are depicted in Figure 2 and include the following:

- Successful completion of the programme (119 patients, or 6.3% of terminations).
- Discontinued participation of their own accord (572 patients, or 30.1% of terminations).
- Dismissed for administrative reasons (i.e., violations of programme regulations and policies) (459 patients, or 24.1% of terminations).
- Programme terminated due to the patient's death (516 patients, or 27.1% of terminations).
- Programme discontinued because the patient is under criminal investigation (237 patients, or 12.4% of terminations).

Unfortunately, the report provides no explanation of what constitutes successful completion of the programme. It may involve those patients who leave the programme in accordance with Paragraph 19 of Decree No. 200, which states:

In the event a decision is made to discontinue OMT, to prevent withdrawal syndrome, the patient will receive gradually reduced dosing of medication (through short- or long-term detox courses) as required, depending on the patient's health and the dose of medication they are receiving as of the day when the decision is made to discontinue opioid maintenance therapy. (5)

FIGURE 2. REASONS FOR TERMINATION OF PATIENT INVOLVEMENT IN OPIOID MAINTENANCE THERAPY PROGRAMME BY REGIONS (OBLAST)



- Successfully completed the program
- Discontinued participation of their own accord
- Dismissed for violation of programme (administrative/disciplinary reasons)
- Patient's death
- Patient under criminal investigation

DATA FROM KYIV AND KYIV OBLAST

As of 1 February 2019 (when the study protocol was written), data from the Centre for Public Health indicated that funded OMT sites in Kyiv (n = 14) and Kyiv Oblast (n = 2) involved 1439 patients, including 1265 patients in Kyiv and 174 patients in Kyiv Oblast (see Table 2). A total of 1145 (79.6%) patients were men, and 294 (20.4%) were women. Methadone in tablet form was provided to 1167 patients (81%); methadone in liquid form was provided to 45 patients (3.2%). A further 227 patients (15.8%) were treated with buprenorphine. For self-administered therapy, medicines were dispensed to 506 OMT patients (35.1% of total participants) who received take-home doses of medication for a certain period of time (e.g., seven to 10 days). In addition, 167 patients (11.6%) received a prescription to purchase medication at their own expense, and 54 patients (3.7%) received OMT medicines in hospital settings (i.e., at in-hospital facilities or—in the case of patients with a confirmed disability status—at home).

As of October 2019 (the completion of the study), the most recent data available from the Centre for Public Health on funded OMT sites in Kyiv (n = 14) and Kyiv Oblast (n = 2) involved 1362 patients, including 1190 patients at the OMT sites in Kyiv and 172 patients at the sites in Kyiv Oblast (see Table 2). There were 1,096 (80.5%) men and 266 (19.5%) women. Methadone in tablet form was dispensed to 1,011 patients (74.2%); methadone in liquid form was provided to 133 patients (9.8%). Buprenorphine was provided to 218 patients (16%). For self-administered therapy, medicines were dispensed to 605 OMT patients (44.4% of total patients) who received take-home doses of medication for a certain period of time (e.g., for seven to 10 days). In addition, 51 patients (11.1%) received prescriptions to purchase medication at their own expense, and 102 patients (7.5%) received medicines in hospital settings (i.e., in-hospital facilities or—in the case of patients with a confirmed disability status—at home).

TABLE 2. NUMBER OF PATIENTS RECEIVING SERVICES FROM FUNDED OPIOID MAINTENANCE THERAPY SITES IN KYIV AND KYIV OBLAST, BY SERVICE TYPE, BEGINNING OF THE STUDY AND ITS COMPLETION

Opioid maintenance therapy medicines		1 September 2019					1 February 2019						
		Total number of patients	Those receiving medication for self-administered	Those receiving a prescription	Those receiving medication in hospital or at home	Number of male patients	Number of female patients	Total number of patients	Those receiving medication for self-administered	Those receiving a prescription	Those receiving medication in hospital or at home	Number of male patients	Number of female patients
Total: Kyiv	Buprenorphine	205	106	41	0	156	49	215	97	45	0	165	50
	Methadone (liquid)	133	0	0	0	116	17	45	0	0	0	37	8
	Methadone (tablet)	852	452	110	61	676	176	1005	368	122	35	797	208
	Subtotal	1190	558	151	61	948	242	1265	465	167	35	999	266
Total: Kyiv Oblast	Buprenorphine	13	3	0	0	12	1	12	0	0	0	11	1
	Methadone (tablet)*	159	44	0	41	136	23	162	41	0	19	132	27
	Subtotal	172	47	2	41	148	24	174	41	0	19	146	28
Total		1362	605	151	102	1096	266	1439	506	167	54	1145	294

* Methadone (liquid) is not provided in Kyiv Oblast

Based on the data from 1 February 2019 to 1 September 2019, we can see that the number of patients at funded OMT sites in Kyiv and Kyiv Oblast decreased from 1439 to 1362 patients over the seven months. The number of people on OMT decreased more significantly in Kyiv (by 75 patients) than in Kyiv Oblast (only two patients). The decrease in patients at funded sites in Kyiv can be attributed to multiple reasons, including mortality and other natural factors. These factors are shown in Figure 2.

The decrease also could be related to barriers related to the strictness of the rules or the complexity of the admission criteria, both of which can hinder the admission of new patients to OST programmes. For instance, while Kyiv was one of four regions in the country at the end of 2018 that had OMT programmes that were expanding—it had 95 new patients during the year, although it did rank last among those four regions (see Table 3)—the most common reason for the termination or suspension of programme involvement was “dismissal for administrative/disciplinary reasons.” In other words, people were dismissed from the OMT programme for non-compliance or a breach of rules. Dnipropetrovsk Oblast (the national leader on the increase indicator in 2018) had a similar number of administrative dismissal cases, although—unlike in Kyiv—this rate was almost equal to the mortality rate among OMT patients in the region. Also unlike Kyiv, Dnipropetrovsk Oblast is still demonstrating a rapidly increasing number of patients: as of 1 September 2019, there were 2065 patients at the OMT sites in the region, an increase of 157 patients compared to 1 February 2019 (when there were 1912 patients).

TABLE 3. INCREASE IN THE NUMBER OF PATIENTS AT FUNDED OPIOID MAINTENANCE THERAPY SITES BY REGIONS (OBLAST), 2018

High increase	Dnipro	+249	Cherkasy	+159
	Zaporozhie	+112	Kyiv	+95
Average increase	Donetsk	+75	Kherson	+57
	Kirovograd	+64	Poltava	+41
	Mykolaiv	+69	Chernihiv	+37
	Sumy	+65	Lviv	+37
			Odessa	+36
Low/no increase	Vinnytsia	+21	Transcarpathia	+5
	Volyn	+9	Rivne	+9
	Ivano-Frankivsk	+28	Kyiv Oblast	+1
	Luhansk	+16	Khmelnysky	0
	Kharkiv	+18		
Decrease	Zhytomyr	-11	Ternopil	-4
			Chernivtsi	-1

A number of positive trends can be seen in Ukraine, particularly in Kyiv Oblast. This includes an increased share of patients who are receiving take-home doses of OMT medication (for a period of between seven and 10 days) for self-administered therapy: this rose from 35.1% to 44.4% of total patients.

In summary, we would like to emphasize that the analysis of the two data sets clearly demonstrates the importance of studying the factors that may cause a decrease in the number of OMT patients. It can be particularly helpful to understand whether the rules and policies currently applied at funded OMT sites are enabling or restrictive for patients, and whether they should be reviewed in order to increase both retention rates and the number of patients receiving services (10–13).

Barriers hindering access to programmes and patient retention at funded opioid maintenance therapy sites in Ukraine

Almost from their very first days, OMT programmes in Ukraine have come under close scrutiny from the international research community. In fact, evidence-based justification of OMT efficacy and advocacy for programme scale-up were facilitated by experts from universities in the United States, particularly from the Schools of Medicine and Public Health at Yale University (1, 2, 14–18). Ukrainian researchers also have been involved in these studies, and their contribution to the field has been increasingly valuable in recent years: a number of papers on OMT issues authored by (or under the leadership of) Ukrainian experts have been published in international peer-reviewed journals since 2013 (19–25).

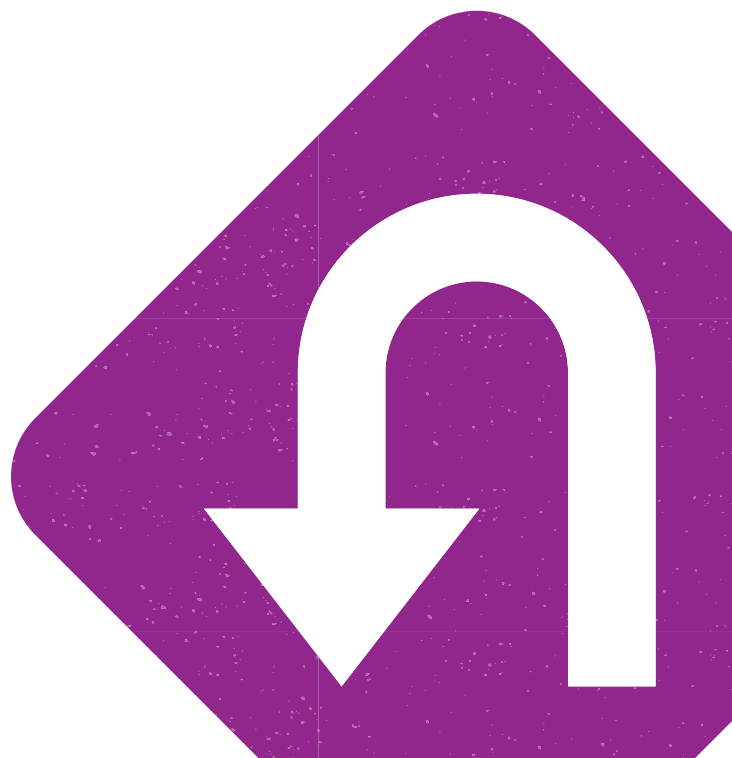
We believe that attention has been drawn to OMT programmes in Ukraine because of the low annual numbers of new patients throughout the period of the OMT implementation projects. According to UNAIDS, the estimated number of people who inject drugs in Ukraine is 346,000 individuals, of whom only 11,853 (or less than 3.5%) currently receive OMT services (26). According to a report published by the Centre for Public Health, 2018 was the first time that the number of new patients at funded OMT sites returned to the level of 2013, which was the highest on record (with 1,275 new patients) during the period of OMT programmes in Ukraine (see Figure 1) (9).

Different authors have investigated factors that have contributed to the low annual increase in the number of patients at funded OMT sites. The first group of factors—which may result in refusal to initiate OMT or in its suspension during the course of treatment—involves a set of regulatory norms governing the provision of OMT in Ukraine that affect the status and opportunities of people who become patients of publicly funded programmes. These involve the following:

- Mandatory registration as an OMT patient with a drug addiction diagnosis (27, 28).

- Restrictions that result from the status of being a patient in an OMT programme who has a registered diagnosis. This includes limited opportunities to travel in Ukraine and beyond, and possible impediments to employment, the use of a driver's license and more (29, 30).
- The number of patients in funded OMT programmes is limited by strictly regulated admission criteria. There is a shortage of funded OMT sites, and their number has not been increasing significantly over time. As such, the total capacity of funded OMT sites does not correspond to the estimated number of drug users who need services. This results in long wait times for people who inject drugs, as they wait for a scale-up of services or a local placement opportunity with a particular service provider (28, 30).
- Criminalization of drug use results in people who inject drugs having little trust of funded OMT services. It also raises fears (sometimes justified) of police harassment and abuse among OMT patients (31–33).

The second group of factors that may cause people to refuse to participate in an OMT programme or for their enrolment to be suspended are related to



operational procedures of the programme and the interactions between personnel and patients. This group of factors involve the following:

- A lack of understanding among patients about the treatment process and goals. In particular, they do not fully understand how the treatment should be completed or if it can be completed at all. As a result, people strongly believe that unlike illicit drug use, therapy can never be completely stopped (16, 22).
- The lack of flexible dosing regimens. This results in concurrent illicit drug use as patients receiving OMT take additional illicit drugs or medication to deal with withdrawal symptoms experienced because of lower or inadequate OMT dosage or because they are in the initial phase of treatment and adjustment of drug dosage (16, 17, 34, 35).
- A lack of flexibility around the choice of modes for dispensing medication—and excessive regulation when transferring patients from daily directly observed on-site therapy to self-administered therapy—are some of the most prominent challenges associated with programme initiation and patient retention (16, 30).
- The strict control of patient behaviour in programmes and the associated high risk of programme dismissal for patients who are non-compliant. Patients may face stigma and manipulation in their interactions with health-care personnel (17, 28, 34).
- Inflexible hours for dispensing medication at treatment sites that are inconvenient for patients (16, 28).

The third cluster of factors is based on intrinsic characteristics of the patient population. These factors explain why patients avoid services or interrupt treatment, and why individuals may prefer to avoid programme enrolment altogether:

- Low motivation for treatment, which can also be interpreted as a sign of depressive disorders (22), a “lack of wanting” (34), or a lack of efficient redirection/referral from other programmes (e.g., harm reduction projects) (22).

- A lack of support from family, relatives or other people who use drugs due to negative misconceptions about OMT (either as a strategy to continue and one that might increase drug use) (16, 22, 34).

The research and review of the factors in all three clusters shows a deep level of analysis and a profound interest among researchers in finding solutions to improve access to OMT programmes in Ukraine. Published articles focus on a range of factors, including:

- Barriers to participation in OMT programmes (16, 28).
- Willingness to enrol—or determinants of willingness to enrol—in OMT (22, 24).
- The positive impact that patient retention in OMT programmes has on comorbidity treatment outcomes (1, 14, 15, 19, 21, 23, 35).
- The overall quality of life in health-related aspects among people involved in OMT programmes (14, 21, 30, 35).

Despite this depth of research, the review of published articles does highlight a lack of comprehensive research on patient satisfaction among patients enrolled in OMT programmes in Ukraine. Instead, the focus has traditionally been on narrower aspects of programmes or particular factors contributing to dissatisfaction with treatment (such as barriers to treatment or issues around patient retention). Although the issue of patient satisfaction in OMT programmes is currently receiving more attention in some countries, no studies in this field are carried out in post-Soviet countries, particularly Ukraine (36–41). A rare exception was a series of pilot studies that focused on satisfaction with OMT services among patients who had been transferred from OMT services in specialized addiction treatment facilities to OMT services in primary care facilities (23). Nonetheless, we believe the approach to patient satisfaction in this series of pilot studies was rather narrow.

RESEARCH DESIGN

Mixed-method approach

As the design of this study is based on qualitative and quantitative methodological components, it was implemented in the framework of the mixed-method approach. Since this approach can provide a deeper and more valid understanding of answers to research questions, mixed-method designs have been increasingly used in a wide range of fields in recent years, including implementation studies aimed at the analysis of specific practices (51–53).

Within the mixed-method approach framework, qualitative methods can be used to set research questions, improve understanding of the factors that cause the implementation of evidence-based practices to succeed or fail, or define strategies to enable their implementation. At the same time, quantitative methods can be used to test and validate research hypotheses using the existing conceptual model, and to better understand the factors that contribute to the successful implementation of these evidence-based practices (52, 54).

Different strategies are recommended for merging qualitative and quantitative methods of data collection in the mixed-method approach framework; in this study, we use a sequential exploratory design (55). The purpose of this method is to use the qualitative component to develop an instrument and to determine the classification of respondents and variables for the well-informed use of the findings in order to generalize to larger samples.

The qualitative component was implemented using the strategy of purposeful sampling with maximum variation (52). This strategy is used to cover significant differences and common patterns that emerge out of high sampling heterogeneity. Interviews were conducted until reaching the data saturation point (the data saturation principle) (56). Overall, the point of data saturation is usually

defined as the moment after which any subsequent collection of data does not result in the production of new codes, topics or research questions (56–58).

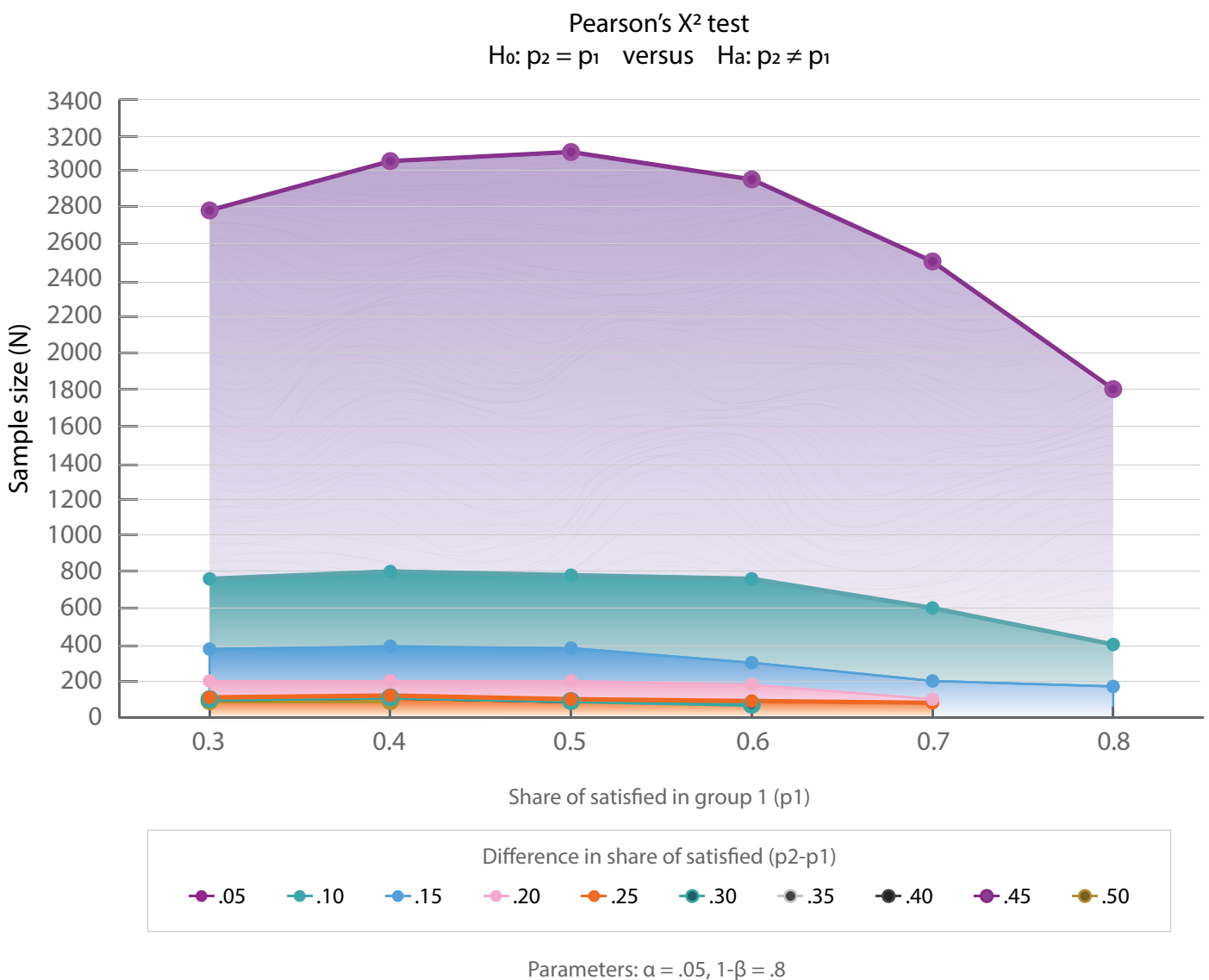
Sampling for the quantitative component of the study was performed using publicly available data for Kyiv and Kyiv Oblast from the Centre for Public Health as of 1 February 2019 (8). At the time of sampling, the number of patients enrolled in programmes at funded OMT sites amounted to 1,439. The majority of patients in Kyiv ($n = 866$) were receiving OMT medication from three OMT sites located in the drug addiction (“narcology”) dispensary facilities; a further 336 individuals were receiving their OMT medication from the site based at the Kyiv AIDS Centre. Fifty-three patients (5%) were receiving OMT from 11 OMT sites located at primary health-care facilities in Kyiv.



It was decided that it would be reasonable not to include most “hard-to-reach” patients in the sampling, such as patients who receive OMT medication in tuberculosis hospitals (n = 10) or at home (n = 54). Thus, the target patient population of funded OMT sites has been reduced to 1,375 people. Since there are no data on the exact number of patients on treatment in the private OMT programmes, we suggested that the two cohorts of patients would be equal. Therefore, the total target population amounted to 2,750 patients.

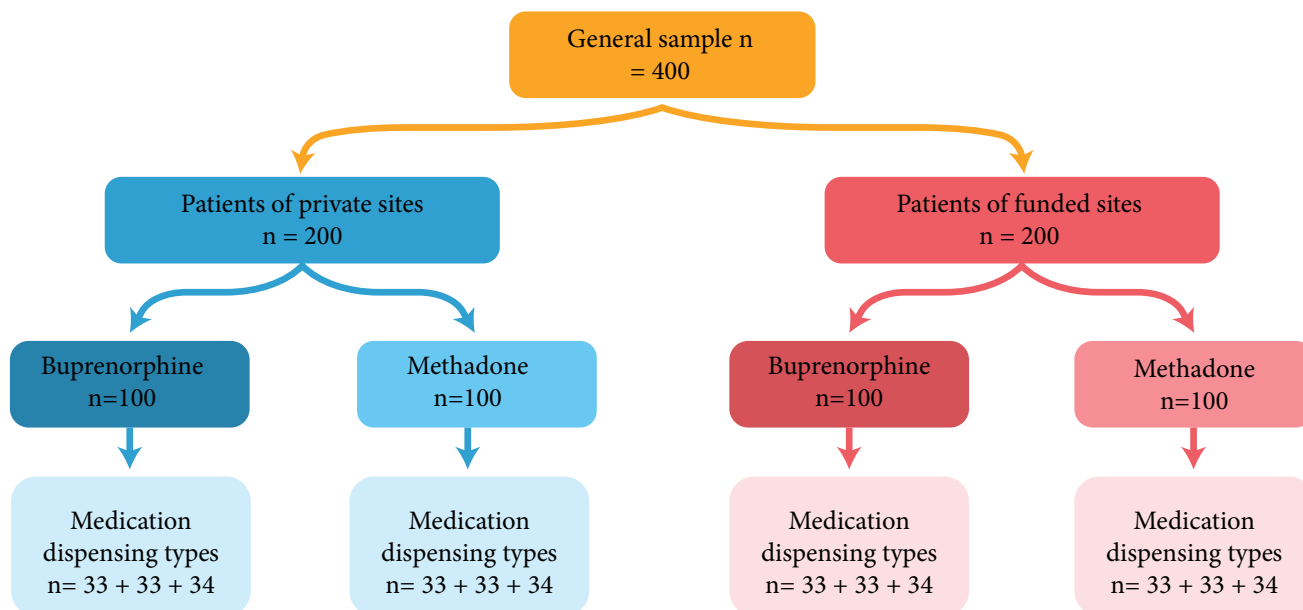
Figure 3 shows the estimated sample size with different satisfaction levels in one group of participants (those in funded clinics) compared to the other group of participants (those in private clinics). Given the sample size of n = 400, statistical power is sufficient to indicate a difference in satisfaction levels between the groups if the parameter difference is 10–50%.

FIGURE 3. ESTIMATED GENERAL SAMPLE SIZE



To ensure the maximum variability of available types of OMT programme patients in the study, we used multi-stage quota sampling (see Figure 4). The two main groups to compare involved a group of patients attending funded sites and a group of patients attending private sites. Further quota sampling was performed based on the type of medication and distribution (daily pick-ups, take-home medicines for 10 days collected from the OMT site, or prescriptions for medication to be purchased in pharmacies). During the sampling process, we also made sure that the share of women in the sample never went below 20%.

FIGURE 4. SAMPLING STRATEGY



Research ethics and confidentiality

The protocol and tools of this study were reviewed by the Ethics Review Board of the Ukrainian Institute on Public Health Policy. Its official registration number is: IRB-FWA#: FWA00015634. The protocol was submitted to the Ethics Review Board twice: the first time was prior to the start of the first (qualitative) component of the study, and the second time was after amendments to the protocol had been incorporated, as required to start the second (quantitative) phase of the study.

The OMT patients recruited for this study were fully informed of the study, their right to opt out of it and of the existing procedures to ensure the confidentiality of the study participants. Prior to the interview and survey, each participant went through the informed voluntary consent procedure. Each participant has signed the informed voluntary consent form, which specified the goals of the

study and outlined the possible risks and expected benefits related to enrolment; it also provided contact details for the Ethics Review Board and the Chief Research Fellow. To maintain confidentiality, the names of participants were not recorded in any form that was entered into the database; rather, identification numbers (codes) were used for identification purposes in all forms used for the database.

Each interview participant received compensation of 200 UAH (approximately 8 EUR) for their time and travel expenses. Participants who filled in the survey questionnaire received a gift certificate worth 100 UAH (approximately 4 EUR) as compensation for their time and expenses. If their survey participation was interrupted by any of the parties, compensation was still provided in full.

PHASE 1: QUALITATIVE STUDY COMPONENT

The quality component of this study was implemented through semi-structured interviews with patients of OMT programmes. The interviews were conducted following a preapproved interview guide (Appendices 2 and 3). Topics covered in the interviews involved the following:

- The needs and expectations associated with treatment.
- Whether the needs of OMT patients were met or unmet during the course of treatment.
- The interaction between patients and site personnel or other patients.
- Enrolment in specific OMT programmes, or refusal to be enrolled in those programmes.
- How expectations, needs or perceptions of OMT programmes change over time.
- Overall satisfaction with OMT services.

In addition to interviews with OMT patients recruited specifically for this study, a similar set of survey questions was given to people who inject drugs who had been recruited for another study project—Investigating Opportunities for the Implementation of Prison-based Needle and Syringe Exchange Programmes in Ukraine—that we were simultaneously conducting in Dnipro, Kyiv, Lviv and Odesa. If a respondent from one study met the sampling criteria for the other study (i.e., they were an OMT patient at the time of the interview), they were asked to respond to an additional set of questions. As a result, eight focused interviews and eight interviews with respondents from another study were conducted, with respondents being asked about their experience in OMT programmes. For data analysis in our research, we used transcripts of the interviews and field notes.

Results of the qualitative study component

Within the scope of the study, the main purpose of semi-structured interviews was to highlight various aspects and criteria of satisfaction with OMT services among patients in order to develop a data-based questionnaire tool. This was accomplished through the description of services, interaction with various actors (such as medical personnel, psychologists and social workers), and the physical setting of the OMT sites. Based on the collected data, we then developed questions to be used during interviews to assess the satisfaction of patients with certain aspects of OMT services.

While analysing the interviews, we tried to see the logic in the narratives shared by our OMT patients, particularly the role of OMT in their lives, and we attempted to summarize their life experiences to assess their overall satisfaction with treatment. This did pose some challenges, though. While some assessments of the OMT experience by patients were perceived by researchers as rather negative, respondents nonetheless summarized their overall experiences with the service as “satisfactory.” This raised a question: how do respondents perceive how to respond to the question about their overall satisfaction with a service? Why do they tend to give a “positive” evaluation of the OMT service as a whole, even if they have evaluated some of its components as “unsatisfactory”? We were surprised by the homogeneity of the gained results: although the typological diversity of the sample met the required parameters, the narrative logic in respondent stories was pretty much the same in every interview or case.

Another recurring feature identified from the analysis of the field material that was contradictory to expectations was related to assessing subjective well-being in the context of injecting drug

use and a subsequent transition to OMT. While respondents generally considered their enrolment in OMT to be a life-changing event, it was almost impossible for them to describe how their lives had changed or to identify those changes during the process of data analysis. We realized that sampling in a qualitative study had certain limitations, and that the narratives we received could reflect these

limitations. Eventually, the phenomenon in question was categorized as “lacking energy or motivation” and later transformed into the category “subjective assessment of the quality of life,” which we believe needs further study in the context of the above-mentioned paradox of the overall satisfaction with OMT and the evaluation of changes in the lives of respondents since beginning OMT.

Interaction with health-care personnel: directly observed therapy and service on “an assembly line”

According to respondents, communication with medical personnel at OMT sites feels pretty much like being on “an assembly line.” The patient can only ask questions pertaining to OMT; the doctor has no time to answer any other health-related questions from patients. Moreover, if a patient becomes “talkative,” it can be considered suspicious. Interaction is mostly limited to a simple routine: take medication, drink water, sign a form or receive a prescription, and leave. According to study respondents:

Yes, it's really like an assembly line. You sign, they give you pills. And the table stands like this. . . . You see, I cannot come to pick it up myself; I wait till the nurse or doctor give me medication. (ГБА93АД)

Well, of course, with the nurses, with a psychologist and [with] doctors you can only communicate on business. That is, about treatment and not about anything else. You have to be careful not to say too much. That's why I try to avoid talking to doctors. And to the psychologist, either. (КВВ74ВС)

Interviewer: Are you all standing in line?

Respondent: When I need to get my prescription—no, I just come in. There's no line for getting prescriptions. Just coming in, that's it. And sign. As I understand, not so many people get prescriptions. (ГБА93АД)

This simple routine is conducted under direct observation in order to ensure that the patient is strictly following the procedure. This includes adherence to the standard norm of “chew and drink, without looking away,” and controlling unused take-home medications if the patient gets a prescription.

And they control . . . they want to see whether the patient is stable or not, to make a conclusion if they can let him go or not. I mean, our drug addiction specialist acts like an inspector. (ГАИ78АД)

They set it up straight from the very beginning. . . . I give them my [plastic] cup. The cup must be transparent. It's when I was taking the pills, right? So I would give them a transparent cup. They would put the pills in this transparent cup. They would not give it back to me until it's all dissolved. And even then, when I take that cup and while I was drinking it, I couldn't even turn away from them. Because it was considered like . . . they told me: [if] you do it once again, we will consider it as an unauthorized attempt to take away the pills . . . even though those pills were already dissolved. (ГБА93АД)

At first, I was buying it [buprenorphine] in the street; later, there was some organization out there in Sevastopol Square. I got there, and I started buying it there. I mean, I was paying for the prescription list and I was buying this buprenorphine. And there was a requirement

that you show them how many stickers you have left . . . You know, those stickers that indicate for how many days you have pills. For example, there are three days left, and you should have three or four of them left. And I failed twice. . . . Well, it just happened that I took more [than one dosing], injected more, to tell you the truth. And they kicked me out of there. (ЦСЛ73АД)

Interviewer: Were you asked to come over, to show your leftovers, to check how much you had left?

Respondent: It happened once, I was asked. Well, I showed them my leftovers. That's it. (БЮВ82АД)

The doctor–patient interactions can take a different form if the doctor is interested in having the patient receive a required service. In such cases, health-care personnel can try to manipulate the patient, such as by threatening to withhold medication if the patient does not take the desired tests.

They're forcing me to do it right now. I'm saying, "but I'm going to do it in April anyway, as this is when my year is over. And I'll have all the tests." But they wanted a medical certificate that I don't have [tuberculosis], that I can visit OMT sites with other people. I mean, they kind of forced me. She did not give me medication. She said "go get it done." And I really don't like the procedure, when I have to cough and spit in the test-tube. . . . And I have to do it in a special room. . . . But . . . She didn't give me therapy. I went, after all, had that test done. And they gave me a certificate that I could visit OMT sites. And she calmed down. But now, again. It's been how long? January, February, March, April. Some three or four months. But she says it was last year, it was December. Now it is a new year, so I have to go get such a certificate again. (КВВ74ВС)

Interaction with the psychologist: controlling off-site drug use

None of the respondents had an experience of voluntarily seeking on-site psychological service. Typically, OMT patients are referred to the on-site psychologist if they are suspected of using illicit drugs. From the point of view of the respondents, this is the job of the psychologist: performing punitive functions. For that reason, patients try to avoid interacting with the psychologist.

I know that some patients were caught using [illicit] drugs. Those patients are also asked to go to the psychologist. So every day when he comes to take medication, he first has to go to see the psychologist, and they would talk, and only then he can go. . . . Apparently, because she [the psychologist] wants to know why he's using illicit drugs and what can be done. (КВВ74ВС)

Interviewer: You told me about the psychologist. There's a psychologist at Demeyevka. Have you talked to the psychologist?

Respondent: Yes.

Interviewer: What was the reason, if it's not a secret?

Respondent: Well, what reason. . . . He asks what kind of illicit drugs you use and what you don't.

Interviewer: So, mostly they want to know about violations.

Respondent: Well, yes. Alcohol and all that.

Interviewer: Was it your choice to go see him, or did he invite you?

Respondent: He invited. (БЮВ82АД)

The psychologist was passing by and she saw me with a beer, so she reported me to the doctor. The doctor asked me to come to her office and said: "Don't let it happen again! Because next time there will be a panel meeting, and we will discuss your dismissal from the site." That's it. After this, of course, I don't really like the psychologist. (КВВ74ВС)

Interaction with the social worker: services patients do not want and behaviour control

As a rule, a social worker is available on-site either constantly or on a regular basis (in the case of visiting social workers at private sites). However, only two respondents were able to describe their interaction with a social worker. In one instance, the interaction took place when the social worker invited the respondent to take part in a survey; in the other, the respondent attended an event at the social worker's invitation, but the respondent was unable to remember what kind of event it was or what was going on there.

Interviewer: In general, how do you interact with doctors, nurses, maybe a psychologist (if available)?

Respondent: I don't know. I haven't seen a psychologist. There's a social worker, a young man. I went to see him. If I'm not mistaken, 1.5 or two months ago they had a survey and they asked whether I was satisfied with everything. They've had my phone number, and I responded to their questions. It was an anonymous survey: whether I am satisfied with everything, whether I was abused or mistreated, whether anyone is rude or not, whether everything is fine to me. (ГБА93АД)

Interviewer: There's a social worker at your site. His name is Vlad.¹ Are you in touch with him?

Respondent: Yes, we communicate normally.

Interviewer: Anything useful you've got from him?

Respondent: Well, he has invited [me] to come over to his workshops. [They are] on Wednesdays on the 2nd floor. I've been there a couple of times.

Interviewer: Anything interesting for yourself?

Respondent: Well, some.

Interviewer: What were these [workshops] about?

Respondent: I don't remember. (БЮВ82АД)

The following quotes—taken from field notes—describe the performance of social workers from different OMT sites. The first quote describes interactions between an on-site social worker and a patient at an OMT site in Kyiv:

Once there was a female client accompanied by her mother who wanted to see the doctor. Mom came to talk about her daughter's hepatitis C treatment, whether it's feasible and makes sense. Like, is there any sense if her daughter is anyway on opioid maintenance therapy at their site plus additional Dimedrol [diphenhydramine] injections. Later on, I will tell about the interaction with the doctor. But it was interesting to see how Vlad¹ [the social worker] was doing there. He was sitting peacefully right until the mom said that her daughter was receiving therapy from one more site. Vlad woke up and immediately started speaking to the girl: "Do you understand that it is illegal?! You can be dismissed from the free-of-charge programme." The girl went into denial: I know everything; I used to go there; [I'm] not doing this anymore. He [Vlad] did not care about anything else in the conversation, even when the doctor said "maybe [the daughter] should go to see a psychologist first," and pointed out to Vlad, [saying] "here, he could help you out arrange it."

Vlad then offered to send her to a psychologist, whose services were paid for by *** [the name of the organization has been removed]. Some clinic at *** [location removed] where you can get 16 sessions of cognitive therapy, but the client's willingness is crucial. It didn't really look like the girl was eager to get the treatment; she was rather happy with everything. But they all—mom and the doctor and Vlad—started to

press her and persuade [her]. In the end, she agreed, but it was forced consent, and I don't really believe that this client would go to that programme. (Field notes)

The next quote illustrates a function of the social worker: what we have called a “warden.”

About one-half of the two hours spent at the clinic we've been around outdoors, near the entrance gate and also at a crossroads, which is 10 meters from the gate, in the street. At the crossroads, patients found a place for themselves sitting on a fence like on a bench. And Violeta [the social worker] was trying to drive them out in a friendly manner: “Go sit on that bench under the trees. Don't sit here; I'll get a reprimand” [the bench under the trees was in a playground]. (Field notes)

One of our respondents defined her occupation as “medical and social support worker for OMT patients,” while describing her participation in a TV show:

"We saw you on TV" [say the staff]. I'm not an ordinary patient for them anymore. After the recent TV show with that show host, I corrected them. The show host introduced me as a doctor. I said: “I am a medical and social worker assistant.” So as soon as I went on the air, I corrected his mistake. But when I recently came there [to the treatment site], they [the

doctors] talked to me like, “Oh, Olga, so you're our colleague. ” “Are you kidding?” [she asked] “No, why?” “The main show host said you are a doctor,” [they replied,] “then it's true. You are a doctor.” (ГАН78АД)

This quote provides a good (although somewhat ironic) description of the process of redefining the scope of activities of social workers within the narcology field. Social workers try to be like addiction doctors in many respects, and they often act in unison with medical personnel at the OMT site. Just like a health-care worker who persistently pushes a patient to take tests that the patient does not want or see as necessary, the social worker can persuade patients to use services that they do not want. Similarly, they can control the behaviour of patients in OMT programmes.

Considering the number of clients that a social worker deals with at a large site, their interactions with individual patients may be considered to be as routine as the interactions between patients and on-site health-care personnel. As such, OMT programme participants can be as reluctant to interact with a social worker as they are to interact with medical staff; for many of them, it is something to be avoided wherever possible, all the more so because it is not directly required for the acquisition of medication.



The physical setting of the opioid maintenance therapy site

Our respondents had few concerns about the physical setting of the therapy sites. Female respondents mentioned a door latch for the toilet, and one respondent briefly noted that a renovation would not be a bad idea. We can say respondents were very careful about giving specific evaluations of anything directly related to the site.

Interviewer: Do you like the facility itself?

Respondent: Well, to me, everything is fine. [It would be nice if] the toilet door could close. The toilet door doesn't close. But you know, it's such a little thing. In principle, everything is fine. Well, honestly, it's embarrassing. I went to the toilet room, and immediately there was a kid coming in. . . . It's nonsense. You know, here you have a toilet and here you have the door immediately opening, and voila.

Fix a door latch. Well, maybe that's the way it should be—I don't know—so that no one could close down there. I think that's the way it should be. (ГВА93АД)

Interviewer: Is there anything that could be done to improve [your OMT experience]? Maybe there is something you don't like about the site? Any changes to be made? What do you think about it?

Respondent: Well, no, it's fine. What's there to change? I don't see anything. Maybe some renovation could be done. (БЮВ82АД)

Concurrent drug use and dissatisfaction with dosing

Half of the respondents reported having used some kind of illicit drugs in addition to daily OMT medication. On the one hand, this can be a characteristic of drug addiction: a person who is addicted to drugs may need to increase the dosage to feel satisfied. On the other hand, an insufficient daily dose may be the result of both the medicine itself and inflexible, overly-standardized medication dosing.

Interviewer: So from 2005 to 2018, you all the time . . .

Respondent: . . . have been eating OMT pills every day. [Then] I quickly ran home to polish [top up] with Dimedrol and Sonata (Zaleplon) and to make an injection. (КВВ74ВС)

With the lads, yes, of course. I mean, I don't have connections with the personnel. With the lads—yes, of course. After the clinic, we sometimes go get hammered a bit, have a joint, something like this. (ММВ82АД)

The paradox of overall satisfaction with opioid maintenance therapy

When it comes to general respondent satisfaction with OMT, many reported being satisfied with everything. When discussing specific issues, however, they often indicated dissatisfaction with various aspects of service delivery and intake. Despite this, some used superlatives to express their satisfaction with OMT services:

I think everything will work out great. Thanks to the programme. Because it's about getting support, it is a rock. When you know that you are going to get up tomorrow and you don't have to do anything [special], to take the trouble: you just need to get dressed, say your prayers, take a bus, get to the programme si and get your pills. And you start living—having your work, some errands to do, taking care of children. (PAA89BC)

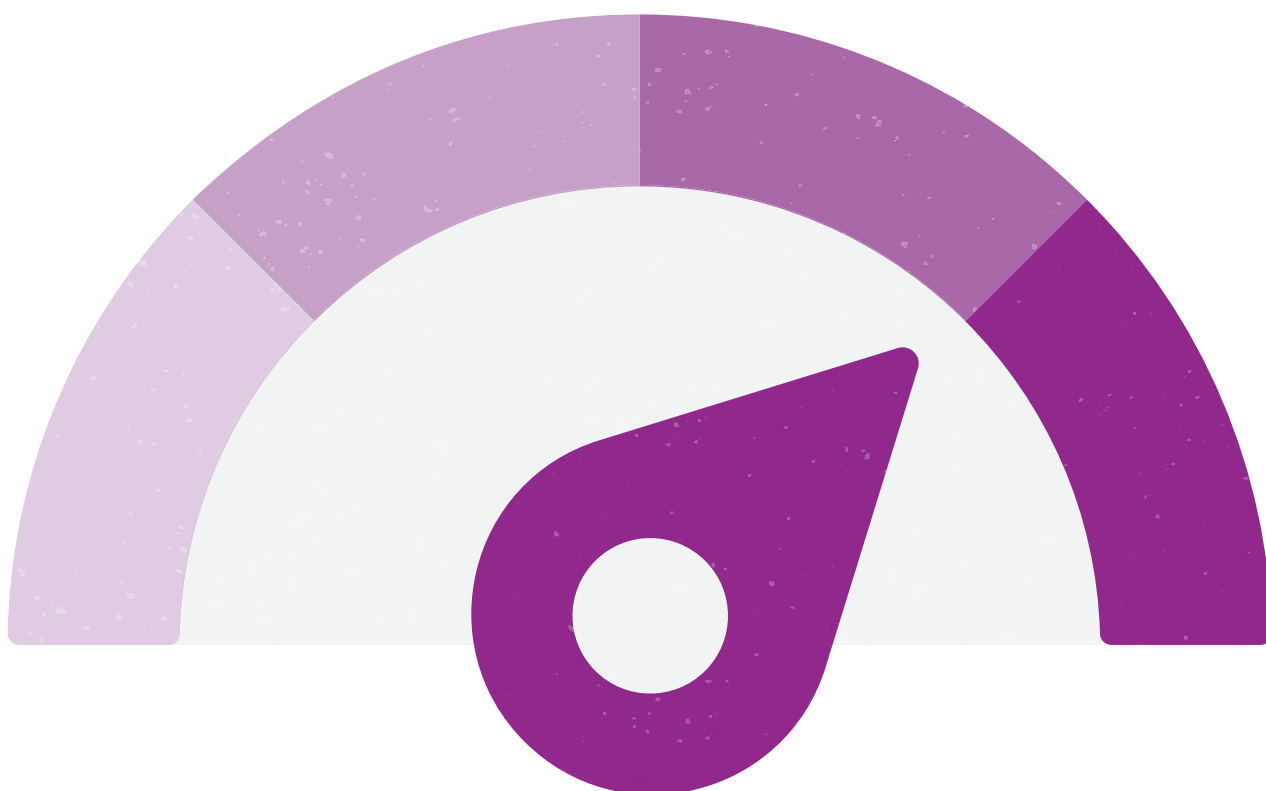
Another respondent expressed their “satisfaction with the OMT service” through satisfaction with the medication itself:

Interviewer: That is, how would you express your feelings about your treatment site?

Respondent: It's satisfying.

Interviewer: Satisfying?

Respondent: Oh well, especially. . . . The medicine is satisfying, to me. (ЦСЛ73АД)



Subjective assessment of the person's well-being during participation in the opioid maintenance therapy programme

We would like to share several quotes that reveal a rather depressed state of mind among some respondents at the time of the survey (or maybe simply at that point of their lives). As you can see from the first two quotes, while these respondents indicate their mood has stabilized, rather than feeling better, they feel “stably bad.”

Interviewer: You have been on [OMT] for six years now. Do you now have anything . . . if something has come into your life, or maybe your life so far is quite the opposite. . . .

Respondent: It's all become stably bad. Previously, there used to be ups and downs, now everything goes evenly. Bad, but stable. (MMB82AД)

Interviewer: We are now talking about today. Let's say . . . you have been in the programme for quite a long time already, your expectations might have changed. . . . Maybe you're now thinking a little bit differently. Do you have anything new now?

Respondent: Yes, I slowed down a little bit. I stopped rolling downhill. It means a whole lot, you might understand. When you roll downhill, you end up in the morgue. When you at least stop, it's already, mmmm. . . . Well, this drug in the tablet form—it just gave me the opportunity to stop for a while. Whatever problems you are facing, here they allow you at least, a little bit. . . . well, [a chance to] stop and think, you know?

Interviewer: Good. You stopped, you have thought. So what? Anything else, besides there is a stop?

Respondent: (Sighs). Not yet, to be honest. Not yet. Well, you understand. . . . (gives a smile). (ЦСЛ73АД)

Other respondents describe their situation as being far from “normal.” One respondent reported being somehow “stabilized” by his job, while two other respondents had no jobs:

And I . . . I've slipped, fallen back. I don't even know how to tell you. Only work keeps me from living somewhere at the train station or under a bridge. (ЦСЛ73АД)

I don't think I live a normal life now. My life is a mess. I can't get a normal job for myself, nothing. That is, I live with an addiction. Thank God there's such a programme, so I'm not looking for money for these drugs. The programme helps me a lot. (ГБА93АД)

Interviewer: Why [do you say] there is no point?

Respondent: Who needs me, who cares? No job, no anything. Nobody needs me. I tried to go here and there, to find something anywhere, to get a job. There is nothing. (КБВ74ВС)

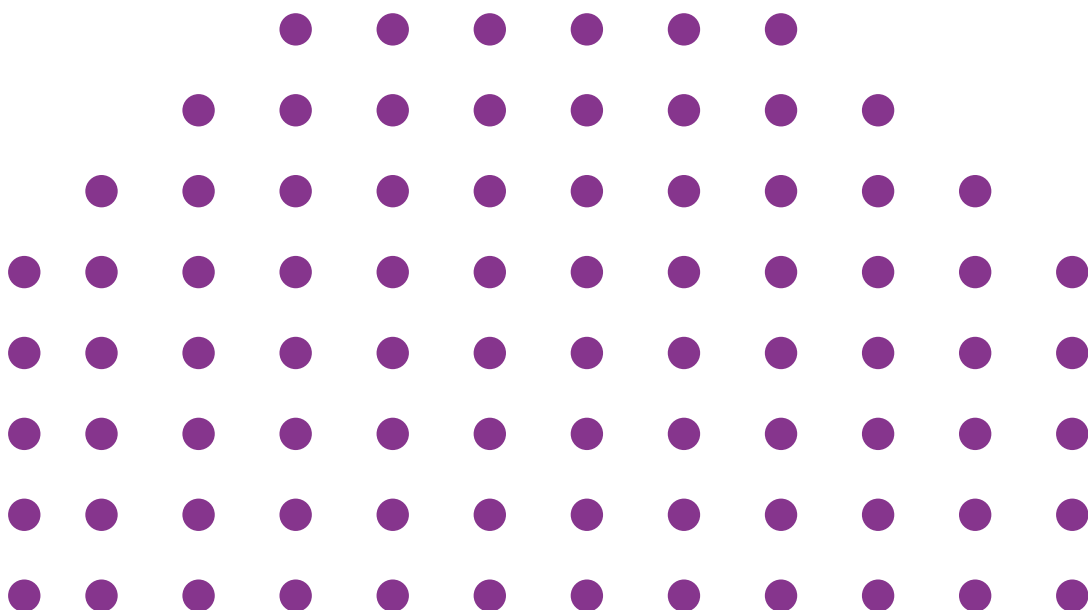
Conclusions

The analysis of the interviews highlights how the interactions between on-site personnel and OMT programme participants can be seen as part of a supervision system framework, wherein every element has a specifically assigned function. Medical personnel are in control of therapy administration, and they prevent unauthorized attempts to take away medicines; the psychologist is to control any concurrent drug use beyond the OMT site; the social worker is in control of patient behaviour at the venue. At funded OMT sites that have large numbers of patients—no data are available on the number of private sites—interactions with on-site personnel may be limited by their high workload and the overall site capacity.

Within the framework of the supervisory control system—which does not provide opportunities for patient-centred approaches to address the individual needs of patients—programme participants tend to avoid any non-compulsory or optional interaction with on-site personnel. Besides that, medical personnel and psychologists have levers of control that they use to manipulate patients. For example, they can force patients to take tests and undergo medical examination under the threat of withholding OMT or dismissal from the programme. Similarly, social workers, even though they do not have powerful levers of control, try to act as medical personnel to force OMT clients to sign up for unnecessary services, which also drives clients away. These factors contribute to the perception among patients that on-site personnel are representatives of supervisory authorities.

Although respondents may have complained about some particular aspects of their OMT programme, they eventually consider these insignificant compared to the most essential thing: the access to and availability of medicines. For patients, the OMT programme is identified with the medicines, and their availability leaves them feeling satisfied. Indeed, patients see their own enrolment in OMT as an opportunity to obtain medication rather than to access an integrated set of services.

Despite this satisfaction, subjective assessments of quality of life and well-being among OMT programme participants suggest “lacking energy or motivation” and a low assessment of the quality of life among patients. The available opportunities to improve the subjective assessment of well-being among patients through medical, psychological and social support services are not used to the best advantage by psychologists, medical personnel and social workers, all of whom are primarily guided by their supervisory control roles.



PHASE 2: QUANTITATIVE STUDY COMPONENT

Study rationale

As discussed earlier, the study of patient satisfaction with treatment helps shift the focus from objective treatment outcomes to subjective characteristics, such as patient needs and expectations (43). The study of the subjective assessment of the quality of life among patients can be used as an indicator of subjective satisfaction among patients with both treatment and treatment efficiency. The traditional medical care model, which is aimed at eliminating diseases and their symptoms, is not functional for the provision of treatment and care to people living with chronic diseases. Therefore, there is a need for a humane focus on health care, particularly to improve understanding of the needs of patients in OMT programmes and to provide them with adequate support.

Taking into account the chronic nature of drug-related issues and their impact on different life domains among people who inject drugs (60–63), researchers have been paying greater attention in recent years to the concept of quality of life among people who inject drugs (64–67). In addition to traditional indicators (such as mortality and morbidity), new measures were used to assess the impact of disease and impairment on daily activities and human behaviour (health-related quality of life, or HRQL). Although the HRQL is often used as a synonym for quality of life (68, 69), it is important to understand that an HRQL study is mostly focused on the impact of diseases on people's daily activity and functional status (64, 70, 71). This measures the impact of the disease on quality of life, but it does not assess the actual quality of life, which has been described as “the missing measurement in health” (72). For instance, many studies still measure HRQL in people who inject drugs (73–75), particularly among those receiving OMT (64, 65, 76, 77). At the same time, however, some researchers point

out the importance of changing the approach from understanding treatment as a process of “cure” to instead measuring the factors that affect the quality of life during the process of care related to chronic diseases, particularly the impact of OMT for treating drug addiction (68). In such studies, the focus is shifted, for example, from measuring retention rates in treatment programmes, reduced illicit drug use and criminal activity rates after OMT initiation to measuring subjective determinants of quality of life as determined by the patients themselves (78–81).

WHO defines quality of life as the perception that individuals have of their lives in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns (72). In the early 1990s, WHO initiated the development of a universal quality of life assessment tool, known as WHOQOL-100; in 1996, it published the guidelines on the use of the optimized, abbreviated version of WHOQOL-100, the WHOQOL-BREF. The WHOQOL-BREF tool contains a total of 26 questions that cover four domains: physical health, psychological, social relationships and environment. By 2003, the WHOQOL-BREF had been validated in 23 countries, including Russia (82). In 2004, Ukraine conducted its first study to measure quality of life among people who inject drugs who initiated OMT using buprenorphine, with measurements taken at the beginning of treatment, and then at three and six months after the initiation of treatment (83). It is noteworthy that no other studies using WHOQOL-BREF—including studies of quality of life in other populations—have been conducted in Ukraine since then (or if they have, we are not aware of it).

Despite specific treatment needs among people who inject drugs (64), there are still a limited number of studies that focus on the impact that independent variables (such as the impact of dual diagnosis, gender, age and current status of substance use) have on the quality of life of people who inject drugs (74). One of these studies demonstrated that dual diagnosis had a significant impact on all four WHOQOL-BREF domains, and a negative correlation with older age and female gender in some domains; the current status of substance use seemed to have no significant impact on the quality of life (84). While other studies have also reported no relationship between quality of life and drug use, a number of psychosocial factors (such as family support or friends) did appear to have an impact on the current quality of life of people who inject drugs (49, 85, 86). According to another study, the overall quality of life of OMT patients had negative correlations with advanced age, specific diseases (such as arthritis or ulcers), severity of drug use, a record of detoxification treatment and a recent hospitalization for mental health (87).

The relation between satisfaction with treatment among OMT patients and quality of life assessments has been analysed in several studies with a similar design (36, 64, 80, 83, 88). To understand the dynamics of changes in assessments of quality of life and satisfaction with treatment, measurements were taken at the initiation of treatment and after one or two short periods. Under such a design, significant relationships were reported between OMT and quality of life: measurements taken at the initiation of therapy and after a short period of time demonstrated a statistically significant positive relationship. However, there is a clear lack of research with a focus on the relationship between OMT and quality of life over the longer term (74). The studies that we found of the long-term impact of higher quality of life assessments in patients who were retained in OMT for more than one year do not report any positive dynamics; in some life domains, in fact, they demonstrated a decrease in the quality of life in the course of the treatment process (49, 75, 89). It is unclear whether this can be an indicator of decreased satisfaction with treatment itself.

Taking into account the lack of research into factors that determine or affect treatment satisfaction and quality of life among OMT patients in Ukraine—and given the widespread view of OMT as a means to normalize the lives of people who inject drugs—we developed a wider understanding of the purpose of this study. The purpose of the study was revised as follows: **to examine satisfaction with OMT in the context of the subjective assessment of quality of life in patients as one of the treatment outcomes.**

General characteristics of the sample

The data used for analysis included 376 questionnaires fully completed by patients enrolled in OMT at private and funded OMT sites. Study participants were recruited in Kyiv and the Kyiv Oblast region. The selection criteria involved the following:

- Over 18 years of age.
- On OMT.
- Type of site (funded or private).
- Type of medication (methadone or buprenorphine).
- Form of therapy administered (medication administered daily on-site, take-home medicines for 10 days collected from the site, or medication collected from the pharmacy/through prescription for 10 days).

Participants also signed an informed voluntary consent form to participate in the study.

Out of the 376 study participants recruited according to the sampling criteria, 178 were patients of funded sites and 198 were patients of private sites. Overall, 118 participants (31.4%) were women. A total of 143 individuals (38.0%) were collecting medication daily at OMT sites, 78 (20.7%) were collecting medication from the site once every 10 days, and 155 (41.2%) received medicines from the pharmacy by prescription. Other characteristics of the study respondents (presented in the Table 4) include the following:

- The average median age was 37 years (interquartile range 32–39).
- 127 respondents (33.8%) reported being unemployed.
- 43 respondents (11.4%) reported receiving a social security allowance for disability.
- 188 respondents (50%) injected drugs at least once within the previous month.
- 133 respondents (35.4%) reported having an incarceration experience in their life.
- HIV and viral hepatitis C were reported by 23.6% and 58% of study participants, respectively.

Characteristics of the sample by site type

As we can see from the initial analysis of the sample, the demographic characteristics of respondents were comparable for patients from funded and private sites, including their average median age (37 years and 36 years; $P = 0.073$), self-reported unemployment status (37.6% and 30.3%; $P = 0.133$) and average median age at first use of a substance (17 years and 18 years; $P = 0.412$).

Respondents from these groups, however, do have significant differences in the following characteristics (calculations are based on median values):

- OMT patients in funded sites are more likely to receive social security allowances for disability (16.3% compared to 7.07%; $P = 0.005$).
- OMT participants in private sites were more likely to have injected drugs within the recent month (63.1% compared to 35.4%; $P = 0.001$).
- Programme participants in funded sites were more likely to have a record of incarceration (42.7% compared to 28.8%; $P = 0.005$), but participants in private sites had on average spent longer in prison (36 months compared to 30 months; $P = 0.045$).



TABLE 4. CHARACTERISTICS OF THE SAMPLE, BY SITE TYPE

Sample characteristics	General sample		Patients of funded sites		Patients of private sites		P value
	N	%	N	%	N	%	
	376	100	178	47,3	198	52,7	
Social and demographic characteristics							
Median age (25–75%)	37	32-39	37	33-40	36	31-39	0,073
Women	118	31,4	53	29,8	65	32,8	0,524
Unemployed	127	33,8	67,0	37,6	60,0	30,3	0,133
Receive a social security allowance for disability	43	11,4	29	16,3	14	7,07	0,005
OMT participation							
Receive OMT from more than one site (n = 281)	75	26,7	26	19,3	49	33,6	0,007
The type of site for state-run sites (n = 178)							
Drug addiction dispensary			124	69,7			
AIDS Centre			22	12,4			
Other			32	18,0			
How OMT is dispensed							
							<0,001
Receiving medication administered daily	143	38,0	63	35,4	80	40,4	
Receiving medication once every 10 days	78	20,7	68	38,2	10	5,1	
Receiving a prescription	155	41,2	47	26,4	108	54,6	
OMT medication							
							0,720
Methadone	198	52,7	92	51,7	106	53,5	
Buprenorphine	178	47,3	86	48,3	92	46,5	
Substance use							
Injected drugs at least once within the last month	188	50	63	35,4	125	63,1	<0,001
Median age at first use of opiates (25–75%)	18	15-20	17	15-20	18	16-20	0,412
Medical characteristics							
Tested for HIV	331	88,0	162	91,0	169	85,4	0,141
HIV-positive (n = 331)	78	23,6	43	26,5	35	20,7	0,614
Currently on antiretroviral therapy (n = 78)	71	91,0	40	93,0	31	88,6	0,769
Tested for hepatitis C	305	81,1	156	87,6	149	75,3	0,008
Positive status for hepatitis C (n = 305)	177	58,0	102	65,4	75	50,3	0,044
A history of incarceration							
Has a record of incarceration	133	35,4	76	42,7	57	28,8	0,005
Average median months served in prison (25–75%)	35	12-60	30	4-60	36	13-60	0,045

Results of the quantitative study component

Respondents completed the survey on a tablet using an automated self-administered survey tool (CASI) based on a licensed version of REDCAP data collection software (projectredcap.org). On average, it took respondents 24 minutes to complete the questionnaire (the ideal time to complete it was between 18 and 33 minutes). In addition to posing questions from the WHOQOL-BREF tool to measure quality of life, the questionnaire posed questions on the following topics:

- The social and demographic characteristics of respondents.
- The satisfaction of the respondent with the OMT services in general, particularly their assessment of (and satisfaction with) the physical setting of OMT sites, the quality of medical care, and the social and psychological support on offer.
- Additional intake of prescribed medicines and unauthorized use of medicines and/or illicit drugs.
- Incarceration experience.
- Testing and treatment experiences pertaining to HIV, hepatitis C and other diseases.

The results of assessments by programme participants

Satisfaction with opioid maintenance therapy, quality of life, and the need for opioid maintenance therapy and health care services

The data presented in Figures 5 and 6 confirm the results received from the analysis of the interviews: the overall satisfaction with OMT services among programme participants is rather high. The reliability of the data is confirmed by similar values of service assessment (rated as “good” and “very good” by 72% of respondents) and the overall satisfaction with the OMT service (71%). Meanwhile, overall assessments of the quality of life, health of respondents and physical setting of OMT sites are much lower: between 38% and 42% of participants scored their well-being and the condition of OMT sites as “good” or “very good.”

FIGURE 5. RESPONDENT’S ASSESSMENT OF OPIOID MAINTENANCE THERAPY SERVICES AND QUALITY OF LIFE

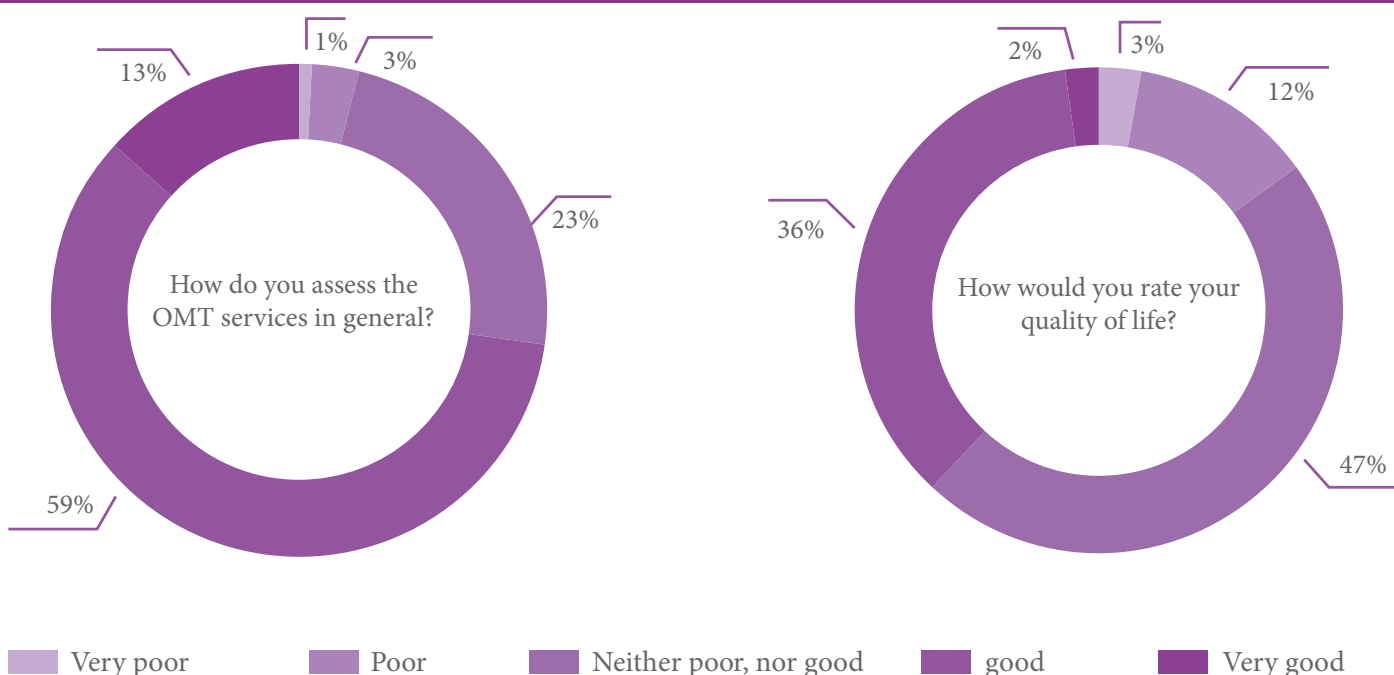
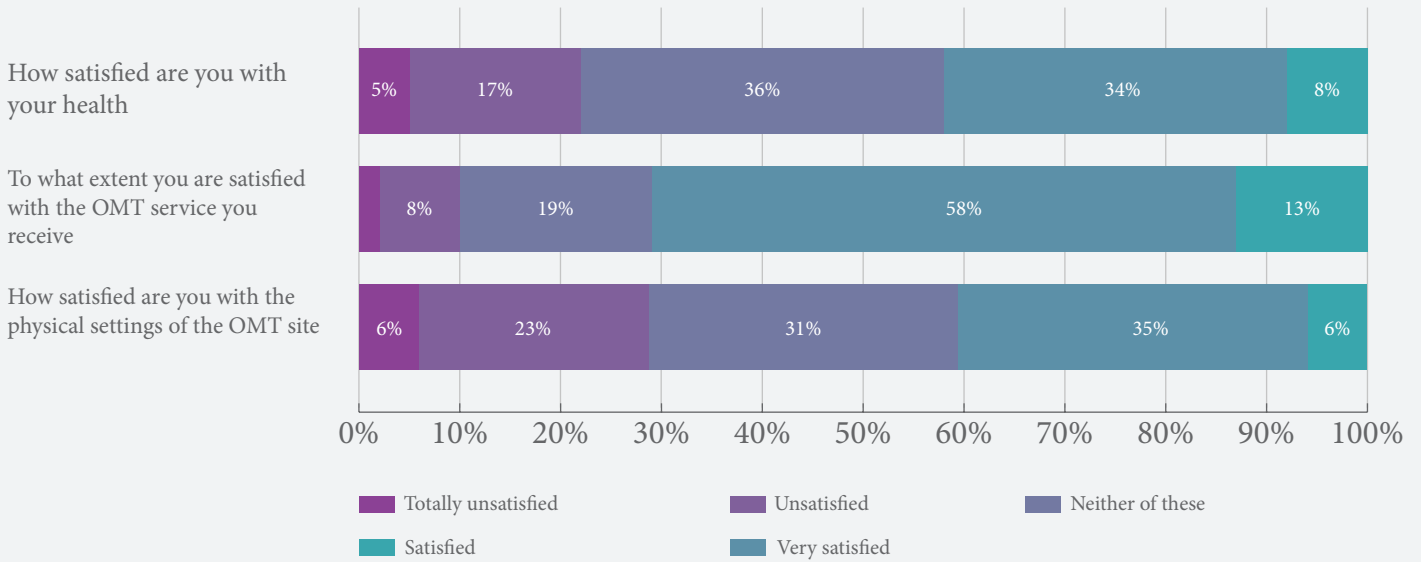
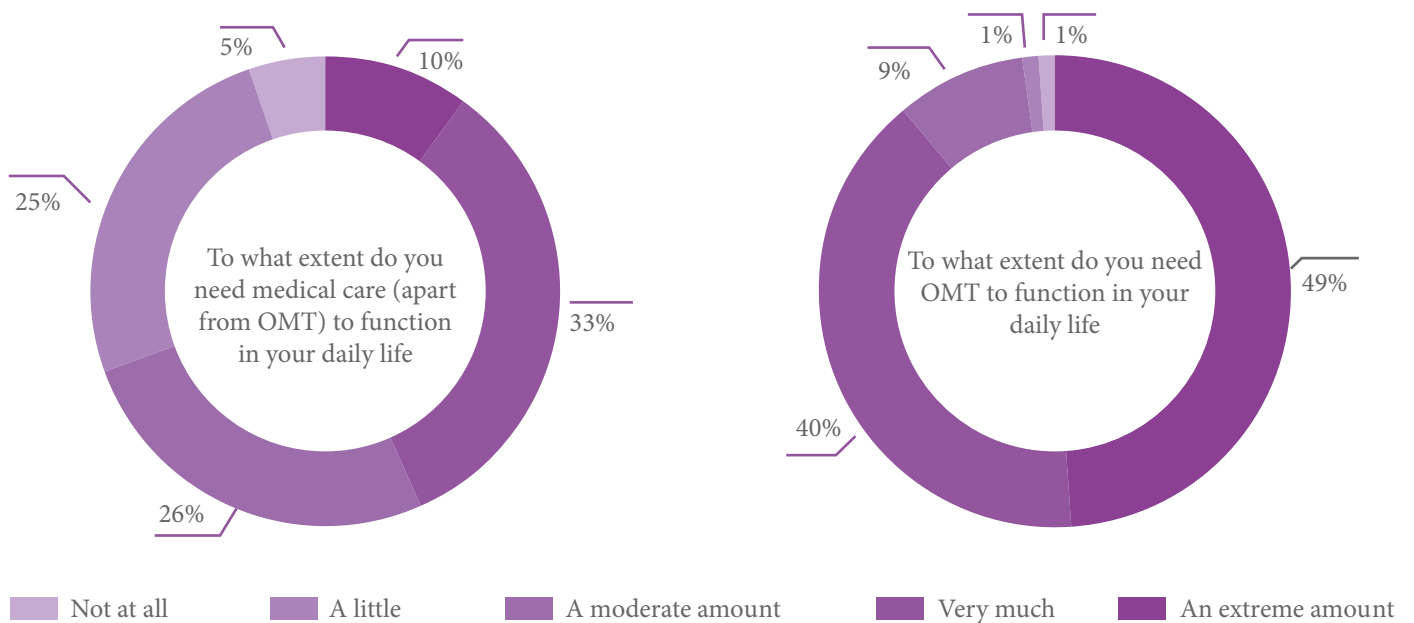


FIGURE 6. SATISFACTION WITH THE PHYSICAL SETTING OF THE OPIOID MAINTENANCE THERAPY SITE, THE SERVICE AND THE PERSON'S HEALTH



As Figure 7 shows, respondent evaluations set their need for OMT as “very high” (89%), although their need for other (non-OMT) medical services seems to be much lower (43%).

FIGURE 7. ASSESSMENT OF THE NEED FOR MEDICAL CARE AND OPIOID MAINTENANCE THERAPY

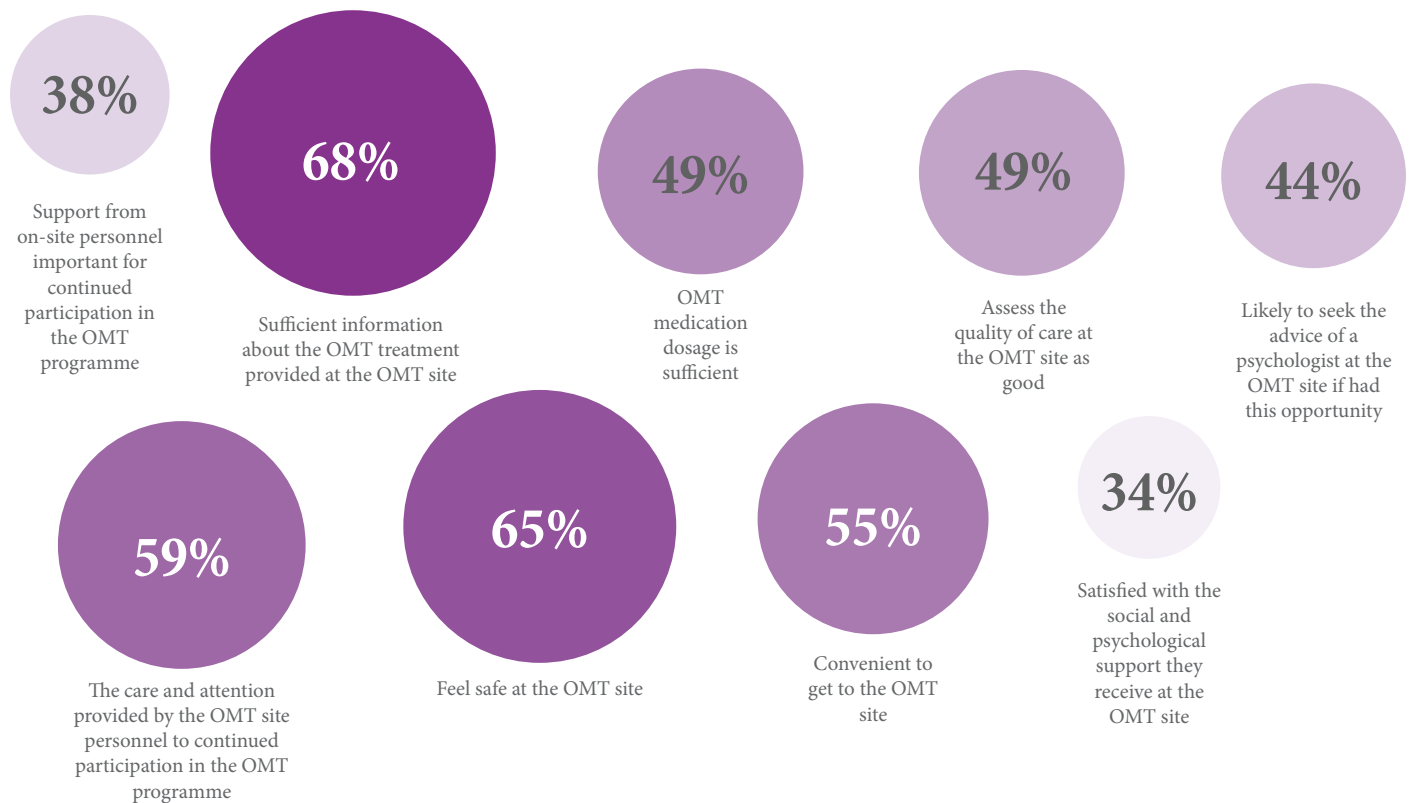


Opioid maintenance therapy as an integrated set of services

Figure 8 shows summarized data on different criteria used in the assessment of the OMT service as an integrated set of services and interactions. When asked whether support from on-site personnel is important for continued patient retention in the OMT programme, 38% of participants confirmed that this support is important. In addition, 59% of respondents said that receiving care and attention from the OMT on-site personnel is important for their adherence to treatment, but only 34% of participants were satisfied with the social and psychological support they received at OMT sites.

Forty-nine per cent of respondents assessed the quality of medical care as good, and 49% also said that the OMT medication dosage is sufficient for them. As Figure 8 shows, 68% of study participants believed that they received sufficient information about OMT, 65% reported they felt safe at the OMT site, and 55% said the facility location was easy to reach.

FIGURE 8. SUMMARIZED DATA ON QUESTIONS ABOUT OPIOID MAINTENANCE THERAPY PROGRAMMES



As we can see in Figure 9, however, if safety is considered in the context of data safety, most respondents reported that they were not confident about the confidentiality of data they provide to the OMT site ($n = 155$) or that they were only somewhat confident ($n = 90$). We can therefore assume that for programme participants, feeling safe is not positively related to feeling confident about the safety of their data. Moreover, the perception of safety with regards to the confidentiality of data has a statistically significant negative relationship ($P = 0.001$).

FIGURE 9. PERCEPTION OF SAFETY AND CONFIDENCE IN CONTEXT OF PERSONAL DATA SAFETY



Characteristics of opioid maintenance therapy programmes at funded and private sites

Table 5 shows statistically significant differences (P value) in the assessment of OMT programmes against the following parameters:

- OMT participants at funded sites are more likely to face resistance if they try to withdraw from the programme than participants at private sites (18.4% compared to 6.5%; P = 0.012).
- Patients at funded sites more frequently report having filed a formal complaint about services than patients at private sites (16.9% compared to 7.1%; P = 0.003). Patients at funded sites were less likely to report feeling at peace (on the relaxed/anxious scale) when seeing a doctor than patients at private sites (median feeling of being relaxed/at peace of 64 and 74, respectively; P = 0.002).

The frequency of “seeking social worker professional services” is a parameter with high statistical significance (P < 0.001). For instance, patients of private sites were more likely to report that they had never gone to see their social worker 52.5% (n=105) than respondents at funded sites 36% (n = 64). The lack of social workers at their site was reported by 5.6% (n = 10) of respondents at funded sites and 16.2% (n = 32) of participants at private sites. The exception was participants (n=42) who reported having no social worker at their OMT site. Among the rest of the participants (n = 334), those at private sites reported a stronger feeling of anxiety during consultations with social workers (n = 59, 50–87%; P < 0.001) than participants at funded sites (n = 77, 55–95%; P < 0.001).

TABLE 5. CHARACTERISTICS OF OPIOID MAINTENANCE THERAPY PROGRAMMES AT FUNDED AND PRIVATE SITES

Characteristics	General sample		Patients of funded sites		Patients of private sites		P value
	N	%	N	%	N	%	
Total respondents	376	100	178	47,3	198	52,7	
Were informed about the programme rules at the most recent initiation of the programme	313	83,2	153	86,0	160	80,8	0,242
Aware of the process for withdrawal from the OMT programme	267	71,0	132	74,2	135	68,2	0,202
Faced resistance when attempting to withdraw from the programme (n = 184)	21	11,4	14	18,4	7	6,5	0,012
Satisfied with the duration of treatment in the OMT programme	328	87,2	155	87,1	173	87,4	0,932
The toilet door at the site closes well	208	55,3	103	57,9	105	53,0	0,346
Have ever complained about services at the OMT site	44	11,7	30	16,9	14	7,1	0,003
Probability of filing a complaint in the future							0,755
Very unlikely	56	14,9	26	14,6	30	15,2	
Unlikely	99	26,3	42	23,6	57	28,8	
50/50	93	24,7	44	24,7	49	24,8	
Likely	95	25,3	49	27,5	46	24,8	
Very likely	33	8,8	17	9,6	16	8,1	
Seeking help from the social worker							<0,001
Never sought care	168	44,7	64	36,0	105	52,5	
1-3 times	109	29,0	71	39,9	38	19,2	
Seeking care on a regular basis	57	15,2	33	18,5	24	12,1	
No social worker at this site	42	11,2	10	5,6	32	16,2	
Median of feeling relaxed/at peace while attending the OMT site (on a scale where 0 = feeling distressed/anxious and 100 = feeling relaxed/at peace)	74	50-88	72,5	50-86	76	58-90	0,077
Median of feeling relaxed/at peace while receiving OMT medication from the nurse (on a scale where 0 = feeling distressed/anxious and 100 = feeling relaxed/at peace)	74	51-94	73	50-93	75	57-97	0,266
Median of feeling relaxed/at peace while consulting with the on-site doctor (on a scale where 0 = feeling distressed/anxious and 100 = feeling relaxed/at peace)	73	50-89	64	50-86	74	52-90	0,002
Median of feeling relaxed/at peace while consulting with the on-site social worker (on a scale where 0 = feeling distressed/anxious and 100 = feeling relaxed/at peace) (n = 334)	73	50-92	77	51-95	59	50-87	<0,001

WHOQOL-BREF domain indicators

As Table 6 shows, characteristics such as gender, age and the format used to dispense medication are not statistically related to any domain that measures the quality of life. However, the type of OMT site is related to the physical domain of quality of life: study participants who receive OMT at funded sites reported a worse physical domain of quality of life. One of the possible explanations is that a greater number of participants at funded sites confirm having a disability status. Patients receiving buprenorphine also tend to do better on indicators of physical and psychological domains of quality of life than those receiving methadone, and HIV-positive status and diagnosed hepatitis C are associated with lower scores on quality of life indicators in both the physical and psychological domains. Finally, respondents who reported being unemployed or receiving a disability allowance have lower quality of life measures across all domains.

TABLE 6. MEAN (AND STANDARD DEVIATION) FOR WHOQOL-BREF QUALITY OF LIFE DOMAINS, BY PARTICIPANT CHARACTERISTIC

Characteristics	Physical	Psychological	Social	Environment
Average for the entire sample	51,5 (18,8)	62,3 (17,1)	51,3 (25,5)	51,1 (15,0)
Age				
< 37 years	51,8 (17,8)	62,7 (16,5)	52,9 (25,1)	51,3 (15,5)
≥ 37 years	51,3 (19,8)	61,9 (17,6)	49,9 (25,9)	51,0 (14,6)
Gender				
Male	50,8 (18,6)*	61,9 (16,7)	50,0 (25,6)	51,4 (15,4)
Female	53,1 (19,4)*	63,2 (17,9)	54,2 (25,1)	50,6 (14,1)
Unemployed				
Yes	45,1 (16,4)***	56,7 (16,3)**	42,1 (23,8)***	45,0(13,7)***
No	54,8 (19,2)***	65,2 (16,8)**	56,0 (25,1)***	54,2(14,7)***
Receiving social security allowance for disability				
Yes	33,7(14,8)***	49,3 (14,0)***	41,3 (21,1)**	43,2 (12,6)**
No	53,8(18,1)***	64,0 (16,7)***	52,6 (25,8)**	52,1 (15,0)**
Type of the site				
Funded	48,4 (19,5)**	60,5 (17,3)	50,2 (25,5)	50,0 (15,2)
Private	54,4 (17,8)**	64,0 (16,8)	52,3 (25,5)	52,2 (14,9)
Medication				
Methadone	49,0 (18,0)**	59,6 (16,6)**	48,1 (24,3)*	50,1 (14,3)
Buprenorphine	54,3 (19,4)**	65,3 (17,2)**	54,9 (26,4)*	52,3 (15,7)
Medication administered daily				
Yes	51,9 (18,5)	61,4 (17,3)	51,8 (25,0)	50,2 (16,0)
No (prescriptions or dispensed for self-administered therapy)	51,3 (18,5)	62,9 (17,0)	51,1 (25,9)	51,7 (14,4)
HIV-positive				
Yes	43,9 (16,9)**	56,8 (15,8)**	49,3 (22,0)	47,6 (13,5)*
No/don't know/refuse to answer/not tested	53,5 (18,8)**	63,8 (17,1)**	51,9 (26,3)	52,0 (15,3)*
Hepatitis C positive				
Yes	48,3 (17,5)**	59,5 (15,7)**	51,2 (24,5)	49,7 (14,1)
No/don't know/refuse to answer/not tested	54,4 (19,6)**	64,8 (17,9)**	51,4 (26,4)	52,4 (15,7)

*** p-value<0,001, ** p-value<0,05, *p-value<0,1

A statistically significant difference between participants in funded and private sites is found in the physical domain of quality of life (Figure 10). Across the entire sample, the lowest quality of life scores in the physical domain are found to be related to a reported disability pension

allowance, with a more evident negative relation among participants of funded sites. As we have already mentioned, OMT patients in funded sites are generally more likely to be receiving disability pension allowances (16.3% compared to 7.07%; P = 0.005).

FIGURE 10. PHYSICAL DOMAIN OF QUALITY OF LIFE IN TERMS OF RECEIVING A DISABILITY PENSION ALLOWANCE AND THE TYPE OF SITE



DISCUSSION OF STUDY RESULTS

Assessment of satisfaction with the opioid maintenance therapy service

According to the study results, overall satisfaction with OMT services is generally high among patients of both funded and private sites. This is very similar to the findings of a previous study in Ukraine that examined the satisfaction of patients of funded sites when they transitioned from receiving OMT at their registered local health-care provider to primary health-care facilities (23). The findings are also in keeping with similar studies conducted in other countries and regions (36–39, 48, 90). However, if we look more closely at particular aspects of satisfaction with OMT as an integrated set of services, the satisfaction of patients does not measure very high. In particular, 49% of participants evaluated the quality of care at OMT sites as good, only 34% were satisfied with the provided social and psychological support, and 42% were satisfied with the overall physical setting of OMT sites.

At the qualitative stage of the study, we called this a “paradox of satisfaction with OMT.” Going through the narratives of respondents, it is easy to identify aspects that logically (from the perspective of the researcher) should have led to dissatisfaction or had a stronger negative impact on overall satisfaction with the service. When asked a direct question about whether they are satisfied, however, respondents inevitably replied they were satisfied and issues they’d been critical about were of no importance.

In order to explain this effect, it is important to note that we tried to approach the “OMT service” as a set of interactions between patients and OMT sites that result in patients receiving medication. However, when patients responded to the question about satisfaction with the OMT service, they hardly assessed the “OMT service”: if that were the case, overall satisfaction might not have measured

higher than 50% (based on the distribution of results by individual criteria). Taking into account the fact that 89% of respondents pointed out that they need OMT to function in daily life, responses to the question on overall satisfaction with the OMT service may actually have provided an answer to whether patients are satisfied with the fact that they have an opportunity to receive OMT, rather than whether they are satisfied with the integrated services they receive alongside the medication.

The measure of perceived safety in the context of data confidentiality is also somewhat paradoxical. Having pointed out that they feel insecure about the confidentiality of their data, participants nevertheless report they “feel safe” at the OMT site. As a result, we have a negative relation here instead of a positive correlation (which, according to the researcher’s logic, should have been found). The relationship between these variables clearly demonstrates the differences between the logic of researchers and the logic of OMT service clients.

What we describe as the “OMT satisfaction paradox” is referred to in other studies as a “de-synchronization paradox”: that is, the lack of correlation between subjective and objective outcomes, such as objective or clinically relevant outcome measures and a patient's subjective perception based on how he or she feels after surgery (91, 92). In the context of satisfaction with OMT, this paradox was highlighted in several studies, including those where the authors considered “general satisfaction with OMT” as a guaranteed outcome in the assessment of OMT programmes using “hard indicators” and standardized quantitative methods (93–95). The authors of these studies call for the use of qualitative methods to address individual patient experiences and to understand the “contents” of

services or treatment, rather than to identify patients as “satisfied” and assess OMT programmes according to their global goals.

These paradoxes can also be explained by a change in expectations that results from patient experiences gained while participating in OMT programmes. As Locker and Dunt point out, expectations are constantly changing in light of that gained experience, and satisfaction scores would be related to the changing experience (96). Carr-Hill has come to the conclusion that memory or cognitive dissonance may be among the factors explaining how expectations affect patient satisfaction (97). According to the cognitive dissonance concept,

people tend to find a way to be satisfied with their choice (in this case, their enrolment in OMT) to avoid cognitive dissonance between dissatisfaction with the service and the fact they consume it nonetheless. Other researchers (94, 98) further highlight that people confronted with a chronic disease or a long-term specific condition (such as drug addiction) may develop a “response shift” in their assessment of themselves and the conditions they face: in adapting to such illnesses, conditions or situations (including OMT enrolment), patients may overestimate their satisfaction with services or provide answers that seem (to someone who has not had similar experiences) to be conflicting.

Impact of opioid maintenance therapy satisfaction on the quality of life of patients

The design of this study did not provide the opportunity to assess the impact of OMT enrolment on quality of life, because we did not take measurements at different intervals of treatment (such as treatment initiation and after six months). Based on the answers to questions about satisfaction with the OMT service and assessments of quality of life, however, we can assume that in the context of the data obtained, these two parameters are poorly linked. In this regard, symmetrical answers to two questions—about assessing the quality of care and the sufficiency of the OMT medication dosage—were noteworthy. The number of participants (49%) who rated the quality of medical care as “good” was exactly the same as the number of those who reported the medication dosage was “sufficient.” Knowing that the majority (89%) of patients reported needing OMT to function in daily life, we can further assume that assessments of particular services are related not to the quality of the respective services, but rather to the quality of access to OMT medication that on-site specialists (such as medical personnel and social workers) make available.

A study involving patients of the first buprenorphine programme conducted in Ukraine in 2004 (see Table 7) showed a significant increase in measures for all quality of life domains over the period of treatment

(measurements were taken at treatment initiation and then at six months). As previously indicated, this research design is quite common, and it consistently demonstrates a positive relationship between OMT and quality of life (80). At the same time, some studies (50, 75, 77) have noted that quality of life measurements measured at OMT initiation tend to be significantly underestimated as people who inject drugs often come to a decision to start OMT at a critical moment, often under the pressure of challenging life circumstances, while measurements taken a few months after treatment initiation only show a short-term effect.

Furthermore, a sharp increase in quality of life measures may implicitly indicate some kind of “Hawthorne effect,” a positive and transitory change in a behaviour being evaluated under experimental conditions (99). Such a change in behaviour occurs not because of any alterations in the independent variable, but rather because participants know they are being observed or studied. Quality of life assessments could, in some cases, reflect or be sensitive to this effect (100). For instance, involvement in the study and apparent interest in the patient’s quality of life could lead to a positive perception of the treatment or service and, consequently, to higher scores for both treatment (or services) and the respondent’s quality of life.

Thus, the chronic nature of drug addiction—and, consequently, the indefinite period of participation in the OMT programme—call for more routine

measurements of quality of life in order to assess the dynamic of progress rather than short-term effects among OMT patients.

TABLE 7. INDICATORS OF QUALITY OF LIFE DOMAINS FROM THE CURRENT STUDY COMPARED WITH A 2008 STUDY ON THE QUALITY OF LIFE OF OPIOID MAINTENANCE THERAPY PATIENTS IN UKRAINE

Quality of life domains	A sampling of this study		Sample of the 2008 pilot study of OMT patients—zero months after OMT initiation		Sample of the 2008 pilot study of OMT patients—six months after OMT initiation	
	The mean ± standard deviation	Minimum/maximum value	The mean ± standard	Minimum/maximum value	The mean ± standard deviation	Minimum/maximum value
Physical	51,5 ± 18,8	4-93	44,8 ± 17	6-81	73 ± 11,7	25-88
Psychological	62,3 ± 17,1	12-100	44,08 ± 18,2	6-75	69,7 ± 9,2	25-81
Social relationships	51,3 ± 25,5	0-100	45,4 ± 20	0-100	52,4 ± 11,5	0-81
Environment	51,1 ± 15,0	13-97	50,3 ± 15,36	25-94	67,6 ± 11,1	31-94

Source: Dvoryak S, Grishayeva I. First experience of opioid therapy with buprenorphine in Ukraine. *Heroin Addict Relat Clin Probl.* 2008;10(1):13-8.

Assessing the quality of life of opioid maintenance therapy patients

Since there are no other studies that use the WHOQOL-BREF tool to assess the quality of life among people who inject drugs in Ukraine except for the one by Dvoryak S. and Grishayeva I. (discussed above), we could only use the outcomes of the 2004 study as our starting point to understand the subjective assessment of quality of life among OMT patients (83). In this regard, this study also does not provide a complete understanding of the low or high values for quality of life among OMT patients in a particular sample, as no similar data on quality of life among the general population or any other specific population are (or were) available.

In 2006, an Australian study was published on interpreting data on preliminary population norms using the WHOQOL-BREF tool (101). According to this research, the norms for WHOQOL-BREF domains—mean and (standard deviation)—were as follows: 73.5 (18.1) for the physical health domain, 70.6 (14.0) for the psychological well-being domain, 71.5 (18.2) for the social relationships domain, and 75.1 (13.0) for the environment domain. Measurements for all quality of life domains are usually reported to be significantly lower among people who inject drugs than among the general population (61, 76, 89, 102, 103); one study reports that quality of life measurements among people who inject drugs also tend to be significantly lower compared to populations with life-threatening and chronic diseases, such as chronic heart disease, stroke, spinal cord injuries and neurological diseases (104). As the author suggests, however, none of these diseases can compare with substance addiction when it comes to the intolerance and non-acceptance expressed by society, which can be one of the reasons for the low quality of life scores among people who inject drugs.

According to our study, a statistically significant negative relationship was found between quality of life domains and the following independent variables:

- Unemployment.
- Receiving disability pension allowances (i.e., confirmed disability status).
- Receiving OMT from a funded site.
- Treatment with methadone.
- HIV-positive status.
- Hepatitis C infection.

Being unemployed and receiving a disability pension allowance are negatively related with all four domains. Relatively similar data, which we collected from the qualitative component of the study, show that having no employment is a factor that affects the subjective assessment of well-being. Therefore, the most vulnerable people in terms of quality of life are the most formally disadvantaged groups of OMT patients—the same groups who are eligible to receive OMT from funded sites on a priority basis.



CONCLUSIONS AND RECOMMENDATIONS

Based on the results of this study, we can draw the following conclusions and make some recommendations for further advocacy.

Routine monitoring of satisfaction

Studies like this one can be conducted using a routine monitoring format as an integrated component of the monitoring and evaluation framework at OMT sites. This allows us to understand the dynamics of satisfaction with treatment and treatment environment, interactions with OMT service providers and subjective treatment experiences. All these factors can influence the long-term patient retention in OMT programmes. For this reason, such interventions can and should be advocated for by the community.

Quality of life as an indicator of treatment efficiency

For an improved understanding of the goals and outcomes of the treatment of chronic diseases like drug addiction, we recommend considering the assessment of patient quality of life as an indicator of treatment efficiency. In order to do that, the quality of life of patients should be assessed on a regular basis, for instance, such as every three or six months. Such approach may result in the development of interventions aimed at improving the quality of life of OMT patients.

Improved quality of life among patients is likely to lead to increased satisfaction with OMT programme components beyond the supply of medication (which, as noted, is the current focus of patient satisfaction). In particular, emphasis should be placed on patients who are the focus of OMT programmes, especially people with dual diagnoses (such as drug addiction with HIV and/or hepatitis C coinfection), who currently account for more than 40% of all clients in OMT programmes. We believe that the government should not only provide such patients with the opportunity to enrol in OMT programmes as a priority response measure, but also to continue working with these people as

they receive treatment in the programme in order to help them reach at least average (for patients on OMT) scores in all quality of life domains. The same is true for OMT patients with disabilities, who need more comprehensive care to improve their quality of life assessment. Moreover, we think that one of the strategies here can be the development of palliative care for OMT patients who need it.

Another vulnerable sub-population is patients who report being unemployed: their quality of life scores are also significantly lower across all domains. Reintegrating patients into social life by creating additional employment opportunities can be one of the most important advocacy projects aimed at improving patient quality of life, satisfaction with treatment and retention in OMT programmes.

Opioid maintenance therapy as a set of integrated services

Since Decree No. 200 declares OMT to be an integrated set of medical, social and (as applicable) psychological care and supports, the community (including patients) should work to ensure that governmental obligations are put into force. For instance, although the declared set of services is formally provided at OMT sites in Kyiv and the Kyiv Oblast region, our study shows that the content and quality of these services suggest they are mostly aimed at monitoring patient behaviour rather than providing patient-centred support and assistance to people on treatment.

Full implementation of the right to health

Since WHO defines health as “a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity,” (119) it is important to focus on a wider understanding of the health of OMT patients as a condition that significantly affects their quality of life and well-being. Community and civil society should request to guarantee the full realization of the right to health instead of just providing improved access to treatment.

LIMITATIONS FOR RESEARCH INVOLVING MARGINALIZED GROUPS

To better understand the specifics around collecting and analysing data involving OMT patients and people who inject drugs, it is important to recognize certain limitations.

Respondents are typically recruited for a study through community-based organizations that work directly with them. These recruiters act as gatekeepers who determine who will take part in the study, selecting participants according to a list of selection criteria provided to them by the research team. These selection criteria are often fairly common, which allows the recruiter to choose from a large number of people who meet them. This is important, because the recruiter may have an interest in inviting certain respondents to participate in the study, as described in classic works that discuss social interactions between different actors in ethnographic studies (105, 106).

In the context of this study, we can say that for the qualitative part selected respondents not only met the required criteria, but also had noteworthy features that the recruiter revealed before the interviews. For example, there was a person who has been coming to the OMT site every day for 15 years for daily pick-ups and who refuses to be transferred to receiving prescriptions for self-administered therapy. There also was a female respondent who the recruiter wanted to make an activist.

By describing the study to the respondent and asking further questions, the recruiter establishes a framework in which the study or interview will take place. While the theme of the study is not always significantly reflected in the life of every respondent (e.g., HIV treatment or satisfaction with OMT may not have ever been among their personal experiences or priorities), placing the respondent into the frame of the interview may encourage them to start acting according to the desired or

approved scenario. For instance, if the recruiter tells them the title of the study (“Satisfaction with OMT”), respondents may want to express their opinion about different satisfaction categories, even though they had never thought about any of those categories before the interview/survey (107).

The respondent is often initially identified as belonging to a group constructed for the study by the research team according to the selected criteria. In order to support their position on a particular issue in the context of the study, respondents express not only their own “personal” opinion, but also that of their group or community, or perhaps even of any other people actively interacting with the group (108, 109). As a result, it can be apparent during the interview that what we are hearing from our respondents is a “recording”—a message that they have heard from someone else (such as HIV service or OMT personnel).

This is more than just retransmitting someone else's opinion or imposed constructs as an “other in the interview,” however—these constructs are part of the “self-presentation” of the respondent to the interviewing researcher, a concept discussed in the field of discursive psychology (111, 112). In order to save face in the event of potential conflict between personal opinion and social norms, the respondent may want to choose the conformity strategy—that is, to offer an answer that he or she feels is socially acceptable to the perceived norms or opinions of the interviewer. Even if a respondent feels they have a connection with the interviewer, they still may want to conceal their personal opinion as much as possible. As a result, we may see how a respondent—whose life and behaviour generally do not meet social norms—tries to play different roles, shifting from one scenario to another within the same interview, even if they are contradictory. For example, a respondent might say they would never join a suspicious company

of people hanging around the OMT site while simultaneously knowing exactly who those same people are and what they are doing.

Respondents often use so-called explanatory models in their narratives when discussing their condition, health or illness. Such models, which are discussed in the framework of critical medical anthropology approaches (113–115), explain a disease, its emergence or development through association with a particular culture and or certain life experiences. For instance, people who inject drugs may consider addiction as a purely physical addiction that is "cured" by a dose of either drugs or OMT medication, rather than as a complex web of social, physical and psychological problems that require long-term treatment—as it would be categorized, for example, by a researcher.

Due to the social exclusion and marginalization that can result from long-time drug use—and possibly an HIV-positive status—people who inject drugs can develop psychological protection mechanisms and coping strategies to counteract the pressure they face. These mechanisms are studied as part of the psychoanalytic theory of defence mechanisms. As a result of the efforts to counteract and neutralize this everyday pressure, people who inject drugs tend to suppress the information that

causes discomfort, or to transfer it to other people or otherwise project it on to them (116). During interviews, for example, we are often told a story of someone else (rather than the respondent) who is concurrently using illicit drugs and OMT medication.

A number of studies are conducted in Ukraine involving members of marginalized groups. This includes including biobehavioural studies every two years, studies of patients receiving OMT and antiretroviral therapy, implementation studies of all kinds of existing public health programmes and interventions, and more. Each of these studies offers some form of remuneration package to participants. As a result, we can see the emergence of a so-called professional respondent, someone who (thanks to the recruiter) can take part in any or all of these studies in order to receive participation-based rewards. The reduced quality of information that is obtained with the help of these professional respondents has already been discussed in several studies devoted to public health in general and people who inject drugs in particular (117, 118). One of the respondents who participated in our study told us she had previously (within a few months) taken part in another survey on the quality of service at an OMT site.

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APPENDICES

Appendix 1. Stages of the study and recommendations for their implementation in practice

The study had the following stages:

- 1.** Discussing and coordinating the design of the study, writing the protocol of the study and submitting the protocol to the Ethics Review Board.
- 2.** Discussing the results of the qualitative component, developing a tool to conduct the survey, incorporating amendments to the study protocol (as required), making changes to the protocol of the study and submitting the protocol to the Ethics Review Board.
- 3.** Providing training for interviewers on the basic issues of research ethics related to the recruitment of study respondents and data collection.
- 4.** Identifying private OMT sites at the field phase of the study.
- 5.** Undertaking interim data extraction during the field data collection phase to share data for mutual discussion, make adjustments to the data collection process, develop further data collection strategy and provide additional training for interviewers (as required).
- 6.** Analysing results.
- 7.** Discussing study results.
- 8.** Presenting study results.

Study design and protocol

The research design of this project was initially discussed by a team of researchers and the study stakeholder (the Eurasian Harm Reduction Association, or EHRA). Since research tools (Appendices 2,3,6) are now readily available, discussions around future projects in other countries could take place at the community level with the invited researcher (or researchers). It is important to understand the specifics of using these tools, as researchers have to follow the established set of steps while conducting a study.

Research in this field addresses sensitive issues, and its participants belong to marginalized groups. The study design, interview guides and informed voluntary consent form all should be specified in the study protocol and reviewed by the relevant ethics committee (the Ethics Review Board). With regard to the tool for measuring satisfaction with opioid maintenance therapy (OMT) services, it has both permanent components and parts that can vary from country to country, depending on the study context (Appendix 6).

The roles and responsibilities of participating parties should be differentiated when the study design is discussed by the community and the external researchers or consultants. It is worth noting that the community and the research team may not necessarily share the same views and opinions on all issues. Accordingly, the community may have knowledge of what is going on in the field, while the researchers or consultants offer their own expertise based on research experience, previous work conducted in the field or experience with the topic of study. The researchers will prepare a study protocol that includes a review of previously conducted scientific research on the country background and context; they also will explore how this country context corresponds with the study topic and existing tool, thus advancing arguments to support their views.

For conducting this study we suggest a mixed–method approach, so it is important that the researchers have a good grasp of both qualitative and quantitative methods. They should also have experience analysing both types of data. It is important to understand that all major agreements between researchers, the community and its members will be made during the writing, approval and amendment of the protocol. We want to encourage communities and their members to engage actively in the work at these particular stages; doing so will allow them to provide feedback and comments, reflect on the proposal and make suggestions. Further adjustment may take place at later stages (as discussed below), but major edits and revisions to the design of the study can only be made at the initial writing, approval and amendment stage.

We have provided the guide that we developed for semi-structured interviews (Appendices 2, 3), but we understand that the contents of this tool will vary depending on the specific focus and issues of OMT programmes. For that reason, we encourage the researcher and the community to discuss additional, context-specific questions that should be asked during interviews with respondents. We suggest conducting at least eight interviews, but the exact number will be determined during the course of the study. To some extent, data saturation is reached depending on the experience of the researchers, particularly their familiarity with the scope of issues related to drug use and OMT programmes.

It is important to ensure that at least two recruiters are involved in the recruitment of survey participants, even when performing only small amounts of qualitative research. This will help to avoid serious bias, which may occur if all recruitment is done by a single recruiter (whose views on participant selection can critically affect the presentation of the group as a whole). Such bias can also result in the presence of questions in the quantitative part of the study that are irrelevant to a wide group of respondents.

Approval of our study was provided by the Ethics Review Board of the Ukrainian Institute on Public Health Policy. This should make it possible to conduct a similar study in other countries. It is the responsibility of the researcher and community to submit their country-based components for the approval of the Ethics Review Board, including appropriate changes and amendments to the rationale section, interview guides

and questionnaires. In accordance with the established set of steps, changes and amendments to the protocol can be submitted during two separate steps: in the first, the main protocol and the interview guide can be amended; in the second, only minimal revisions can be made to the main text of the research protocol, but the questionnaire should be amended with new blocks of survey questions.

It is important to discuss the outcomes of the qualitative component with the community. This will ensure they are actively involved in the development of further updates for the quantitative portion of the study. Community members and future interviewers also can test the questionnaire with their peers during this discussion to see whether the questions are clear and easy-to-understand, and how long it would take to complete the questionnaire. At this stage, it is also advisable to discuss and determine the sampling strategies and to collect data on various OMT sites and methods of dispensing medication.

Collecting the data

Prior to the field phase of our study, we applied to Vanderbilt University in the United States for support for our research through the use of their licensed REDCap data collection platform, which has been developed by university experts. REDCap is a secure web application for building and managing online surveys and databases.

In order to have a working tool that allows users to fill in a questionnaire, you need to assign a code to the questionnaire via the platform and to access it from the connected tablet. You may need some technical assistance from someone skilled in computer programming for this phase. We also recommend that data are collected using cloud- or web-based platforms, which requires additional material and professional resources that should be taken into account at the budget development stage. For instance, the average cost of renting a website platform might be 30 USD per month, while the cost of professional services (a specialist to help you connect your tablet to the platform) varies from country to country.

We also strongly recommend that you ensure Internet access as the tablet should be connected to the Internet while the study is completed, which allows you to control the quality of the data that you receive in real-time. This may require an allocated budget for mobile or wireless data. Adherence to the proposed set steps is important to protect the data you collect.

When administering the survey, the interviewer will first read out the text of the informed voluntary consent statement to the potential survey respondent (or have the respondent read the printed statement on their own). They will then assign a respondent code and have this code recorded in the questionnaire form on the tablet. Next, they will provide the tablet to the respondent to fill in the questionnaire; when the respondent is finished, the interviewer will check and confirm the full completion of the survey by clicking the “Submit” button.

Other things to consider include the following:

- Use the built-in timers in the software to measure how long it takes to complete the survey (i.e., the time required to fill in the questionnaire from the first question to the last one).
- Ensure that respondents fully complete the questionnaire. After the respondent finishes answering the questions, the interviewer must check the questionnaire to ensure that all of the questions have been answered before using the “Submit” button.

It is critical to plan for the award of additional survey certificates. As stated in the informed voluntary consent form, these certificates are provided to every respondent who takes part in the survey as compensation for their time and effort, and they are provided even if the survey is interrupted and the

questionnaire cannot be completed for any reason. This includes causes beyond the control of participants and researchers (e.g., communication failure) or those that are intentional (e.g., time constraints). As such, you are likely to award more certificates than you receive completed questionnaires.

Training interviewers

After setting up your tablets, continue to the next stage of the training for the interviewers. At this point, it is important not only to discuss research ethics and how to interact with respondents, but also to have interviewers practice the approved procedure to ensure they learn it well and can follow it without unauthorized changes. This is crucial, because people tend to adapt their job routines in their own way according to their views, but this can introduce uncontrollable changes into a study that affect the quality of the data. For this reason, it is important to demonstrate how the interviewers should start communicating with the respondent, what terms and wording should be avoided, how they should inform the respondent about the subject of the study, and why it is crucial that they secure the informed and voluntary participation of the respondent. It is also necessary to speak with interviewers about the importance of not influencing the data collected via the questionnaire: they should avoid providing an explanation to respondents about the purpose of questions or advising them how to answer particular questions.

In our study, we had a team of four interviewers who recruited participants. This team consisted of two female interviewers and two male interviewers from four different organizations working in the field of advocacy and the prevention of HIV and other diseases among people who inject drugs. We consider the composition of this team to have been a major asset for our project: having four individuals with different backgrounds from different organisations helped prevent possible bias in the recruitment process, which may occur if (for instance) all project members are from a single organization and share goals and a vision. It is important to gather information about as many different sites as possible (in our case, OMT sites and facilities), and to involve the recruiters and interviewers in this process.

The field data collection phase

It is important to understand some specifics of fieldwork. In the beginning, when interviewers are still learning and trying to find the most convenient formats for interacting with respondents and the most effective communication strategies, project performance will not be very high. By the time the middle of the field phase is reached, however, skills have already been developed and performance will increase. It will fall again by the end of the study: when the easiest sampling options have been used, more effort is required for interviewers to find eligible respondents who meet certain criteria.

It is also important to plan accordingly in order to have enough time for the field stage of your study. If you start rushing your interviewers through this stage, the quality of the data you get can deteriorate dramatically.

As mentioned earlier, an online data collection tool helps control the work of interviewers and allows timely corrections if collected data are dramatically different from what is expected. It is also important to go repeatedly through key points with interviewers. For example, how should they invite respondents to participate in the study? How should they offer a certificate for participation in the study? If interviewers choose to do these things in their own way rather than according to the outlined procedure, it can cause data distortion, skewing the results. Within the field stage of our project, for instance, we held seven meetings with our interviewers over two months in order to address issues that arose.

The context of the work will be subject to change. If a significant change occurs during the study, you will need to make a joint decision (all parties involved in the research) on how to proceed. In our case, one of the large funded OMT sites decided to transfer study participants from self-administered therapy by prescription back to directly observed therapy with daily pick-ups. As a result, sampling for the required quotas became more complicated, which posed an additional challenge for the interviewers. Ultimately, the sampling quotas were filled by involving eligible people from other sites within the region, but this required the interviewers to travel extensively throughout the region, which was beyond the initially agreed budget and time frame.

During the field phase, you will need to adhere to variability as a key concept of data collection. For instance, it is important that interviewers change their work sites in order to collect data from various locations. This helps avoid data distortion and ensures that the quality of collected data corresponds to the parameters set out in the study protocol. It also is important to ensure that each interviewer visits a variety of sites to collect data rather than collecting all data from a single large site.

Other recommendations for this phase include the following:

- We found that interviewers were quite uncomfortable to demonstrate how they approached a potential respondent to establish contact. It is possible that they would be more at ease if they were asked to practice the task many times in a friendlier environment.
- Poor internet connection (to mobile networks) at the sites was a major problem. We advised our interviewers to arrive early to check the quality of the connection so that they could plan their work accordingly.
- It is recommended that interviewers keep a safe distance from the facility while interviewing people for confidentiality reasons (i.e., to avoid undesirable attention from health-care personnel and to prevent any negative outcomes for the project).

At some point, we noticed that all interviewers had sharply increased rates of completed questionnaires. We held a special meeting with interviewers to discuss the issue, and while the reason for the increase is still unknown, questionnaire rates went back to normal after the meeting.

It was expected that asking interviewers to avoid putting pressure on respondents will help ensure influence-free communication during the survey. In practice, however, these expectations turned out to be rather unrealistic. Instead, the more relevant issue is the kind of influence that the interviewer has on the respondent. In our view, the interviewer—who comes from the same community as the respondent—can contribute to the wider involvement of respondents in community mobilization activities, even beyond the study itself. In this case, the interviewer also serves as a representative of the community, and relations between community activists and peers who are participating in OMT programmes can be influenced by the performance of the interviewers, and their confidence and attentiveness during the interview.

Finally, we strongly recommend allowing extra time for analysing the data and writing the report. In particular, we would recommend having at least two months allocated to these tasks: our experience suggests that you should anticipate spending twice as much time on this stage as you did on collecting the field data.

Concluding study recommendations

We would like to emphasize the importance of a flexible approach to the research process. In order to be flexible, however, one needs to plan accordingly from the beginning. Rushing things will result in poorer research and outcomes. As the study process typically involves multiple parties, the sequence of actions are inter-related. As such, all stakeholders who are responsible for a particular task need to have sufficient time to complete it.

Appendix 2. Guide for conducting semi-structured interviews with patients on opioid maintenance therapy

Please tell me about yourself, about your family, what you do, where you work, about your drug use background....

Needs and expectations related to treatment

Please tell me how you started taking opioid maintenance therapy (OMT).

- What was going on in your life at that moment?
- How did you learn about OMT?
- Did you have any previous experience of non-medical use of medicines/OMT medicine (i.e., prior to initiating your OMT programme).

Did you have any experience of drug addiction treatment prior to the initiation of your OMT programme? If yes, please tell me about this experience.

- What was it like?
- What were your expectations regarding participation in OMT programmes?
- Did you have any additional treatment needs besides OMT?

Please tell me more about the process of your OMT initiation.

- Did you have someone who helped you get started on OMT (e.g., relatives, friends, acquaintances, social workers or health workers)?
- What were your first impressions of OMT, and what were the first challenges you encountered?
- Has there been anything else (good or bad) in your life that happened unexpectedly during treatment for you?

What was the attitude of your family members or relatives to initiating OMT?

- Were they supportive or did they try to dissuade you?
- Did you have particular expectations about employment opportunities, getting education/new qualifications, etc.?

Interactions with opioid maintenance site personnel and other patients

- Please tell me more about how you take your OMT medication.
- How is this process organized?
- How do you get to the OMT site?

- How do you communicate with other people at the OMT site (e.g., doctors, social workers and other patients)?
- How do you spend your time after taking OMT medication?
- How would you like to spend time after taking your OMT medication?

Please tell me more about your interactions with nurses, doctors and social workers at the OMT site.

- Do you receive any services in addition to OMT at your treatment site?
 - If you have had any additional questions or requests for the site personnel/non-staff social workers, please tell me more about this.
- Have you heard about other patients seeking additional services at the OMT site?
 - If yes, what kind of services were they seeking? How did personnel respond to their requests?

Please explain your understanding of the process of OMT.

- Have you been told how this treatment process works, and about treatment prospects and programme completion time?
- Have you been told about the available options to discontinue therapy of your own accord and seek referral to other programmes? What do you know about them?

Satisfaction/failure to satisfy the needs of patients on opioid maintenance therapy in the course of treatment

Please tell me how your dosing regimen was selected.

- Do you think your dosing regimen is satisfactory (both in the past and currently)?
- Did you want to change your medicine or medication delivery format? Have you approached your treatment site personnel with such requests?
 - If yes, please provide more details.
- If your request was satisfied, how could you explain this? If it didn't work out, why?
- How did you solve this issue while acting on your own?
- How do other patients solve similar issues?

Please tell me how patient behaviour is monitored at the OMT site, and how difficult or easy it is for you and other patients to comply with the existing rules.

- Please explain why.
- Have you had any experience of breaking these rules? Please provide details.
- Is there a standardized list of rules?
- Is there a set of informal rules?
- From your point of view, do on-site personnel violate any rules?
- Did you have an opportunity to seek external support to solve your issues at the OMT site? Please provide details.

Participation/refusal to participate in particular opioid maintenance therapy programmes

Please tell me about your experience with discontinued treatment/OMT services.

- Was it your own decision or a decision made by on-site personnel? Please describe how it happened.
- Please tell me what happened next: did you resume using street drugs, did you go into remission, did you undergo rehabilitation, or did you resume OMT again?
- Do you think your experience of discontinuing therapy was unique, or do lots of people face similar challenges?

Changing expectations/needs/perceptions pertaining to participation in opioid maintenance therapy programmes over time

As a whole, how would you describe your participation in the OMT programme relative to your initial expectations?

- Have you been able to satisfy the needs you've had prior to OMT initiation?
 - o Which needs have been (or have not been) satisfied?
- Do you have new needs?
- Do you think it is the same for other patients, or is it different?
 - o What is the difference, if there is one?
- What would you like to change in the programme? What additional services would you add for yourself and for other patients?
- Would you recommend OMT or advise your friends/close contacts/relatives who use opiates/opioids to get involved in OMT? Why?
 - o Who would you advise to get involved with it?
 - o Who you would advise not to do it?

Appendix 3. Guide for conducting semi-structured interviews with experts

Overview

- Please tell me what you do and where you work.
- What is your work experience with people who use drugs?

Patient needs and expectations related to treatment

How would you describe people who seek OMT service(s)?

- What can you say about where they are in their lives when they come to the programme?
- How do they learn about the programme?
- What motivation(s) do they have?

- How do their relatives and close contacts participate in this process?
- How do referrals work to refer people from other programmes to OMT?
- Do you think this process works well or poorly?

What kind of expectations and needs do you think patients have prior to the initiation of the OMT programme?

- To what extent do you think that these expectations are well-grounded?
- What needs can be satisfied by participation in OMT programmes?

The process of opioid maintenance therapy initiation and treatment

Please tell me more about the process of initiating OMT.

- What kind of challenges do patients encounter most often?
 - o How can this be changed?
- How is the dosing regimen selected at your OMT site and at other sites?
 - o How is the dosage changed or adjusted over time?
- What are the rules of conduct at the OMT site? How are these explained to patients?
 - o From your point of view, how hard or easy is it for patients to abide by these rules?

Please explain the process of OMT.

- What are the treatment prospects and programme completion time?
- What options are available to discontinue therapy of one's own accord, and/or to refer patients to other programmes?
- Which organizations/programmes do you work with?
- Do you think it [treatment] could be changed or improved? What would it take to do this?

Please tell me how you interact with patients and other people who are interested/involved in treatment (relatives, close contacts, social workers, clinicians, etc.).

- What kind of questions/requests do you receive from them?
- How do you manage (if you do) to solve the ongoing issues of patients?

Patient satisfaction with opioid maintenance therapy programmes

- How helpful do you think the OMT programme is in meeting the needs of patients?
- What needs can and cannot be satisfied by participation in OMT programmes?
- Do you think the range of services offered currently by OMT programmes is sufficient?
 - o What would you like to add, remove or modify?

Appendix 4. The informed consent form for the qualitative part of the study

We invite you to take part in a study conducted to examine client satisfaction with provided services among clients of opioid maintenance therapy (OMT) programmes. The study is commissioned by the Eurasian Harm Reduction Association (EHRA) and conducted by the non-governmental organization Centre for Support, Research and Development.

This study has two parts. The first part involves semi-structured interviews, which will be used to develop a tailored questionnaire. The second part uses that questionnaire to conduct a survey among people receiving OMT services (part two).

This study is carried out in Kyiv and the Kyiv Oblast region. You will be asked to participate in a semi-structured interview that will take up to 90 minutes.

To make an informed decision about whether or not to participate in this study, you need to know the implications. We will explain to you the possible risks and benefits of your participation. This will help you decide whether you are willing to be a part of the study. You will be provided with detailed information about the study, and interviewers will answer all questions that may arise. Then you will be able to make a decision regarding your participation in the study. To confirm your willingness to participate in the study, you will be asked to say it out loud in order to have it audiotaped. You will be given a copy of this informed consent form countersigned by your interviewer.

Your conversation during this interview will be audiotaped. Transcripts of the interview will be made by our transcribers using this audio recording. These transcripts will not contain any personal information that could identify you. All collected hard copy forms will be kept in the office of the Centre for Support, Research and Development for at least three months after study completion until the data are entered into a digital form and the analysis is completed. A backup copy of the study databases, interview audio files and transcripts will be stored on secure web servers hosted by the Centre for Support, Research and Development, which are inaccessible to external users.

Remuneration

You will receive a reimbursement of 200 UAH as compensation for your time and travel expenses. The remuneration is given upon the completion of the interview. If the interview is interrupted by either party, the remuneration will be given in full anyway.

Rights of study participants

Your participation in this study does not affect any of your rights. You will be able to ask the research team any questions you might have and receive answers. By signing the consent form, you agree that you have received information about the study and that you are willing to participate in it. You will be provided with a copy of the form, countersigned by you and me (the interviewer).

This study has been reviewed by the Ethical Review Board of the Ukrainian Institute on Public Health Policy to make sure that your rights as a research participant are secured. Should you have any questions or concerns about your rights as a survey participant, please contact the Ethical Review Board of the Ukrainian Institute on Public Health Policy (anonymously) at _____ [phone number], or contact Senior Researcher, Mrs. Olexandra Dmitrieva, by phone: _____ [phone number].

Voluntary participation/right to withdraw from the study

Your participation in this study is completely voluntary. You will be able to discontinue your participation in the study at any stage of the interview. Your informed consent to participate in the study is without prejudice to any of your legal rights. If you decline to participate, all forms that have already been completed will not be used.

Risks

Research of this kind may entail possible risks to your anonymity and confidentiality. Besides that, risk of psychological harm may be associated with participation in research such as this study, which covers sensitive topics of drug use and health-seeking behaviour, including access to OMT and other health services. Details on the steps taken by the research team to maintain your confidentiality and minimize any inconveniences that may be caused by the participation in this study are listed below.

Confidentiality

We will take all possible care to ensure that your personal data are protected. The research team will maintain the confidentiality of your personal data and information. Any published reports or other publications using information obtained from this study will not include your name or any other data that could identify you. An anonymized code will be used so that your name cannot be identified. Identification numbers (codes) will be used for identification purposes in all data-containing forms.

In order to minimize any inconvenience/discomfort in discussing drug-use practices and OMT services, all interviewers were trained in ethical issues related to data collection before we started the study. They were trained to speak openly and in an unbiased way about drug use and challenges related to accessing OMT and other health-care services.

Benefits

You may not have any direct benefits from your participation in this interview. However, the data collected during this study will hopefully help improve the quality of OMT services in Ukraine.

Signature of the staff member who obtains your consent:

Date:

(please write your name in printed letters and put your signature)

Appendix 5. The Informed Consent Form for the quantitative part of the study

We invite you to take part in a study conducted to examine client satisfaction with provided services among clients of opioid maintenance therapy (OMT) programmes. The study is commissioned by the Eurasian Harm Reduction Association (EHRA) and conducted by the non-governmental organization Centre for Support, Research and Development.

This study has two parts. The first part involves semi-structured interviews, which will be used to develop a tailored questionnaire. The second part uses that questionnaire to conduct a survey among people receiving OMT services.

This study is carried out in Kyiv and the Kyiv Oblast region. You will be asked to complete a questionnaire. This process will take about 30 minutes. There will be a total of about 400 people taking part in the study.

To make an informed decision about whether or not to participate in this study, you need to know the implications. We will explain the possible risks and benefits of your participation. This will help you decide whether you are willing to be a part of the study. You will be provided detailed information about the study, and interviewers will answer all questions that may arise. Then you will be able to make a decision regarding your participation in the study. To confirm your willingness to participate in the study, you will be asked to say it out loud to have it audiotaped. You will be given a copy of this informed consent form counter-signed by your interviewer.

Study data will be entered into electronic/digital forms, which will be automatically uploaded to the general database. All information about study participants will be collected in electronic format only. All collected electronic forms will be kept in the office of the Centre for Support, Research and Development for a minimum of one year upon the completion of the study.

Remuneration

You will receive a gift certificate as compensation for your time. The gift certificate will be given upon the completion of the questionnaire/interview. If the interview is interrupted by either party, the remuneration will be given in full anyway.

Rights of study participants

Your participation in this study does not affect any of your rights. You will be able to ask the research team any questions you might have and receive answers. By signing the consent form, you agree that you have received information about the study and are willing to participate in it. You will be provided a copy of this form countersigned by you and me (the interviewer).

This study has been reviewed by the Ethical Review Board of the Ukrainian Institute on Public Health Policy to make sure that your rights as a research participant are secured. Should you have any questions or concerns about your rights as a survey participant, please (anonymously) contact the Ethical Review Board of the Ukrainian Institute on Public Health Policy at _____ [phone number], or contact the Senior Researcher, Mrs. Olexandra Dmitrieva, by phone: _____ [phone number].

Voluntary participation/right to withdraw from the study

Your participation in this study is completely voluntary. You will be able to discontinue your participation in the study at any stage of the interview. Your informed consent to participate in the study does not affect any of your rights to any of your legal rights. If you decline to participate, all forms that have already been completed will not be used.

Risks

Research of this kind may entail possible risks to your anonymity and confidentiality. Besides that, risk of psychological harm may be associated with participation in research such as this study, which covers sensitive topics of drug use and health-seeking behaviour, including access to OMT and other health services. You will find details below on the steps taken by the research team to maintain your confidentiality and minimize any inconveniences that may be caused by your participation in this study.

Confidentiality

We will take all possible care to ensure that your personal data are protected. The research team will maintain the confidentiality of your personal data and information. Any published reports or other publications using information obtained from this study will not include your name or any other data that could identify you. An anonymized code will be used so that your name cannot be identified. Identification numbers (codes) will be used for identification purposes in all forms that contain data.

In order to minimize any inconvenience or discomfort when discussing drug use practices and OMT services, all interviewers were trained in ethical issues related to data collection before we started the study. They were trained to speak openly and in an unbiased way about drug use and challenges related to accessing OMT and other health-care services.

Benefits

You may not have any direct benefits from your participation in this interview. However, the data collected during this study will hopefully help improve the quality of OMT services in Ukraine.

Signature of the staff member who obtains your consent:

Date:

(please write your name in printed letters and put your signature)

Appendix 6. Questionnaire (WHOQOL-BREF+OMT+SDC)¹

D1. What is your gender?

- Female
- Male
- Other_____

D2. What is your age (completed years)?

D3. How many times have you been a client of OMT programmes, apart from the current one?

W1. How would you rate your quality of life?

- Very poor
- Poor
- Neither poor nor good
- Good
- Very good

O1. How do you assess the OMT service in general?

- Very poor
- Poor
- Neither poor nor good
- Good
- Very good

W2. How satisfied are you with your health?

- Very unsatisfied
- Dissatisfied
- Neither satisfied nor dissatisfied
- Satisfied
- Very satisfied

O2. To what extent are you satisfied with the OMT service you receive?

- Very unsatisfied
- Dissatisfied
- Neither satisfied nor dissatisfied
- Satisfied
- Very satisfied

W3. To what extent do you feel that physical pain prevents you from doing what you need to do?

- Not at all
- A little
- A moderate amount
- Very much
- An extreme amount

O3. To what extent do you need OMT to function in your daily life?

- An extreme amount
- Very much
- A moderate amount
- Not at all

W4. How much do you need any medical treatment (apart from OMT) to function in your daily life?

- Not at all
- A little
- A moderate amount
- Very much
- An extreme amount

W5. How do you enjoy your life?

- Not at all
- A little
- A moderate amount
- Very much
- An extreme amount

W6. To what extent do you feel your life to be meaningful?

- Not at all
- A little
- A moderate amount
- Very much
- An extreme amount

O4. To what extent is the support from on-site personnel important for your continued participation in the OMT programme?

- Very much
- Extremely
- A moderate amount
- Not at all
- A little

O5. How important are the care and attention provided by the OMT site personnel to your continued participation in the OMT programme?

- Very much
- Extremely
- A moderate amount
- Not at all
- A little

W7. How well are you able to concentrate?

- Not at all
- A little
- A moderate amount
- Very much
- Extremely

O6. How sufficient is the information about the OMT treatment provided to you at the OMT site?

- Not at all
- A little
- A moderate amount
- Very much
- Extremely

W8. How safe do you feel in your daily life?

- Not at all
- A little
- A moderate amount
- Very much
- Extremely

O7. How safe do you feel at the OMT site?

- Very much
- Extremely
- A moderate amount
- Not at all
- A little

To what extent do you agree with the following statements about the OMT site you are attending?

O8. Its premises are quite spacious.

- Strongly agree
- Mostly agree
- Neither agree nor disagree
- Mostly disagree
- Strongly disagree

The toilet door at the facility closes well.

- Yes
- No

O10. The facility is clean

- Strongly agree
- Mostly agree
- Neither agree nor disagree?
- Mostly disagree
- Strongly disagree

O11. In the room where I receive my medicines, there is a place where I can have a seat when I talk to a doctor.

- Strongly agree
- Mostly agree
- Neither agree nor disagree
- Mostly agree
- Strongly disagree

O12. How satisfied are you in general with the physical settings of the OMT site (e.g., the size of the facility, and does it have a well-functioning toilet equipped with a door-latch and comfortable waiting areas)?

- Totally unsatisfied
- Unsatisfied
- Neither of these
- Satisfied
- Very satisfied

W9. How healthy is your physical environment (such as buildings, roads and parks)?

- Not at all
- A little
- A moderate amount
- Very much
- Extremely

In the next several questions you will be asked about how you have felt over the past four weeks, or how you have been able to perform certain tasks.

W10. Did you have enough energy for everyday life?

- Not at all
- A little
- Moderately
- Mostly
- Completely

W11. Are you able to accept your bodily appearance?

- Not at all
- A little
- Moderately
- Mostly
- Completely

W12. Do you have enough money to meet your needs?

- Not at all
- A little
- Moderately
- Mostly
- Completely

W13. How available to you is the information that you need in your day-to-day life?

- Not at all
- A little
- Moderately
- Mostly
- Completely

W14. To what extent do you have the opportunities for leisure activities?

- Not at all
- A little
- Moderately
- Mostly
- Completely

O13. Is the OMT medication dosage that you receive sufficient for you?

- Not at all
- A little
- Moderately
- Mostly
- Completely

W15. How well are you able to get around?

- Good
- Very good
- Neither
- Poor
- Very poor

O14. How convenient is it for you to get to the OMT site?

- Very convenient
- Convenient
- Neither
- Inconvenient
- Very inconvenient

O15. How do you assess the quality of care at the OMT site?

- Good
- Very good
- Neither
- Poor
- Very poor

O16. How often have you sought care from a social worker at your OMT site over the past six months?

- There is no social worker at this site
- Never sought care
- Sought care 1–3 times
- Seeking care on a regular basis

O17. How satisfied are you with the social and psychological support that you receive at the OMT site?

- Very dissatisfied
- Dissatisfied
- Neither satisfied nor dissatisfied
- Satisfied
- Very satisfied

W16. How satisfied are you with your sleep?

- Very dissatisfied
- Dissatisfied
- Neither satisfied nor dissatisfied
- Satisfied
- Very satisfied

W17. How satisfied are you with your ability to perform your daily living activities?

- Very dissatisfied
- Dissatisfied
- Neither satisfied nor dissatisfied
- Satisfied
- Very satisfied

W18. How satisfied are you with your capacity for work?

- Very dissatisfied
- Dissatisfied
- Neither satisfied nor dissatisfied
- Satisfied
- Very satisfied

W19. How satisfied are you with yourself?

- Very dissatisfied
- Dissatisfied
- Neither satisfied nor dissatisfied
- Satisfied
- Very satisfied

W20. How satisfied are you with your personal relationships?

- Very dissatisfied
- Dissatisfied
- Neither satisfied nor dissatisfied
- Satisfied
- Very satisfied

W21. How satisfied are you with your sex life?

- Very dissatisfied
- Dissatisfied
- Neither satisfied nor dissatisfied
- Satisfied
- Very satisfied

W22. How satisfied are you with the support you get from your friends?

- Very dissatisfied
- Dissatisfied
- Neither satisfied nor dissatisfied
- Satisfied
- Very satisfied

O18. How satisfied are your relatives/close contacts with your participation in the OMT programme?

- Very dissatisfied
- Dissatisfied
- Neither satisfied nor dissatisfied
- Satisfied
- Very satisfied

O19. How satisfied are you with the quality of your relationships with your relatives/close contacts?

- Very dissatisfied
- Dissatisfied
- Neither satisfied nor dissatisfied
- Satisfied
- Very satisfied

W23. How satisfied are you with the conditions of your living place?

- Very dissatisfied
- Dissatisfied
- Neither satisfied nor dissatisfied
- Satisfied
- Very satisfied

W24. How satisfied are you with your access to health care services?

- Very dissatisfied
- Dissatisfied
- Neither satisfied nor dissatisfied
- Satisfied
- Very satisfied

W25. How satisfied are you with your transport?

- Very dissatisfied
- Dissatisfied
- Neither satisfied nor dissatisfied
- Satisfied
- Very satisfied

O20. On a scale from 1 to 10, where 1 means “feeling distressed/anxious” and 10 means “feeling relaxed/at peace,” what would best describe how you feel on average while **attending the OMT site**?

O21. On a scale from 1 to 10, where 1 means “feeling distressed/anxious” and 10 means “feeling relaxed/at peace,” what would best describe how you feel on average while receiving **OMT medication from the nurse**?

O22. On a scale from 1 to 10, where 1 means “feeling distressed/anxious” and 10 means “feeling relaxed/at peace,” what would most exactly describe how you feel on average **while consulting with the on-site clinician**?

O23. On a scale from 1 to 10, where 1 means “feeling distressed/anxious” and 10 means “feeling relaxed/at peace,” what would best describe how you feel on average while **consulting with the on-site social worker**?

In the next several questions you will be asked how often you have felt or experienced certain conditions over the past four weeks.

W26. How often do you have negative feelings such as a blue mood, despair, anxiety or depression?

- Never
- Seldom
- Quite often
- Very often
- Always

O24. How likely is it that you would seek the advice of a psychologist at the OMT site if you had this opportunity?

- Very unlikely
- Unlikely
- 50/50
- Likely
- Very likely

O25. Have you ever complained about customer service at the OMT site in a formal way (such as calling the OMT hotline or filing a letter of complaint)?

- Yes
- No

O26. How likely is it that you would file a complaint in the future (if necessary)?

- Very unlikely
- Unlikely
- 50/50
- Likely
- Very likely

O27. Were you informed about the programme rules when you initiated your programme (the most recent one)?

- Yes (1)
- No/I don't know (0)
- Refuse to answer (98)

O28. If you have participated in OMT programmes more than once, has it ever been your choice to discontinue any of these programmes?

- Yes (1)
- No/I don't know (0)
- Refuse to answer (98)

O29. If you have initiated OMT programmes more than once, have any of these programmes been discontinued at the request of on-site personnel?

- Yes (1)
- No/I don't know (0)
- Refuse to answer (98)

O30. Are you satisfied with the duration of treatment in the OMT programme?

- Yes
- No

O30.1. If not satisfied, would you prefer to extend the treatment period or to make it shorter?

- Shorter treatment period
- Extended treatment period

O31. Are you aware of the algorithm for withdrawal from the OMT programme?

- Yes (1)
- No (0)

O32. If you have already tried to withdraw from an OMT programme, did you experience counteraction from health-care personnel who opposed your decision?

- Yes (1)
- No (0)
- Refuse to answer (98)

O33. Do you feel confident about the safety (non-disclosure) of personal data that you have shared or provided to personnel at the OMT site?

- Absolutely not confident
- Not confident
- Neither of these
- Confident
- Highly confident

D4. How old were you when you first used opiates/opioids (non-injecting or injecting)?

D5. When did you have most recently initiate an OMT programme?

_____ Year
_____ Month

D 5.1. If you initiated an OMT programme in early 2018 or later, how many months or days did this process take, from the start date at the site to the dosage selection (including waiting times while on the waiting list, medical tests/examinations and consultations of clinicians)?

_____ months (1)
_____ days (2)

D6. The type of programme you are currently attending:

- State-funded site
- Private site

D6.1. If you receive OMT from a state-funded site, please indicate the type of this site:

- Narcologic
- AIDS Centre
- Tuberculosis dispensary
- Family physician
- Other

D6.2. How much does it cost you to participate in the OMT programme, per month (including the purchase of tests, plastic cups and so on, but excluding travel expenses) (in UAH)?

D7. How is OMT dispensed at the treatment facility?

- Medication administered daily
- Received once for every 10 days
- Receive a prescription (to be filled elsewhere)

D8. OMT medication received:

- methadone
- buprenorphine

D8.1. Dosage at the moment (mg):

D9. Do you take any additional medicines as prescribed by your doctor (drug addiction specialist/psychiatrist)?

- Yes (1)
- No (0)
- Refuse to answer (98)

D9.1. If yes, please specify (check all applicable):

- Antidepressants
- Sleeping pills/sleep aids
- Painkillers
- Tranquilizers
- Other

D10. Have you ever been tested for HIV?

- Yes (1)
- No/I don't know (0)
- Refuse to answer (98)

D11. What was the test result?

- I was told I didn't have HIV (0)
- I was told I had HIV (1)
- I was told the test result was uncertain (2)
- I don't know (3)
- Refuse to answer (98)

D12. In what year did you first learn that you had HIV?

D13. Are you currently on antiretroviral therapy?

- Yes (1)
- No (0)
- Refuse to answer (98)

D14. What is your viral load?

_____copies/ml

- I don't know

D15. Have you ever been tested for hepatitis C?

- Yes (1)
- No/I don't know (0)
- Refuse to answer (98)

D16. What was your test result?

- I was told I didn't have hepatitis C (0)
- I was told I had hepatitis C (1)
- I was told the test result was uncertain (2)
- I don't know (3)
- Refuse to answer (98)

D17. Have you ever taken medication for hepatitis C?

- Yes, I'm currently on therapy
- Yes, I have been on therapy within the past three years
- Yes, I was on therapy more than three years ago
- No, I've never taken medicine to treat hepatitis C (0)
- I don't know (2)
- Refuse to answer (98)

D18. Which of the following are you currently experiencing (please select all that apply)

- Hepatitis B
- Tuberculosis
- Pancreatitis
- Stomach/intestinal ulcer
- Tooth diseases/dental problems
- Vein problems
- Severe headaches
- Diabetes

D19. What is your current employment situation? (Please select all that apply)

- Full-time work (40 hours per week or more) (1)
- Part-time work (2)
- Seasonal work (including day laborers, those on waiting lists, etc.) (3)
- Unemployed (4)
- Unable to work (disabled) (5)
- Housewife/housekeeper (caring for children or other family members) (6)
- Student (7)
- Retired (8)
- Other (9)
- Refuse to answer (98)

D20. Do you receive any disability pension allowances?

- Yes (1)
- No (0)

D21. Do you have a record of incarceration (including pre-trial detention facilities)?

- Yes (1)
- No (2)

How old were you when you first went to jail (including pre-trial detention facilities)?

_____ years (1)

D23. How many times (approximately) have you been in jail (including pre-trial detention facilities)?

_____ Number of times (1)

D24. How many years, months and days in total have you served in prison (including pre-trial detention facilities)?

_____ years (1)

_____ months (2)

_____ days (3)

When was the last time you were released from prison?

_____ Year

_____ Month

D26. How many days within this past month have you used any injecting drugs?

_____ days (no more than 30)

D27. Do you take any additional medicines not prescribed by your doctor?

D28. If yes, please specify (check all that apply):

- Antidepressants
- Sleeping pills/sleep aids
- Painkillers
- Tranquilizers
- Other



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