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eurasian harm reduction association

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SURVEY OF CLIENT SATISFACTION WITH OPIOID SUBSTITUTION PROGRAM IN WESTERN GEORGIA

CONTRIBUTIONS

This report is a publication of joint work between the Eurasian Harm Reduction Association (EHRA), Ilia State University Institute on Addiction Studies, community based organization Rubiconi and Foundation Global Initiative on Psychiatry – Tbilisi (GIP-Tbilisi).

Ilia State University Institute of Addiction Studies was founded in 2013. The mission of the institute is to strengthen the Georgia's capacity to respond to addiction related problems based on contemporary evidence-based approaches. To fulfill this mission the institute implements different local and international research projects and participates in capacity building activities, monitoring of drug situation as well as elaboration of drug demand reduction strategies in the country: https://iliauni.edu.ge/en/iliauni/institutebi-451/adiqtologiis-instituti; https://iliauni.edu.ge/en/

The community based organization Rubiconi's mission is to support right for health and basic/constitutional rights of people with drug use dependency. Rubiconi is a member of the Georgian Harm Reduction Network (GHRN), Eurasian Harm education Association (EHRA), Georgian Network of People who Use Drugs for Humane Drug Policy and Eurasian Network of People who Use Drugs.

The Foundation Global Initiative on Psychiatry – Tbilisi is Georgian-based non-for-profit organization that assists professional communities, NGOs, international agencies, governments, universities and other development institutions in the Caucasus, Central Asia, Ukraine and other countries to improve rights-based mental health care. GIP-Tbilisi is a member of the GIP Federation: https://www.gip-global.org/

EHRA is a nonprofit public membership-based organization uniting and supporting 322[1] harm reduction activists and organizations from Central and Eastern Europe and Central Asia (CEECA) to ensure the rights and freedoms, health, and well-being of people who use psychoactive substances. More information is available on the website: https://harmreductioneurasia.org/

1 As of May, 2021.

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The views and opinions of the authors presented in this report may not represent the views and opinions of the Robert Carr Fund for civil society networks.

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TABLE OF CONTENTS

ACRONYMS

AIDS – Acquired Immunodeficiency Syndrome

ART – Antiretroviral Therapy

EHRA – Eurasian Harm Reduction Association

ENPUD – Eurasian Network of People Who Use Drugs

GDPR – General Data Protection Regulation

GENPUD – Georgian People Who Use Drugs for Humane Drug Policy

GHRN – Georgian Harm Reduction Network

HIV – Human Immunodeficiency Virus

ICD10 – International Classification of Diseases

IT – Information Technologies

PWID – People Who Inject Drug

LEPL – Legal Entity of Public Law

NIDA – National Institute on Drug Abuse

OST – Opioid Substitution Therapy

PR – Public Relations

SAMHSA – Substance Abuse and Mental Health Services Administration

SPSS – Statistical Package for Social Sciences

UNAIDS – United Nations programme on HIV/AIDS

UNODC – United Nations Office on Drugs and Crime

WHO – World Health Organization

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RESEARCH SUMMARY

The research is implemented on the basis of a participatory approach/community-based research and is a product of a collaboration between an academic research team and a community organization of people who use drugs (PWUDs). The aim of the research was to study satisfaction with the services of the opioid substitution therapy (OST) programs in western Georgia among the beneficiaries of the program, their quality of life and factors related to the level of satisfaction and the quality of life.

A mixed methodology is used in the study; the design is sequential and includes both qualitative and quantitative components. The qualitative component included semi-structured interviews with the OST program beneficiaries of Western Georgia, while the quantitative component included cross-sectional research with the representative sample of Western Georgia OST program beneficiaries.

The results of the study revealed the following:

- More than two-thirds of the respondents (73.2%) are satisfied with the OST programs; More than half of the respondents reported that it is convenient to visit the OST site (60.7%), the OST site has good medical quality (53.8%) and the information received from the site staff is sufficient (66.5%).

- While more than two-thirds of the respondents are satisfied with the OST programs, only about one-third of the respondents are satisfied with their quality of life and health (32.4% and 35.1% respectively). Such a discrepancy between the program satisfaction and the quality of life indicates the desirability of setting respondents' quality of life as one of the key indicators of treatment effectiveness.

- About three-quarters of the study participants (75.6%) had never sought help from a psychologist on the site in the last 6 months, while a high percentage of participants reported symptoms of depression and anxiety during the last two weeks (e.g., 64.7% of the entire sample felt anxious, while 68.7% was in low mood). Only 1.5% of the respondents have been receiving regular psychologist services for the last 6 months. 8% of the respondents indicated that they were not aware of the possibility of receiving the services of a psychologist and social worker on the site. At the same time, the mental health problems of the respondents are statistically significantly related to the lower level of satisfaction with the OST program. This situation indicates the need to pay more attention to the mental health problems of the beneficiaries, the need for the screening/monitoring of these problems, the need to proactively offer psychological services and the need to ensure the quality of psychological services.

- Significant differences were identified between private and public program beneficiaries in terms of socioeconomic status (income, employment), satisfaction with the quality of life, and mental health problems. The beneficiaries of the private programs are in a better position in this regard (higher income and employment rate, higher quality of life, and less mental health symptoms) than beneficiaries of the public programs. For example, slightly more than half of the beneficiaries of the public program reported that their income was less than 300 GEL (approx. 74 EUR), while the beneficiaries of the private program accounted for 17% of those with such income. Beneficiaries of the public programs are likely to be among the most vulnerable and were already more vulnerable before joining the program. At the same time, in the last 6 months, the services of a social worker have been systematically used by only 3.6% of the entire sample. 62.2% of the beneficiaries have never used the services of a social worker. 37% of the respondents are dissatisfied with the psychosocial services of the programs. This situation indicates the need to strengthen the psychosocial component in programs in general, and in the public programs in particular, the need to strengthen the professional capacity and professional role of a social worker, the need for psychosocial habilitation and rehabilitation, and especially the need to initiate employment programs with the help of the inter-agency cooperation.

- 90.5% of the respondents stated that the daily dose of the substitution drug was enough for them. At the same time, 39% of study participants reported an episode of illegal drug use in the last 30 days. Among the public program participants, this percentage was statistically significantly higher than among the private program beneficiaries. This may indicate the need for more communication between the treating physician and the beneficiary about the dosage of the drug and the expectations about the right dosage; It may also indicate the need for proactive propositions of evidence-based modules of psychological (enhancement of motivation-oriented) therapy for the beneficiaries, and the need for the relevant professional training of program psychologists.

- Less than half of the respondents (44.6%) feel safe on the OST program sites, which is related to the assurance of data protection and confidentiality. Only a little over a third of the respondents (235 people) are assured of confidentiality. This indicates the need for explicit communication with program beneficiaries on issues related to confidentiality and personal data protection by the program staff.

- 85% of the sample was tested for HIV and hepatitis C, of which only 6 respondents were HIV positive and only 1 was not on antiretroviral therapy (ART). The prevalence of hepatitis C in the tested respondents was 59.8%, 17% of whom were never treated, and 3.9% were undergoing treatment for hepatitis C during the period when research was being conducted. The majority of respondents (94.2%) indicated that they needed the OST services, while only slightly more than a third (33%) stated that they needed other medical services as well. The study found that viral diseases were statistically significantly associated with low levels of satisfaction with respondents' quality of life. This situation indicates the need to more proactively propose appropriate treatment to the tested respondents, which will contribute to improving their quality of life.

- One-third of the respondents stated that they had been in a detention facility, including temporary detention, for which the median number of months spent in the detention facility was 36 months. This situation is an indicator of a punishment-oriented drug policy and speaks about the need for the reformation in drug policy.

- According to the respondents of the quantitative component of the research, less proportion of the beneficiaries involved in the public programs were introduced to the program rules when enrolling (72.6% and 85.8%), and less percentage knew the rules of leaving the program than in the private programs (76.4% and 91.1%). In the qualitative component of the study, respondents talked about the fact that when a drug dependent person is involved in a program, he or she is not in the right state to perceive, understand, and remember the rules that are shared with him or her. This situation indicates that it is desirable to communicate the rules of the program not once, but on a regular basis, especially after respondent feels better in the face of the OST treatment and he / she will be able to fully comprehend the content of the conversation.

- The qualitative component of the research revealed that myths (misinformation) about a number of aspects of the programs (e.g., age of involvement, criteria, etc.) are common among the beneficiaries of the OST programs. Some of the myths have been heard by the program beneficiaries from the general public, which indicates the need to properly inform not only the clients of the program but also the general population about the OST. For this reason, it is necessary to plan the communication strategy both inside and outside the programs - in the format of public relations.

1. INTRODUCTION

1. 1. The Relevance of the Opioid Substitution Therapy (OST) Satisfaction Research

Opioid substitution therapy (OST) is a recognized approach to treating opioid dependent people and managing the problems associated with this condition. Evidence suggests that it significantly improves the quality of life of the program beneficiaries and their loved ones. It reduces the spread of blood-borne infections, the use of illegal opioids, conflicts with the law, health-damaging and risky behaviors related to HIV transmission, overdoses and etc. (NIDA, 2018). The OST programs are supported by the World Health Organization, the United Nations Joint Program on HIV/AIDS, and the United Nations Office on Drugs and Crime (WHO, UNODC and UNAIDS, 2012).

Today, the OST programs are widely implemented in different regions and countries of the world. Based on this experience, both international and national guidelines and protocols have been developed to help meet quality standards. A number of such documents focus on clinical issues (dosing, admission criteria, treatment of groups with special needs, etc.), e.g., the guide of the World Health Organization (WHO, 2009). In addition, documents have been developed and continue to be developed that focus on more practical issues - such as how to implement and develop a program, based on the local context, i.e. the local socio-economic and cultural specifics of a country or a region (WHO, 2014).

Researching the OST programs are critical to developing manual documents and practical recommendations described above for a particular region or a country. This includes, on the one hand, the study of the program effectiveness and the effectiveness determinants; On the other hand, the study of the service satisfaction and the satisfaction determinants by the beneficiaries of the OST programs.

OST programs have been operating in Georgia since 2005. Significant progress has been made since then: the geographical coverage of the program is increasing from year to year, the institutional mechanisms for their implementation are being developed and diversified, the number of beneficiaries are increasing, and so on. Researches have been carried out in the country to study the effectiveness of the programs at different stages of their development (Todadze and Mosia, 2016; Todadze and Kavtiashvili, 2012; Todadze and Lezhava, 2008; Chirikashvili, 2007). A guideline on how to implement the OST programs has been translated into Georgian and was certified by the World Health Organization (WHO); appropriate protocols were developed. All this sets the clinical standards for the implementation of the OST programs in the country and forms the basis for their realization. At the same time, there is still a need for the practical recommendations that will increase the capacity to satisfy the needs of the beneficiaries in different regions of the country, taking into account the local context. It is impossible to develop such recommendations without researching the satisfaction and the factors affecting the satisfaction of the OST program beneficiaries.

Hence, the research presented in this report studies the satisfaction of the beneficiaries of opioid substitution therapy programs in one of the regions of Georgia – Western Georgia. Its results serve to develop practical recommendations that will help decision-makers and service providers to refine their services - taking into account the local socio-economic and cultural context and maximizing tailoring of the services to the needs of the beneficiaries. By the means of this study we attempt to explain what are the issues with the program, which parts need improvement, and how this research might help solve/explain these issues. Therefore, the research is highly relevant and needed.

1.2. A Community-Based Approach to the Research

The present study is founded on a community-based approach to the research in the field of public health.

The community-based approach to the research is participatory, involves a combination of action and research, ensures close collaboration/partnership of the stakeholders (academics, community representatives,

community organizations, etc.) at all stages of the research, and aims to identify-comprehend and overcome inequalities in the social and physical environment.

Such a participatory approach to research emerged on the basis of gathering solid evidence on the socio-economic and political determinants of health, such as: poverty, structural injustice, scarcity of employment opportunities, generally limited access to resources necessary for health, and so on.

The effectiveness of a community-based approach to research is determined by the following: it reduces the gap between the theory and the practice; It provides greater sensitivity to the needs of various marginalized groups; It provides higher competence towards different cultural environments or subcultures; It pays more attention and focuses more on the quality of life; It allows consideration of social, economic and political factors/determinants of health (Israel et al., 1998; IA & FDHR, 2003; Javakhishvili & Sarjveladze, 2007).

The present study is precisely the implementation of a community-based research approach in life. It was carried out by a consortium united on a partnership and participation basis of the stakeholders working in the field of biopsychosocial health and welfare of drug users. The following is a description of the stakeholders in the consortium and their roles in this study:

- A team of academic researchers from *Ilia State University* (Iliauni) *Institute of Addiction Studies* and non-governmental foundation *Global Initiative on Psychiatry – Tbilisi* (GIP-Tbilisi) where managing the research methodology throughout the complete cycle of the research project;
- The team of the community organization *Rubiconi*, which brings together representatives of the community of drug users, and those who provided the fieldwork for the research (recruiting participants in both qualitative and quantitative components of the research and conducting quantitative research interviews);
- Non-governmental Foundation *Global Initiative on Psychiatry – Tbilisi*, which works at the crossroads of mental health and human rights in Georgia and around the world (Belarus, Ukraine, Sri Lanka, Kyrgyzstan, etc.), and which carried out the organizational management of the research project;
- *Eurasian Harm Reduction Association*, which brings together 371 organizations and individual members from the regions of Central and Eastern Europe and Central Asia and works to create opportunities for the sustainable implementation of harm reduction programs and for the improvement of the well-being of drug users in these regions.
- In the process of the research, there was also a close cooperation in terms of information sharing and consulting, with a wider range of stakeholders – relevant public – non-governmental and community organizations (e.g. the *Georgian Harm Reduction Network*, which brings together organizations focused on the implementation of the projects about the rights and biopsychosocial welfare of the drug users in the country) and, with relevant government agencies;
- Partnerships at the international level were also extremely important for the project team: in particular, the project included cooperation with the Ukrainian counterparts – with a similar community-based research project team implemented in Ukraine in 2019, with the support of the *Eurasian Harm Reduction Association*. This cooperation gave us the opportunity to learn from the experiences of our Ukrainian colleagues. In addition, our Ukrainian colleagues allowed us to share their research methodology, as well as a virtual data collection platform – *RedCap*, which significantly facilitated the implementation of our research.

Research was conducted directly by the academic team of *the Ilia State University* (Iliauni) *Institute of Addiction Studies* and NGO *Global Initiative on Psychiatry – Tbilisi* on the one hand, and the team of the CBO *Rubiconi* on the other hand, in close partnership. There was a coordination between the teams, regular exchange/circulation of information, mutual consultations on the implementation of various components of the research.

During the implementation of the research project, knowledge/competencies/skills were shared between these two teams. In particular, the *Iliauni* and *GIP-Tbilisi* Academic Team provided training and supervision to community representatives in conducting quantitative interviews; Representatives of the CBO *Rubiconi*

provided feedback to the academic team on the stages of research design, development of qualitative and quantitative questionnaires, interpretation of the results, and preparation of recommendations. Based on this, both teams gained significant knowledge and experience.

2. OPIOID SUBSTITUTION THERAPY PROGRAM IN GEORGIA – OVERVIEW

During the 1990s, the Soviet-era legacy was inertly preserved in Georgia in many different areas, including drug treatment and drug policy, which mainly focused on law enforcement (Gamkrelidze et al., 2003). Punishment-oriented approaches are still widely used (Beselia et al., 2018). The first law on drug addiction was adopted by the Parliament of Georgia in 2002; *The Law on Narcotic Drugs, Psychotropic Substances, Precursors, and Narcological Aid* defined the lists of prohibited substances and other law enforcement matters, as well as main principles related to the treatment (Parliament of Georgia, 2012); The main provisions are defined as follows:

- The law complies with the requirements of UN conventions;
- Provides special control over substances defined by law;
- Defines the competence of the state for the activities related to the legal circulation of narcotic drugs and psychotropic substances and provides the licensing of the legal circulation of substances subject to special control;
- Determines the priority of preventive measures against violations related to the circulation of controlled substances, which is defined in the law as "Stimulation of anti-drug propaganda".

In the same law, Article 38 of the Narcological Aid, the general principles were as follows: the costs of diagnosis and treatment are covered by the state within the framework of a public program approved by the budget; The method and standards of the treatment are determined by the Ministry of Health and the rule of defining an administrative offense is governed by a joint order of the Minister of Internal Affairs of Georgia and the Minister of Health; The above mentioned law also defined the rules for the use of the substitute medication and substitution treatment. For detailed information see: https://matsne.gov.ge/ka/document/view/14266?publication=13.

The version of the same law adopted in 2012 is in force in Georgia during the preparation of this report. The main principles of the law are practically unchanged (fulfillment of the requirements of international agreements, promotion of state control over the circulation of controlled substances and state control over the activities related to the legal circulation; Definition of measures against offenses and provision of access to psychoactive substances for medical purposes). However, many changes have also been made in various articles over the years; the latter one is relevant for this research, and permits beneficiaries to bring home the substitute medication during the COVID-19 pandemic[3]. Detailed information can be found on the website of the Legislative Herald of Georgia: https://matsne.gov.ge/ka/document/view/1670322?publication=17. Hereby, one can also see the changes in the law over the years, by dates.

Although the legal basis for the implementation of the substitution therapy already existed in 2002, appropriate funds for the implementation of the program was not allocated at that time. In fact, this method of treatment became available to the beneficiaries in late 2005 with the support of *the Global Fund to Fight AIDS, Malaria and Tuberculosis* (Gamkrelidze et al., 2003).

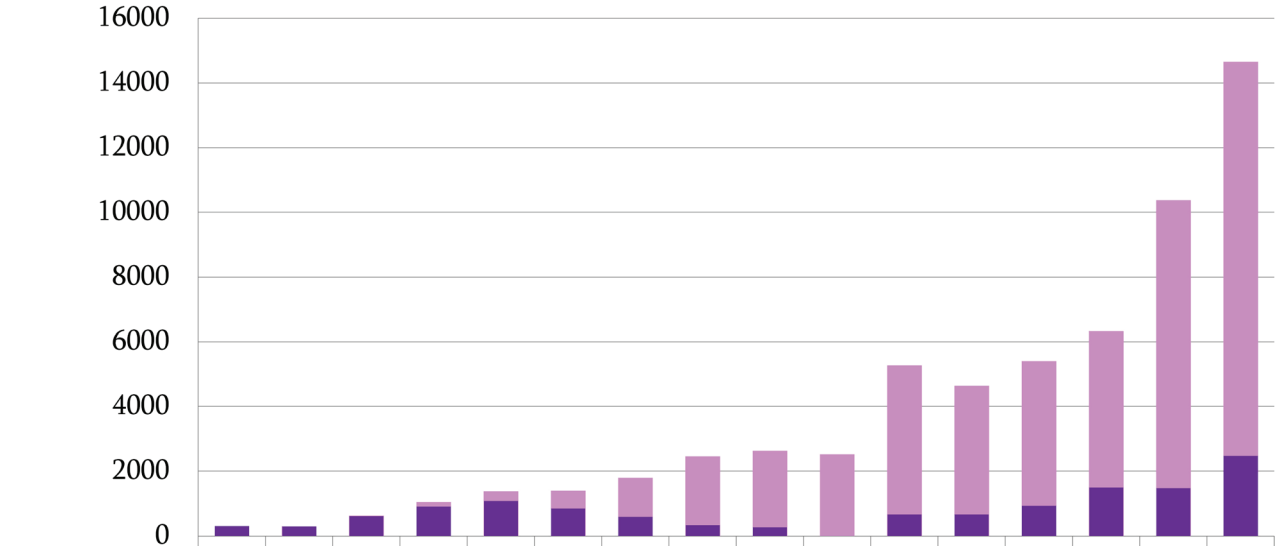
At the time of report writing, the supply of substitution therapy in Georgia is regulated by the Order N01-41/n of the Minister of Labor, Health and Social Affairs of Georgia on the treatment with a special drug substitution program, which defines the treatment method and exclusion criteria, as well as its types and permitted pharmaceutical products (short-term and long-term detoxification, short-term substitution treatment for up to 6 months, long-term substitution maintenance treatment for more than 6 months, and

3 From spring 2020, during the COVID-19 epidemic, the amount of medication to be taken is determined at a maximum dose of 5 days (Order 01-41/n).

inpatient treatment using a substitute pharmaceutical product). According to the order, substitution therapy is intended to improve the somatic and mental condition of people with opioid addiction, to promote their social adaptation and reintegration into society; To contribute to the prevention of the spread of blood-borne diseases; Achieve remission in patients through substitution therapy and medical-social rehabilitation; Facilitate the cessation and reduction of injecting drug use by people with opioid addiction, as well as the cessation / reduction of illicit substance use and the improvement of their psychosomatic status, and reduce the risk of public harm to those involved in the program. For detailed information, visit the link: https://www.matsne.gov.ge/ka/document/view/2374811?publication=0.

Opioid substitution therapy has been in development for 15 years since 2005; During this period, the number of patients involved and the geographical access to treatment and the resources allocated from the state budget were constantly increasing from year to year. The figure below illustrates increase in numbers of clients engaged in OST by years (see Figure 1).

Figure 1 Number of patients[4] covered by OST by years (Beselia et al, 2018)



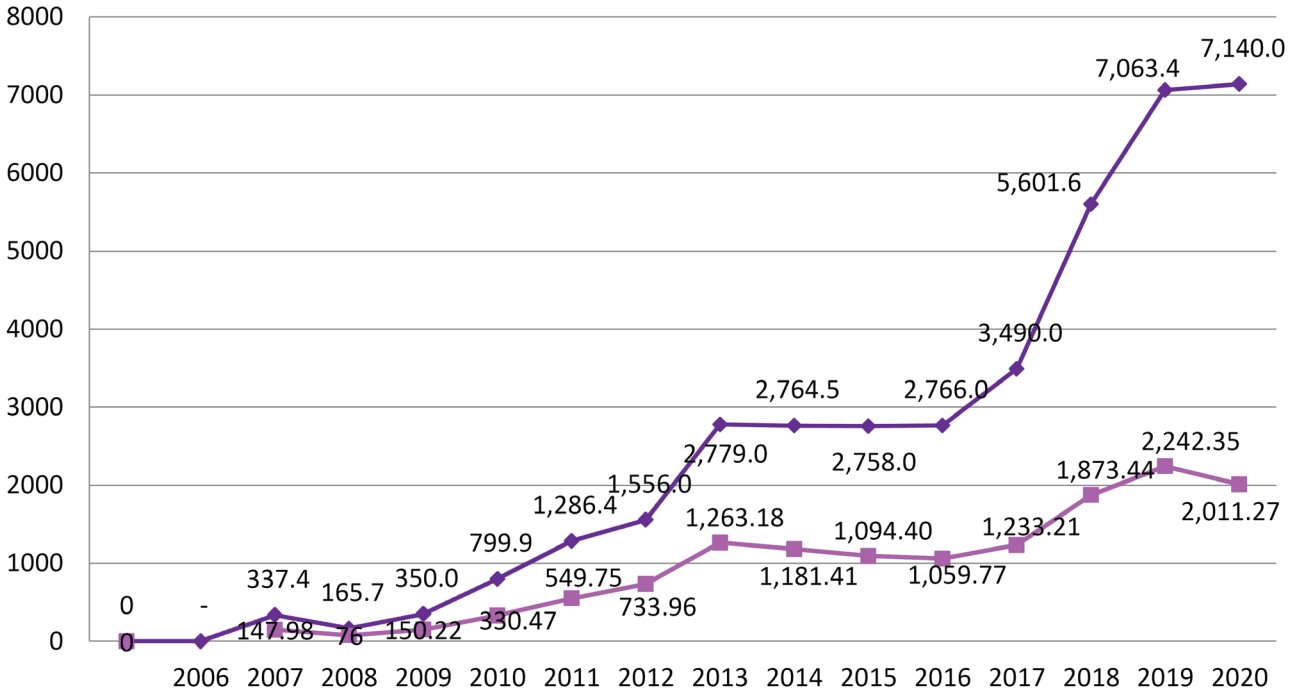
	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018
OST	0	0	8	130	285	552	1,200	2,118	2,352	2,523	4,613	3,968	4,459	4,827	8,897	12,179
Detox treatment	306	300	609	911	1,082	841	584	338	270		656	663	933	1,498	1,473	2472

From July 1, 2017, methadone substitution therapy is being funded from the state budget and services are free for the beneficiaries. There are no waiting lists and demand for OST is fully satisfied in the country. The procedure of inclusion is simple and takes not more than one day. Budget funding trend for the program is also increasing[5]: according to the 2019 plan, 12,150.0 thousand GEL (3,857 thousand EUR) has been allocated from the budget for the State program for the treatment of patients with drug addiction by 2020, out of which 7,140.0 thousand GEL (2,266.67 thousand EUR) has been allocated for the substitution treatment (Government of Georgia, 2019).

4 Numbers presented in Figure 1 include both state and private clinic data; for 2019, we were unable to receive joint numbers. 2019 data from state clinics is presented in chapter 3.1.

5 While considering State budget increase, inflation of Georgian Lari should be taken into consideration: in the period from 2006 to 2020 the Georgian currency gradually inflated: i.e. in 2007 the official average exchange rate was: 1 GEL = 2.28 EUR, while in 2020 it was: 1 GEL = 3.55 EUR

Figure 2: State Funds Allocated for OST Programs[6], 2006-2020 in thousand GEL (dark blue) and EUR (light blue)



By the end of 2020, in Georgia beneficiaries can engage in substitution therapy in methadone and suboxone programs (Suboxone®, combined drug buprenorphine, naloxone; this program has been operating since 2012). The methadone program is implemented by the government agencies; As for the suboxone program, there are two public divisions – one in Tbilisi and another one in Kutaisi, the rest is private. Public program expenses currently[7] are fully covered by the budget allocated for the program; Private program clients pay for the treatment themselves. The cost of treatment in a private program is determined by the amount of medication received. In addition to substitute medication, both public and private clinics are supposed to offer their beneficiaries a variety of health care services (health monitoring, various tests and examinations; also, the services of a psychologist and social worker).

To be included in the program, a person must meet the criteria for an active dependence syndrome on opioid substances (diagnosed using the International Classification of Diseases, ICD10); Also, at least one of the following:

- Age 21 years and above
- Injectable use of opioids
- Diagnosis of HIV or AIDS
- Pregnancy

Migrants and foreign nationals who were involved in a substitution program abroad at the time of departure also have the opportunity to participate in the program. The law also allows exceptions to the listed criteria in the case of special medical and/or social testimony.

As for 2020, in the different regions of Georgia there are 22 state-owned opioid substitution therapy programs in different regions of Georgia; 9 of them are in Tbilisi and there is one program in each of the following cities:

6 Amounts are calculated based on yearly average official exchange rates, retrieved from https://www.geostat.ge/en/modules/categories/92/monetary-statistics

7 Before July 1, 2017, the public program was partially funded from the State budget. Namely, the expenses of the substitute drug were covered by the State while the services were paid out of patients' pocket; since July 1, 2017 methadone substitution therapy is being fully funded from the state budget and services are free for the beneficiaries.

Batumi, Borjomi, Gori, Kobuleti, Kutaisi, Ozurgeti, Poti, Sachkhere, Telavi, Zestaponi and Zugdidi. There is one program in each of the following two penitentiary institutions of Georgia (out of 15 institutions, including treatment, rehabilitation, women and adolescent facilities): Tbilisi N8 and Kutaisi N2 facilities (LEPL National Agency for Health, 2020).

By the end of 2020, the long-term substitution therapy does not work in the penitentiary system; Short-term detoxification is available in the two mentioned above penitentiary institutions, which implies a maximum of 5 months of detoxification treatment (Beselia et al., 2019, in Georgian). Individuals who were undergoing treatment in the penitentiary system at the time of release may still be involved in long-term treatment in the civil sector.

As for private substitution programs, under the auspices of the Georgian Medical Corporation for Addiction operate 10 organizations which implement Subuxone substitution programs: 4 of them are in Tbilisi and there is one organization in each of the following cities: Batumi, Gori, Kobuleti, Kvareli, Kutaisi and Senaki (Sikharulidze, 2020).

3. CHARACTERISTICS OF INDIVIDUALS INVOLVED IN THE OPIOID SUBSTITUTION THERAPY (OST) IN GEORGIA

The information presented in this chapter was provided by *The National Drug Observatory* which, in turn, received the described below data from the *Center for Mental health and Prevention of Addiction*, the main provider of the public substitution therapy programs in the country.

3.1. Information on the Beneficiaries Involved in OST

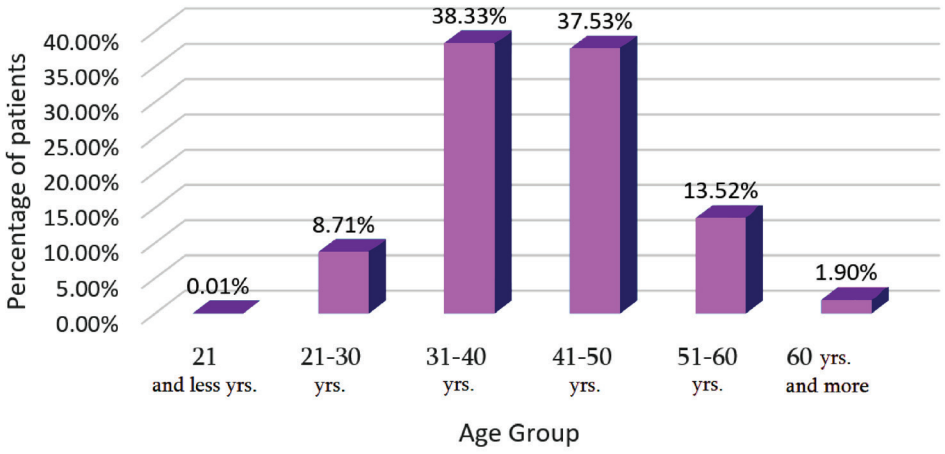
In 2019, 12,926 beneficiaries were enrolled in public substitution therapy programs, of whom, 12,656 were included in the Methadone substitution therapy program and 270 persons – in Suboxone substitution therapy (Table 1).

Table 1: Patients involved in OST public programs operating in Georgia in 2019 (National Drug Observatory; Center for Mental Health and Prevention of Addiction, 2020)

Substitute drug	Number of patients	Female	Male
Methadone	12,656	78	12,578
Buprenorphine	270	0	270
Total	12,926	78	12,848

Most of the beneficiaries of methadone substitution therapy were in the age group of 31-40 years (5,983 patients, 38.33% of the total). The age percentage distribution of the total number of patients can be seen in the chart below (Figure 3). Prior to enrollment in methadone substitution therapy, the leading drugs were predominantly opioid drugs, and concomitant use of various substances (so-called polydrug addiction) were often detected.

Figure 3: Age distribution of patients in Methadone substitution therapy program in Georgia in 2019 (National Drug Observatory; Center for Mental Health and Prevention of Addiction, 2020)

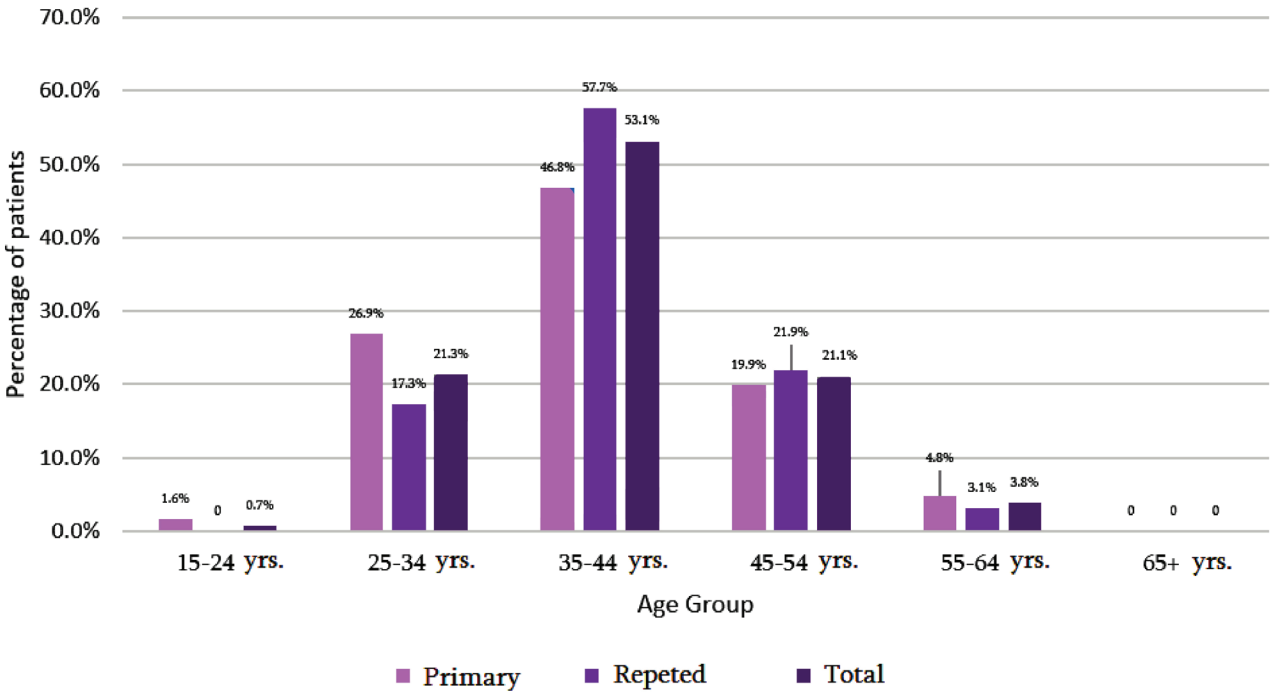


The average daily dose of methadone given to per client was 42 mg and the maximum was 400 mg.

As for the public Suboxone substitution therapy program, most of the 270 beneficiaries were in the age range from 35 to 44 (60%) and prior to enrollment in the program they used opioid drugs, predominantly Buprenorphine.

As for the medical institutions implementing commercial programs of Suboxone substitution therapy, for this report, we had access only to the information provided by the medical facility "Addiction Center" of the Ministry of Internally Displaced Persons from the Occupied Territories, Labor, Health and Social Affairs of Georgia. According to the data of *Addiction Center*, in 2019 they surveyed 446 beneficiaries (445 women and 1 man). The majority of the patients (53.1%) were in the 35-44 age group (Figure 4). Prior to enrollment in the program, the used opioid drugs (predominantly buprenorphine). The average daily dose of Suboxone per client was 9 mg, with a maximum of 18 mg (National Drug Observatory; Center for Mental Health and Prevention of Addiction, 2020).

Figure 4: Age distribution of the patients receiving treatment at "Addiction Center" in 2019 (Suboxone Substitution Therapy) (National Drug Observatory; Center for Mental Health and Prevention of Addiction, 2020)



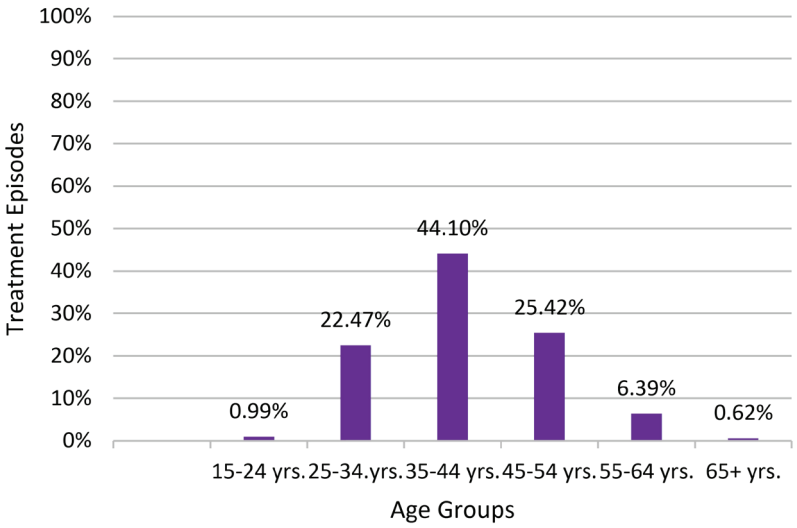
3.2 Information by Treatment Episodes[8]

The data provided by the *National Drug Observatory* reflects treatment episodes in OST programs. It combines data from both public and private OST programs[9]. According to these data, in 2019, overall 10,938 treatment episodes were reported in OST therapy in the country. Of these, 7,369 treatment episodes took place in methadone substitution therapy programs − MST (men were enrolled in 7,328 treatment episodes, women – in 41). The most of treatment episodes in MTS were observed among 35-44 age group (3,250 episodes, 44.10% of total); the least treatment episodes were observed in the age group of 65 and older (46 episodes, 0.62%, see Figure 5).

8 Under treatment episodes it is meant episodes of receiving treatment in the OST programs without taking into consideration whether that was the same person or not who received treatment earlier this year (one person can undergo more than one treatment episodes during the same year).

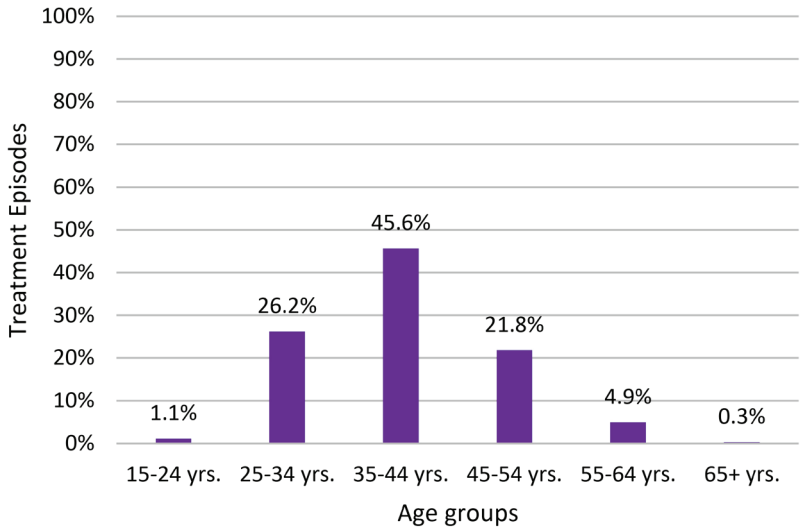
9 The reported statistics of the private (Suboxone substitution therapy) programs do not include the data from only one institution.

Figure 5: Age distribution of patients in methadone substitution therapy program in Georgia by treatment episodes in 2019 (National Drug Observatory; Center for Mental Health and Prevention of Addiction, 2020)



As for the total data of public and private Suboxone substitution therapy programs, 3,569 treatment episodes were observed in 2019. The most episodes were observed among the 35-44 age group (1,629 episodes, 45.6% of the total amount). The least treatment episodes were observed in individuals of 65 and older (11 episodes, 0.3%, see Figure 6) (National Drug Observatory; Center for Mental Health and Prevention of Addiction, 2020).

Figure 6: Age distribution of patients in Suboxone substitution therapy program in Georgia by treatment episodes in 2019 (National Drug Observatory; Center for Mental Health and Prevention of Addiction, 2020)



4. DIFFERENT STUDIES FOCUSED AT THE EFFECTIVENESS OF THE OPIOID SUBSTITUTION THERAPY IN GEORGIA

There are not many studies done in Georgia that examine the physical, psychological, social needs / conditions of the beneficiaries involved in the OST programs, and the impact of program involvement on changing their states. At the same time, there are a number of studies where the problem of people who inject drugs (PWID), including the OST program beneficiaries, are researched, which we will review below.

The Georgian Harm Reduction Network annually examines the users feedback on harm reduction services in order to develop services tailored to the needs of the PWID population. In particular, regular research is conducted on harm reduction service users' satisfaction (mainly, with the Needles and Syringe exchange, and Voluntary Testing and Counselling programs), as well as on the dynamics of their risky behaviors, current states and needs. This also includes information about the PWID participating in the OST programs. For example, in 2019, the *Harm Reduction Network of Georgia* conducted a quantitative cross-sectional research to assess the level of knowledge about the high-risk behaviours associated with injecting drug use, including sexual practices, HIV/AIDS and hepatitis C among beneficiaries of the Needle and Syringe Program (NSP). The study was conducted with the beneficiaries of 11 inpatient harm reduction service centers (minimum term of service use − last 6 months) and included 987 respondents. The data were collected through face-to-face interviews with the beneficiaries. Half of the respondents stated that they had never been involved in opioid (methadone / suboxone) substitution therapy, when at least 58% of the entire sample reported opioid use in the last month. 11.8% of the respondents (116 respondents) were involved in the OST program at the time of the research, while 19% of the respondents (187 respondents) had an experience of participating in the OST program (GHRN, 2019).

The organization, *Partnership for Health Research and Development* conducted a qualitative research in 2017, in 4 cities of Georgia (Tbilisi, Gori, Batumi and Kutaisi) to assess the accessibility and barriers to harm reduction services among people who inject drugs, including women. The data was collected through interviews with the representatives of service providers (12 persons) and the PWID (35 persons). Research revealed the following:

- Stigma and discrimination were named as significant barriers to accessibility of the OST programs both by providers and by beneficiaries. It was noted that stigma is much stronger in the case of female users and that they are being discriminated by family and society as well as by male users.
- The providers of the OST programs named the main reasons for patients leaving the program: frequent migration, stigma, financial problems (in the case of suboxone private program), physical inaccessibility (in the regions).
- Most of the surveyed beneficiaries of the OST programs did not have a desire or attempt to leave the program. The reasons for leaving the program were: the need to walk to the center every day, the fear that the family will find out about it (some beneficiaries hide from their family members that they attend the program because of stigma), and the desire to stop using drugs.
- According to both, providers and beneficiaries, the OST programs meet the needs of the users, although both groups noted the reasons why users may be dissatisfied with the service. The reasons given by providers for the dissatisfaction of the program beneficiaries were: the lack of the dose of the drug, patients detention in the clinic when the drug is administered through a sublingual route in the suboxone substitution therapy program, the short working hours of the centers. To improve the service, beneficiaries reported: possibility to take the drug home, addition of free suboxone substitution therapy centers, separate entrance or different working hours for women, possibility of benefiting from on-site rehabilitation services.
- According to the results, the suboxone substitution therapy program was more in demand and it was

liked more among the beneficiaries than the MST, participants of the study explained that Suboxone is a more desirable medication ("it is mild", "it does not cause strong dependence") (PRAH, 2017).

It should be noted that at present the implementation of the OST programs have undergone changes that partially meet the above mentioned needs of the beneficiaries – for example, due to the COVID-19 pandemic, the practice of taking a replacement drug home for up to 5 days has been established.

Several studies have been conducted in Georgia, to investigate what impact does inclusion in the OST programs have on the mental health and the quality of life of the beneficiaries. One of them is the study conducted in 2016 by Khatuna Todadze and Sophio Mosia, *Progression of the substitution therapy in the users of different types of opioids* (Todadze and Mosia, 2016). The study examined the impact of inclusion in the OST program on the symptoms of anxiety and depression and on the use of narcotic / psychotropic medications without a doctor's prescription in the program beneficiaries. 104 individuals involved in the OST program participated in the study, which in accordance with the aim of the study were divided into categories of the predominantly used drugs 6 months before the enrollment in the program. A total of 5 groups were distinguished: heroin (1), desomorphine (2), illegal methadone (3), buprenorphine (4) and, simultaneous users of several substances (5). The study had a prospective design and participants were assessed for depression, anxiety, risky behavior, clinical symptoms, and the quality of life, before the OST treatment, and 3, 9, 15, and 21 months after the inclusion to examine the dynamics of their condition. Drug/psychotropic substance use was monitored by monthly urinalysis. Results of the study revealed the following:

- Prior to treatment, all five groups showed elevated levels of anxiety and depression, which were highest in the users of several substances at the same time (so-called "poly-drug addiction");

- A significant decrease in depression was observed in all study groups compared to the initial data; Improvement in mood was achieved 3 months after treatment, which lasted throughout the whole treatment process;

- Significant improvement in anxiety levels was observed in all five groups: anxiety level normalization was achieved in the users of heroin, desomorphine, methadone and buprenorphine, but in the users of various substances (so-called "poly-drug addiction") the anxiety index was still close to the clinically significant limit after 21 months of the treatment.

- Urinalysis for narcotic/psychotropic substances showed a significant reduction in illicit substance use in all study groups over a 3-month period.

Based on the study, researchers concluded that the OST significantly improves physical and mental health state of people with opioid dependence, it improves the quality of life and the treatment outcomes of the comorbid diseases; At the same time, it significantly reduces the risk of the illicit psychotropic substance[10] or narcotic drug[11] use and the spread of blood-borne diseases. People with concurent substance use (so-called "poly-drug addiction") have been found to be the most resistant to achieving stabilization, hence they require longer and more tailor-made interventions (Todadze and Mosia, 2016).

In terms of the effectiveness of the OST programs, it is also interesting to look at the study conducted in Georgia, in which 42 randomly selected HIV-positive people were studied, they were involved in the methadone substitution therapy, used antiretroviral therapy (ART) for at least 6 months before the involvement in the OST program and at the same time, they received intensive psychoconsultation[12] (Todadze and Kavtiashvili 2012).

10 Psychotropic substance – a substance of natural or synthetic origin; the substance-containing plant or preparation which is included in the List III of psychotropic substances under special control in Georgia on the basis of appropriate UN conventions (https://matsne.gov.ge/en/document/view/1670322?publication=18)

11 Narcotic drug – a substance of natural or synthetic origin; the substance-containing plant or preparation which is included in the Lists I and II of narcotic drugs under special control in Georgia on the basis of appropriate UN conventions (https://matsne.gov.ge/en/document/view/1670322?publication=18)

12 Under the term "intensive psychoconsultation" the authors mean 3-months, twice a week Cognitive Behavioral Therapy based course.

Risky behavior, the quality of life, depression and anxiety levels and other data were assessed in the study participants, both before the treatment and at 3, 6, 12, and 18 months after the inclusion. Illegal psychoactive substance use was checked by random urinalysis 3 times a month with each patient. According to the results of the study, condition of patients significantly improved in the context of treatment. In particular, the indices of depression and anxiety decreased significantly, the quality of life was increased compared to the initial state. Positive results in testing on drugs were observed in an average of 6.7% of users and among them no risky behavior related to injection was detected. Researchers conclude that the combination of the MST, the ART and the psychoconsultation significantly improves the physical and psychosocial state, the quality of life and compliance with the treatment, it significantly reduces the use of illicit psychoactive substances, the risk of spreading HIV or other blood-borne diseases in the population of people who inject drugs (Todadze and Kavtiashvili, 2012).

One of the earliest researches devoted to the study of the effectiveness of the methadone substitution therapy pilot programs in Georgia also revealed an improvement in the psychosocial state of the patients (Todadze and Lezhava, 2008). The study was conducted in 2006, when there were only three methadone substitution therapy programs in Georgia (2 in Tbilisi and 1 in Batumi), from which a total of 230 patients benefited. The study involved 60 opioid-dependent persons receiving methadone substitution therapy and psychosocial support at the Narcology Research Institute in Tbilisi. Participants were assessed for depression (The Beck Depression Inventory) and anxiety (The Spielberger State-Trait Anxiety Inventory), as well as the quality of life (WHO Questionnaire) and other relevant data before and 3, 6, and 12 months after the enrollment in the MST program. Illegal substance use was monitored by urinalysis 3 times a month with all patients. The results of the study showed a significant improvement in patients' psychosocial state, namely: reduction of depression and anxiety levels and, increase in the quality of life compared to baseline rates. The authors conclude that the methadone substitution therapy is effective in Georgia and they believe that increasing geographical availability of the program and increasing number of patients involved in it may have a positive impact on health and social climate in the country (Todadze and Lezhava, 2008).

The study described above (Todadze and Lezhava, 2008) and another study examining the effectiveness of medical care for the PWID, which was conducted during the same time period by the community organization of people who use drugs (Chirikashvili, 2007), revealed an interesting misconception about the program effectiveness between the expectations of the beneficiaries and the treatment goals set by the medical staff: the beneficiaries' expectations were to improve their quality of life, while the goal of the treatment for the medical staff of the program was to stop the use of illicit psychoactive substances by the beneficiaries. To eliminate such a mismatch between the expectations of the beneficiaries and the goals of the medical staff, a recommendation was developed based on both studies to improve communication between the program's medical staff and the beneficiaries to determine the individual treatment goals of each beneficiary.

There are also other studies which confirm the efficacy of OST in Georgia: Assessing the Costs of Medication-Assisted Treatment for HIV Prevention in Georgia (Kirtadze et al., 2012), Cost-Benefit Analysis of Medication Assisted Treatment and Needle-Syringe Programs in Georgia (Kirtadze, Otiashvili and Tabatadze, 2016) and Intervention Packages against HIV and HCV infections Among People Who Inject Drugs in Eastern Europe and Central Asia: A Modeling and Cost-Effectiveness Study. Results on Cost-Effectiveness analysis: Georgia (Mabileau et al., 2005).

5. RESEARCH DESIGN AND METHODOLOGY

The study was conducted using mixed methods approach. The so-called sequential research design was used: Initially, a qualitative component of the study was conducted, which was a round of semi-structured interviews with the opioid substitution therapy (OST) patients in western Georgia regarding their experience of involvement in the OST program. The results obtained in the qualitative component were utilized to refine the questionnaire to be used in the quantitative part of the study. Quantitative research, in turn, was conducted with a representative sample of patients of the OST programs in western Georgia. The quantitative component of the study was a cross-sectional type of research. The method of simple random sampling was used to select the participants of the study, the sample size was determined separately for the large and small-scale centers (state institutions), as well as for the private institutions. The following measures were used in the study: confidence interval: 95%, margin of error 5%, coverage of 50% of the beneficiaries within 3 days of the study.

5.1. Sampling Method

Qualitative Component of the Study

A purposeful sampling methodology was used in the research: in particular, the representatives of the community organization *Rubicon* selected the respondents from the OST institutions involved in the study. In the sampling process, the focus was on mobilizing the most inclusive selection: to ensure the balance according to gender, age, socioeconomic status, time period of the OST program involvement, and the OST program types (public institution, private institution, buprenorphine substitution therapy, and methadone substitution therapy). The number of interviews depended on saturation. CBO *Rubiconi* representatives informed the potential respondents about the objectives and procedure of the study, shared an informed consent form with those who were interested to participate, linked them to the research team and delivered an incentive of 12.60 GEL (approx. 3.55 EUR).

Quantitative Component of the Study

The quantitative component of the study was conducted with a representative sample of patients of the OST programs in western Georgia. The following procedure was used to determine the sample size: The centers were divided into two categories: public institutions of the substitution therapy (methadone substitution and Subuxone substitution therapy providing institution) and private institutions (Subuxone substitution therapy institution). The sample size was calculated separately for each category. A random selection of the institutions was carried out as follows: public institutions were again divided into 2 categories: small-scale centers (less than 200 patients) and large-scale centers (more than 200 patients). From the small-scale centers randomly the Zestaphoni (110 beneficiaries) and Sachkere (60 beneficiaries) centers were selected. The sample size for 170 patients, with a 95% confidence interval, a 5% error, and an estimate that 50% of beneficiaries could be included in 3 days, was limited to at least 119 individuals (80 beneficiaries from Zestaponi and 39 beneficiaries from Sachkhere).

The large-scale centers were selected randomly – one center from Imereti region (Kutaisi, 800 beneficiaries), one center from Samegrelo region (Zugdidi, 450 beneficiaries) and one center from Adjara and Guria regions (Batumi, 900 beneficiaries). Out of a total of 1,850 beneficiaries, the sample size was determined by the same measurements to at least 319 persons (Kutaisi – 120 persons, Zugdidi – 69 persons and Batumi – 130 persons).

Private institutions are located in different regions and the sample size was calculated from the total number of beneficiaries of the three existing centers (Kutaisi − 250 beneficiaries, Senaki − 200 beneficiaries, Batumi − 240 beneficiaries, total – 690 beneficiaries). The sample size here was determined with 247 persons (Kutaisi – 90 beneficiaries, Senaki – 70 beneficiaries, Batumi – 87 beneficiaries).

Finally, the total sample size (119+ 319 +247 = 685) was limited to 685 persons**.**

Sampling Procedure: During the study period, due to the pandemic, patients were given the substitution drugs to take home (for up to 5 days). It was planned that 5 days a week (Monday-Friday) the interviewers would conduct interviews with every second person who came to the selected institutions. Each beneficiary received an incentive of 9.45 GEL (approx. 2.7 EUR)

5.2. Research Instruments

Qualitative Component: Research Instrument

A Qualitative Research Guide was developed on the basis of a Guide developed by the team of the Ukrainian colleagues from the Support, Research and Development Centre (CRDC), Ukrainian Network of People who use Drugs (VOLNA), Drug-users Ukraine, the Drop-in Centre and the club ENEY who piloted the similar kind of methodology in Ukraine in 2019 with support from the Eurasian Harm Reduction Association (EHRA). The guide included questions/sections on the following issues: Needs and expectations related to treatment in the OST program; Liaison with the institution staff and other patients; Satisfaction/dissatisfaction during the treatment process; Experience of participating in or refusing to participate in the specific OST programs; Changes in perceptions, expectations, and Needs related to participation in the OST programs over the course of the treatment.

Quantitative Component: Research Instruments

Quantitative research instruments included the following components:

1. Demographic and socio-economic characteristics (e.g. gender, age, education level, employment status, marital status, the amount of income, years of participation in the OST program).

2. WHOQOL-BREF Questionnaire (The World Health Organization (WHO) Quality of Life Questionnaire – WHOQOL-100 or of the Who Quality of Life Questionnaire comprised of 100 questions (https://www.who.int/tools/whoqol), the abbreviated version).

3. A questionnaire related to participation in the OST program, which was developed on the basis of a pilot study conducted in Ukraine and adjusted to the Georgian context based on the qualitative data.

4. PHQ-4 (Patient Health Questionnaire - 4, which includes 2 screening questions for anxiety and 2 for depression, removed from GAD-7 and PHQ-9, respectively).

5.3. Data Collection and Analysis

Qualitative data were collected through online interviews (using Skype and Zoom platforms). Skype accounts were created by interviewers for research purposes. The “Rubiconi” representative and coordinator organized the meeting time with the participants and interviewers and connected them with each other. The interview was conducted in a confidential manner, audio recordings of the conversation were made in the process. In case the respondent did not wish to show their face, he/she could refuse to turn on the video camera. Based

on the audio recordings of the interviews the transcripts were made and the data was analyzed using content analysis.
The quantitative data for the study was collected using a questionnaire developed on a tablet-loaded RedCap platform (https://www.project-redcap.org/). An access to the RedCap platform for data collection was provided by the Ukrainian colleagues from SRDC. The RedCap online questionnaire platform complies with the General Data Protection Regulation (GDPR). The completed questionnaire data was loaded from the RedCap platform to the Statistical Analysis Software (SPSS). The quantitative questionnaire data analysis included descriptive statistics and bivariate regression analysis of participants' satisfaction with the OST programs and of their quality of life.

5.4. Ethics Procedures of the Study

Participants were provided with information about the objectives of the study prior to the start of both qualitative and quantitative research. If interested, they were required to confirm their participation by signing the informed consent form. All the data was collected anonymously, the process did not require personal identification, address or other identifying data of the participants (e.g. full date of birth, ID number, etc.).

Protection of the collected data was ensured during the study. Audio recordings and transcripts of qualitative research interviews, as well as collected quantitative data were stored in password-protected files on password-protected computers. The data collection platform RedCap is fully compliant with GDPR regulation. The data was shared among the research team members only by the appropriate methods regulated by the GDPR.

The research was authorized by the *Ethics Commity of the Faculty of Arts and Sciences of the Ilia State University.*

6. RESULTS OF THE QUALITATIVE COMPONENT OF THE STUDY

6.1. Demographic Characteristics of Respondents

A total of 10 semi-structured interviews were conducted within the study (9 men, 1 woman). The average age of the respondents was 48 years (minimum: 39 yr., maximum: 57 yr., SD 6.30); 8 respondents were married, 1 was single, 1 – widowed; Most of them were unemployed (6 unemployed respondents; 1 of them receives a pension of war and military veterans), 3 are employed, 1 – has a socially vulnerable status. 4 respondents have experience of imprisonment by different articles of criminal code of Georgia, including the illegal use of psychoactive substances. We were able to contact only 1 female respondent during the recruitment process, which prevents us from talking about the experiences and needs of this group.

Among the study respondents currently there are 8 patients involved in the methadone substitution program, and 2 – in Suboxone substitution therapy; 9 respondents are benefiting from the state program of substitution therapy and 1 is benefiting from a private program. The duration of the respondents' involvement in the program is quite diverse: the average duration is 6 years (minimum duration of 1 month, maximum – 14 years, SD 4.42); 7 of them have been receiving continuous treatment since the day of enrollment in the program. The mean age of onset of illegal psychoactive substance use in the study respondents is 20 years (SD 1.5); The most commonly used illegal substances were: morphine, heroin, opium; Some of the respondents also have experience of using a substitute drug for non-medical purposes.

6.2. Needs and Expectations before Enrolling in OST treatment

The Need and Experience with other Types of Treatment

Most respondents had no experience with other psychoactive substance use treatments prior to enrollment in the substitution program (except for emergency medical help in case of the overdose/withdrawal). Only 1 respondent had prior experience of being in a abstinence-based treatment program (abroad), which they found to be ineffective and decided to join the substitution therapy.

Awareness about the Opioid Substitution Therapy

Prior to treatment, respondents received information about Opioid Substitution Therapy mostly through informal ways (relatives/acquaintance or people who were involved in the therapy themselves). One of the respondents even thought that substitution therapy was another trap created to "deceive" users, which would be used to repress them.

> *"I knew that my friends were in this program. I gave it a thought and came to this decision (to enroll)" (Respondent #1, male, 43 years old).*

> *"I did not know what it would be, something that you do not know what to expect from; We did not have any information until we got there... I'm telling you, I still thought it might be a trap. Now it sounds ridiculous, but then I was just used to being chased, that I had to hide... It was hard to imagine that one would go and drink what one's body needs..." (Respondent #9, male, 50 years old).*

Lack of information has occasionally become a reason for delaying enrollment in the program. There were cases when the respondent or their family members thought that they would be in a constant state of intoxication while in therapy, or that being in the program would interfere with various activities.

The Motivation for Joining the OST Program

The initial motivation for the study participants to be involved in the program was to get rid of the constant seeking and purchase of psychoactive substances, as well as to get rid of police prosecution, and withdrawal state:

> *"Then I realized, for how long could I keep going to the black market? I don't always have money for it. I went for it [the program] to have it [medication] for me and not ask someone else, not to be on the streets all day and night to get drugs somewhere. Plus, this whole police chasing thing" (Respondent #4, male, 43 years old).*

Barriers to Inclusion in the OST Program

The respondents state that they did not face any difficulties in joining the program, however, the procedures for inclusion, such as submitting the Health Declaration Form from the polyclinic, are a kind of barrier due to the additional cost (70 GEL).

Respondents have diverse, often inaccurate information about the criteria of inclusion as well as the practice related to the Opioid Substitution Therapy. For example, it has been suggested that substitution therapy is used by alcohol-dependent patients, leaving "no room" for opioid users. According to one of the respondents, he/she was not properly examined while enrolling in the program and was therefore refused admission to the program. It has also been suggested that in one of the city's OST programs, enrollment happens by nepotism which hinders the reception of the service for those in real need of the OST program, while individuals enrolled in substitution therapy do not have real medical needs for it. Unfortunately, the research team was not able to re-examine such statements.

In some cases, it was difficult to get the substitute drug during the location change – one of the respondents reported that after arriving from a European country, where he/she was involved in OST, there was a delay of several days in joining the program in Georgia. Document proving that he/she was part of the OST program abroad was not sufficient for enrollment in the methadone substitution therapy and they were asked to submit a Health Declaration Form from the local polyclinic, which delayed the enrollment process (this happened in 2013). However, according to the information received from the second respondent (who was also involved in Suboxone substitution therapy abroad), tey were able to participate in a methadone substitution Therapy program since the day of their arrival in Georgia, for which the analysis of biological material and the examination by a doctor (the presence of withdrawal symptoms) were sufficient.

> *"I arrived in Georgia on Friday and I was waiting until Monday to be enrolled, even if I was already registered there and I had brought a proof document from there. No, we cannot accept you until Monday - they told me. Shall they treat a person with withdrawal symptoms this way when they have the possibility to give it [medication] to them?! I had brought the certificate from Europe which proved the dose I was taking there, it should have been sufficient but they asked for a certificate from here" (2013) (Respondent #3, male, 39 years old).*

> *"I actually got enrolled quite quickly, on the same day... I had my analysis results, Buprenorphine came out... and I was in a bad state when the doctors examined me, I was obviously in a bad state... I was having a withdrawal" (2019) (Respondent #5, Male, 51 years old).*

The respondent, who had to leave Georgia for a European country, described an effective referral system, stating that *"getting the medication was not delayed even by half an hour"* (Respondent N9, male, 50 years old).

6.3. Experiences Related to Being in the OST Program

Inclusion Process Algorithm

As for the procedures related to the enrollment in the program, our respondents shared the following enrollment scheme to us: first, it is necessary to submit a Health Declaration Form from the polyclinic. After that they directly talk to a narcologist in the substitution therapy clinic about their history of use, then they give urine samples, after which they are assigned a substitution medication dose that is adjusted for the first few days to achieve optimal condition for the patient. The procedure for taking a substitute drug is quite simple after the initial steps of treatment, dose selection, and stabilization of the patient's condition – they simply go to the clinic, meet with a doctor to get a medication prescription, then they take the medication.

Informing Patients about the Treatment at the Facility

In many cases, the patient may be in a state of withdrawal, or under the effect of a psychoactive substance during the first appointment with a doctor at a substitution therapy facility, which makes it difficult for them to be provided with appropriate information about therapy prior to treatment. For the same reason, respondents found it difficult to answer the question of which specialty doctors they spoke to and what questions they answered to and whether they received information about treatment or not. However, some of the respondents of the study also mentioned that they did not receive comprehensive information about substitution therapy from doctors even in the following periods (2 respondents). The second part of the respondents received information from the staff of the clinic about the course of treatment, about various options (maintenance therapy, detoxification), and about the possible results and solutions. The source of information about the treatment process could also have been the Harm Reduction Program implementation center, a relative involved in the program, or information received during the treatment abroad.

> *"I don't know, there were so many doctors ... I was a little dizzy, I do not remember well what the questions were" (Respondent #10, female, 51 years old).*

> *"Yes, the doctor tells you in advance that this is a substitution program, you can undergo the treatment, you can leave, you can continue ... What I was wondering was, is it for one month, two months, this is what I was asking [they were answering to me]" (Respondent #8, male, 43 years old).*

The Attitude of Program Staff Towards the Patients in the Program

Respondents mostly talk about the positive attitude of the program staff towards the patients.

> *"They spoke to us humanely, they wholeheartedly took our plight into consideration, I can say nothing but thank you to them" (Respondent N9, male, 50 years old).*

> *"People help you, they take care of you, they welcome you, why should you be dissatisfied" (Respondent N2, male, 39 years old).*

However, one of the respondents encountered inappropriate attitudes and prejudices towards the community of people who use drugs. Different attitudes were reported in Tbilisi and in the regions - according to the respondents, the attitudes in Tbilisi are more humane, caring, and respectful. As for the regions, respondents have encountered inappropriate attitudes and prejudices towards the drug-user community:

> *"They [talking about the clinic representative] have not yet been able to understand to look at them [users] not as criminals, but as patients, it has not yet come to their understanding and will never come ... [service] shall be more patient-centered and not boss-centered [clinic representative]" (Respondent #7, male, 57 years old).*

Satisfaction Level with the Substitute Medication

The respondents in general are satisfied with the substitute medication and have no desire to change the drug. One of the respondents thinks that the quality of the drug methadone is better in Georgia than in another country, where he/she used to receive the same service.

> *"I received information about this program in Athens and it is better in Kutaisi than in Athens. There [in Athens] it is all water [medication]" (Respondent #2, male, 39 years old).*

One of the respondents pointed out a kind of negative dynamics of the effectiveness of the medication from the beginning of the month to the end of it – he/she said that the effect of the drug is more effective at the beginning of each month and less at the end of each month. He suggested, that the facility might not follow the rules for storing the drug:

> *"There are cases, many people also say, that 'maybe the drugs go bad?!' There is an obvious difference, there is good, ordinary, normal, and bad [medication]. Maybe the storage rules are not followed? ... It feels more like that at the end of the month. You have a feeling of deficiency. You notice the difference " (Respondent #5, male, 51 years old).*

Respondents also commented on the differences between medications, methadone and Suboxone, and how different a patient's physiological response to these drugs might be. One respondent noted that patients, who switched from methadone to Suboxone program, have returned back to the methadone program within a few months. There have been cases when prospective patients have chosen a particular program based on their past experience (adverse reaction to street methadone or Suboxone):

> *"In France, I had an experience with methadone (street) and this is not the drug I would like to use, so I avoid it" (Respondent #4, male, 43 years old).*

> *"I tried street methadone in Russia and I had an adverse reaction" (Respondent #5, male, 51 years old).*

One of the respondents shared his opinion that it is better to use psychoactive drugs of natural origin as a substitute drug, because, in his opinion, they have much fewer contraindications than artificially synthesized drugs:

> *"If it is possible to substitute with natural drugs, not so much with artificial drugs. It is harmful to health. The opiate class is not so harmful. Methadone has many negative sides. It has a negative effect on kidneys" (Respondent #5, male, 51 years old).*

Satisfaction with the Selected Dose

The respondents in general are satisfied with the selected dose during the treatment process; According to them, the dosage is selected on the basis of a proper observation, and as a result after taking the drug they are smoothly involved in their daily activities.

> *"20 mg [we chose] from the beginning, but it still did not calm me down, I had insomnia, sweating. Then, after a while, I increased the dose ... I could fell asleep and I was relieved of those anxieties for which I had entered the program, so I settled for that dose. They helped me in that ... the doctors told me to observe carefully, I waited for one or two days, and as it was not sufficient I settled for 40". (Respondent #1, male, 43 years old).*

> *"The dose of the drug was determined in agreement with me, they kept increasing, and when I took 60 mg, I said that I did not need more, that it was enough" (Respondent #2, male, 39 years old).*

However, there also were cases when patients used other psychoactive substances besides the substitute medication to achieve their optimal condition during the day; Nevertheless, they did not communicate about it with a doctor:

"It is tiring to be in the same condition. In the second half of the day you are already weary, done-up, you do not have the guts to do anything; I did not talk to the doctor about this issue, because he cannot offer me anything else, I know that so what's the point... Many patients have a similar problem, so some drink cognac, some drink beer from morning to evening" (Respondent #7, male, 57 years old).

Use of other Services of the Program

The respondents said they were aware of the possibility that they could meet their other medical and psychosocial needs on the spot (in the OST program) or by referral (such as referral for hepatitis C treatment, job search assistance).

"Employees help us, ask us a lot of questions, if we need anything, tell us that there is a facility to get tested for hepatitis C, that the treatment is free" (Respondent #2, male, 39 years old).

Some respondents stated that they more or less regularly meet with a psychologist and social worker (approximately twice a month; in specific cases even at every visit to the clinic) and undergo various examinations for general health monitoring at the clinic base.

Some respondents are dissatisfied with the lack of proper information about additional services - they do not have any information about the duties of psychologist and a social worker in the program (methadone substitution therapy state program and Suboxone substitution therapy state program in Kutaisi).

"There has not been any offer. Neither a psychologist nor anything. I only come to get the medication, this is it" (Respondent #4, male, 43 years old).

"No one has offered any help (from a psychologist or from a social worker), I have not heard of such a thing" (Respondent #3, male, 39 years old).

Over the years, according to the Georgian regulations, it was not allowed to take home a substitute medication dose for several days, except for exceptional cases (exceptions include, for example, a documented business trip, death of a family member, or patient's illness and bed rest. Detailed information is given in the Order N01-41/N of July 3, 2014, of the Ministry of Internally Displaced Persons from the Occupied Territories, Labor, Health and Social Affairs of Georgia on the implementation of drug-addiction treatment with a special drug substitution program). From 19 March 2020, due to the COVID-19 pandemic, substitution therapy patients receive a one-day dose on the spot at the clinic and take the 5-day medication home. Overall, this change is welcomed by the survey respondents as it gives them more freedom − they do not have to make daily visits to the clinic. However, different opinions were expressed regarding the amount of dosage to be taken home. Some respondents (2 respondents) wish that the beneficiaries of the program had the opportunity to take a dose of fewer than 5 days because it is not easy for everyone to follow the dosage and distribute the medication properly for 5 days. According to the order N01-27/n, of the Minister of Health, the dosage to be taken home during the pandemic is defined as a maximum of 5 days; and a maximum of 7 days in case of patient quarantine or self-isolation.

"I wanted to take a 3-day dose and they refused me, it has to be of 5 days, they keep saying... I ask for less, not for more. I am more in control for 3 days dosage" (Respondent #3, male, 39 years old).

"It would be good if they gave us the dose for 3 days. They give you 5 days dose and it would be good if it were 3 days dose. I have friends who cannot control the dosage, they take it at once - they take the 5-day dose in 3 days and for the rest of 2 days they feel bad, which is awful. It would be better if they could go to the facility and get it for 3 days, they will have more control. If they live close by, they can go there, if they live far away, then it is good for them" (Respondent #2, male, 39 years old).

One respondent expressed a desire for the dosage allowed to be taken home to be more than 5 days, for example, a 1-week dose:

"For example, you go on vacation for 1 week, and you have to leave on the 5th day, 2 days before, this

is what I am saying. It would be better if one could take the dose of 3 days or 1 week during this one week, why should it be a problem, I do not understand ... alright, they should not let us take a 1-month dose, but for example of 1 week" (Respondent #1, male, 43 years old).

Desire and Experience of OST Termination and Involvement in other Treatments

Some respondents had a desire to discontinue participation in an Opioid Substitution Therapy program (2 respondents). One had an attempt to voluntarily leave the treatment, however, after a short period of time he/she returned to the program again because he/she was feeling bad.

One of the respondents reported that he wanted to get involved in the drug-free treatment program, which he could not do because of the length of time he waited before joining the program; This respondent then decided to join the substitution program:

"I wanted to get rid of the withdrawal symptoms, but they told me they would take me in 2 weeks' time, and why would I want their help after 2 weeks... 2 weeks was a long time for me and that is why I enrolled for this program (OST)" (Respondent # 4, 43 years old).

According to the second respondent, due to the necessary procedures for switching from substitution therapy to abstinence-based treatment (gradual reduction of the dose, which requires time depending on the case), he could not immediately change the form of treatment, so he changed his mind.

"Once I thought of getting rid of the withdrawal symptoms, but I had to wait for a long time, and then I changed my mind. They made me wait for a very long time, almost 3 months ... I was told to reduce the dose, I was on 50 mg and they told me they could not take me in at 50 mg. If I reduce it to 10 mg, I do not need their help anymore, I will get rid of it home, by myself" (Respondent #3, male, 39 years old).

The Rules of the Clinic and Cases of Their Violation

Formal rules of the substitution therapy facility listed by the respondents were: Prohibition of smuggling the medication out of the clinic; Restriction of telephone conversations while in the clinic; In addition, they do not have the right to miss a visit three times (according to the order of the Minister of Health N01-41/N, the grounds for expulsion from the program are officially 5 unreasonable misses per month); Other psychoactive drugs (including alcohol) should not be used during treatment with a substitute medication; Mandatory monthly inspection/testing; Restrictions on obtaining a driver's license and driving while in therapy. Part of the respondents mentioned (4 respondents) that the staff of the clinic introduced them to the rules of the program, and that they could also find the list of rules on the wall of the facility; The rest of the respondents said that they were not introduced to the list of rules.

Violation of the rules is reported by one of the patients (attempt to smuggle the drug from the program):

"Users do a thousand things. They think, I will take this (substitute drug) and use it as I wish ... There was the case when someone put the powder on his hand, to which the facility staff had a strict reaction - he put everything he had on his hand and he was almost expelled from the program" (Respondent #4, male, 43 years old).

Respondents also talked about the regulations related to the COVID-19 pandemic (keeping the distance, wearing the mask; removing the mask is mandatory to identify a person and give them medication).
Violation of the rules may result in the patient being forcibly detoxified and expelled from the program, after which they are prohibited from re-enrolling the program for six months.

Respondents could not name specify what rules the medical staff is required to follow. However, no one among our respondents recalled witnessing of a gross violation of the rights of the beneficiaries of the program.

Awareness and Attitude of Family/Relatives Regarding the Respondents' Participation in the OST Program

Respondents' attitudes towards informing their family and other relatives about their involvement in the OST program was quite different. For some, it was not a problem, their families were informed about it and they supported respondent's presence in the program. Those family members who did not actively support it, would still prefer respondent to participate in the program rather than take the risk of using illegal substances. Other respondents preferred not to tell anyone about their history of drug use and involvement in the substitution program:

> *"It was 50-50, they did not like it, but they knew my story ... they were not excited ... they talked about how difficult it is to get out of it …" (Respondent #6, male, 56 years old).*

> *"I do not want anyone to know at all, my son is grown-up and I do not want him to know that I am part of the program, it is not necessary. Which child is happy to know that the mother is part of the program, what was in my life is already enough" (Respondent #10, female, 51 years old).*

The beneficiaries of the study and their relatives had rather little information about the program before the respondent was involved in it; At first, they were quite skeptical about this form of treatment, they did not know what outcome they shall expect; However, based on personal experience, this attitude has mostly changed for the better. Respondents who had information about the program from their work (an employee of the Harm Reduction Center) or from a family member, had positive attitudes even before the start of the treatment. For example, one of our respondents was involved in the program by his/her spouse, who was an employee of the Harm Reduction Center, therefore, possessed relevant information about the program.

6.4. Satisfaction with OST Results

Positive Results of the Treatment

The experience of being in the program and the treatment outcomes are generally positively evaluated by respondents. Specifically, the following were named as positive results of being in the program:

- Prevention of adverse experiences (detention for an use of illegal psychoactive substances, overdose);
- Elimination of the need for constant search and procure of psychoactive substances;
- Removal of withdrawal state;
- Financial accessibility of the treatment (free, state-funded OST programs);
- Stabilization of the situation;
- Performing a daily routine;
- Regulating family relationships.

> *"Maybe I saved myself from prison, or maybe from death" (Respondent #8, male, 43 years old).*

> *"If my needs were not met, I would not continue. Nothing hurts, you are in a good mood and you are doing what you want to do. No intoxication or anything, usually everything is done with responsibility" (Respondent #2, male, 39 years old).*

> *"I have 2 friends [in the program], they do not think about street drugs and they say that they are doing their job. They have no problems with the family. There is no longer a quarrel, separation, hard feelings, drugs" (Respondent #1, male, 43 years old).*

6.5. Desired Changes to the Program

Respondents unanimously state that the practice of taking the substitute medication at home should be continued in the post-pandemic period and that the medical staff should be attentive to their individual needs and the amount of dose to be taken with them (as discussed above, 3 days dose instead of 5 days etc.).

Increasing geographical accessibility was also stated as a desirable change - respondents note that opening additional centers will solve the problem of therapy accessibility by avoiding travel costs and time.

Additional centers will also eliminate the problem of large queues at existing clinics (respondents say that during the pre-pandemic period or during the tourist season in resort towns they had to stay in queues for half an hour or more). To solve the problem of queues, one of the respondents considers determining the time slots for a specific visit for each patient instead of a live queue, as the optimal solution. In his/her opinion, this will remove the problem of braking confidentiality caused by standing in the queues.

In some cases, patients' requests for changes in the ways the OST facility operated were approved: patients requested an increase in the working hours of one of the central clinics in the Western Georgia (opening at 08:30 in the morning) on the grounds of better distribution and better day planning; their request was granted after some time.

The study participants also noted that it would be desirable if the substitution medication were sold in pharmacies after presenting the relevant prescription, which would also at least partially eliminate the problems of queuing and traveling to the clinic.

Respondents expressed a desire to change restrictions on people in the program, such as restrictions on employment in the public service[13] *("people like us are excluded")* and restrictions on driving while in the program.

Two participants talked about the problems with video surveillance at the clinic: one of them said that while at the clinic, he could see another patient who came to the facility on the surveillance camera screen, which violated confidentiality. In one of the facilities, cameras were installed in bathrooms of patients, which, according to the respondent, violates human dignity.

Respondents talked about the ways of expulsion/punishment from the program. As mentioned, respondents are aware that patient is unconditionally excluded from the program and for the next six months is prohibited from re-enrolling in the program if he/she secretly takes the drug from the clinic, or if he/she will use other substances (the full list is given in Ministerial Order N01-41/N). One of the participants of the study told us that such strict measures are not necessary for all cases, that it is possible to simply tighten control over the "disobedient" patients, as expulsion from the program in all cases will negatively affect their condition. Another respondent stressed the need to lift the sanction - he/she said it would be more effective to explain the importance and usefulness of the rules to the patient in the event of such violations.

6.6. Conclusions

Overall, study respondents rated the experience of being in substitution therapy as a positive experience and noted that these programs significantly improved their quality of life. However, research revealed cases of misinformation about the program among the beneficiaries. The statements of research participants suggest that the awareness of the general population and the drug-user community about the OST program was quite low in the initial stages of the program implementation in Georgia. Although awareness has increased since then, complete information on the nature and goals of substitution therapy, possible outcomes, course, estimated timing, and options for future patients and their loved ones before starting the treatment are often lacking, which often prevents opioid users from starting the treatment. For example, if potential beneficiaries think that they will be permanently intoxicated after engaging in therapy, or that the treatment process will

13 According to the current legislation, the program beneficiaries do not have right to be employed as public servants.

interfere with their work or family responsibilities, this may not be in line with their wishes and they may refuse to join the program.

Inaccurate information about the criteria and practice of OST is common among respondents, which often leads to patient dissatisfaction (for example, the belief that alcohol-dependent patients are involved in OST, leaving "no room" for opioid-dependent people; Or that the program is accepting novice users who may not even developed an addiction yet and they are going into the therapy for intoxication).

Inaction of medical staff and patients of the program was revealed in various issues, such as providing/requesting information on the course of treatment and possible solutions, discussing satisfaction with the current dosage, providing/requesting information on different treatment options, offering/receiving additional medical services, using the services of a psychologist and of a social worker. The practice of providing information to a patient about treatment seems to differ between institutions or between the practices of specific physicians, since among our respondents there were people who had this information and there were also those who did not receive this information from medical staff.

The experience of study respondents differs when coming from the Western countries to join the program in Georgia, or when leaving Georgia to go to the Western countries. There are beneficiaries who have joined the program of another country without any problem both when arriving in Georgia and when leaving Georgia. However, we have also had cases of delays in engaging in the program. The data was obtained in quite different time periods, suggesting that the existing barrier associated with traveling may have been eliminated over time and with the refinement of the program, however, without quantitative research, it is difficult to be sure about it.

Permission due to the COVID-19 pandemic, which allows OST beneficiaries to take home a 5-day dose of the medication, is rated as a positive change by study respondents. They note that it is desirable that this decision remained in force even after the lifting of pandemic restrictions.

Our research found that medical staff rarely recommends using psychosocial services and does not talk to patients about the benefits and needs of these services. Which probably means that the medical staff themselves are not aware enough about benefits of such services.

None of the respondents of our study had experiences of significant opposition to the therapy involvement process (with the exception of referral from the European country) or cases of gross violations of their rights by medical staff.

Some respondents stated that the dosage of the substitution drug is not enough for them and to avoid discomfort they take various psychoactive drugs in addition to the substitution medicine when they are at home, without saying about this to phisicians (due to the fear to be dismissed from the program).

The problem of geographical accessibility still remains an issue in the country and reveals the need for further multiplication of the OST services in the regions of the country.

It should be noted that only one woman participated in the study, which does not allow us to talk about special needs for this group or problems during their involvement in the program. Our respondent, for example, chose to come to the clinic at a time when fewer people would be there, as she preferred her relatives not to know about her being in the program. Issues such as stigma associated with female users, medical or social special needs can become a significant barrier to accessing treatment for this group.

7. RESULTS OF THE QUANTITATIVE STUDY

7.1. General Characteristics of the Entire Sample

Sixty four percent (441) of the total sample were involved in the public OST program and 36% (247) in the private program. The proportion of locations/cities to receive the OST service was distributed as follows: 31.5% received service in Batumi, 30.7% in Kutaisi, 11.9% in Zestaponi, 10.2% in Senaki, 10% in Zugdidi, and the smallest number, 5.7% received service in Sachkhere.

The median age of the study participants was 43 years, the majority of them (99.7%) were male, more than half (58.1%) were married, the education level of 42.5% was secondary education.

More than a third (38.4%) of the selected respondents indicated that their income was les then 300 GEL (85 EUR), almost same proportion (37.3%) indicated income ranged from GEL 300 to GEL 1,000 (282 EUR). About half were unemployed (48%), and 5.2% were receiving a disability pension.

Majority of study participants (72.7%) were going to the OST site once in every 5 days and 27.3% daily to receive medications.

Nearly two-thirds of them were taking methadone for substitution therapy, while the rest of the respondents (37.2%) were taking buprenorphine. 85% of the sample was tested for HIV and hepatitis C, of which only 6 respondents were HIV positive and only 1 was not on antiretroviral therapy (ART). The prevalence of hepatitis C in the tested respondents was 59.8%, 17% of them were never treated, and 3.9% were treated for hepatitis C during the study period. A third of respondents indicated that they had been in a detention facility, including temporary detention, for which the median number of months spent in a detention facility was 36 months. In the last month, 39% of respondents had an injecting drug use (See Table 1).

7.2. Characteristics of the Respondents According to the Types of the OST Site

Analysis of the research data showed that the median age of the respondents enrolled in the public OST program was 44 years, and the age of the beneficiaries of the private OST program was 42 years (p value <0.01). The proportion of unemployed respondents enrolled in the public program is about twice as much as the proportion of the unemployed respondents enrolled in the private program. (57.4% and 31.2%; p value <0.01). More than half of the respondents participating in the public OST program stated that their income less than 300 GEL, while only 14.6% of the participants in the private program reported the same amount of income (p value <0.01). The study also identified a statistically different proportion of respondents who had an injecting drug use in the past month, with a proportion of 42.6% of public OST beneficiaries, which was 10% higher than the proportion of private OST beneficiaries (p value <0.01). The majority of participants in the public program reported treatment with methadone, while all participants in the private program received treatment with buprenorphine, and this difference was statistically significant (98% and 100%; p value <0.01, see Table 2).

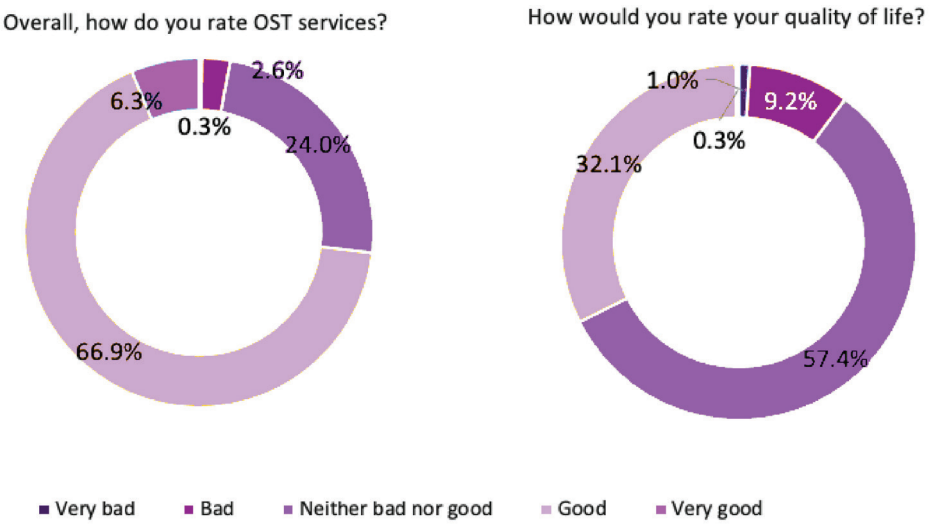
Table 2: Study Participants Characteristics by OST Program Sites

Characteristics	The Whole Sample		Public OST Program		Private OST Program		P- value
	#	%	#	%	#	%	
	688	100	441	100	247	100	
Socio-Demographic Characteristics							
Median age (25% 75%)	**43**	**37-50**	**44**	**38-51**	**42**	**36-49**	**0.00**
Male	686	99.7	440	99.8	246	99.6	0.68
Unemployed	**330**	**48**	**253**	**57.4**	**77**	**31.2**	**0.00**
Receives Disability Pension	36	5.2	26	5.9	10	4	0.29
Education Level (High School)	291	42.5	199	45.4	92	37.2	0.18
Income							**0.00**
Less than 300 GEL	**263**	**38.4**	**227**	**51.8**	**36**	**14.6**	
Between 300 and 1000 GEL	**258**	**37.3**	**141**	**32.2**	**117**	**47.4**	
1000 GEL	**86**	**12.6**	**39**	**8.9**	**47**	**19**	
From 1000 to 3000 GEL	**73**	**10.7**	**30**	**6.8**	**43**	**17.4**	
More than 3000 GEL	**5**	**0.7**	**1**	**0.2**	**4**	**1.6**	
Marital Status (Married)	398	58.1	255	58.2	143	57.9	0.22
Participation in the OST Program							
OST Service reception site							**0.00**
Kutaisi	**211**	**30.7**	**121**	**27.4**	**90**	**36.4**	
Zugdidi	**69**	**10**	**69**	**15.6**	**0**	**0**	
Senaki	**70**	**10.2**	**0**	**0**	**70**	**28.3**	
Batumi	**217**	**31.5**	**130**	**29.5**	**87**	**35.2**	
Zestafoni	**82**	**11.9**	**82**	**18.6**	**0**	**0**	
Sachkhere	**39**	**5.7**	**39**	**8.8**	**0**	**0**	
Frequency of going to OST site for medications							0.79
Goes to the site daily	188	27.3	122	27.7	66	26.7	
Goes to the site once in 5 days	500	72.7	319	72.3	181	73.3	
OST Medication							**0.00**
Methadone	**432**	**62.8**	**432**	**98**	**0**	**0**	
Buprenorphine	**256**	**37.2**	**9**	**2**	**247**	**100**	
Psychoactive substance use							
Intravenous drug use during the past month	**268**	**39.1**	**187**	**42.6**	**81**	**32.8**	**0.01**
The median age of the first non-intravenous opioid use	19	17-22	19	17-22	20	17-22	0.59
HIV / AIDS and hepatitis C							
Tested for HIV / AIDS	583	85	374	85.2	209	84.6	0.78
HIV positive	6	1	5	1.3	1	0.5	0.28
On HIV treatment	5	83.3	4	80	1	100	0.62
Tested for hepatitis C	584	85.1	378	86.1	206	83.4	0.53
Positive for hepatitis C	**349**	**59.8**	**244**	**64.6**	**105**	**51**	**0.00**
Hepatitis C treatment							**0.01**
Currently under treatment	**23**	**3.9**	**14**	**3.7**	**9**	**4.4**	
Never treated	**99**	**17**	**69**	**18.3**	**30**	**14.6**	
Experience of imprisonment							
Was imprisoned (including temporary detention)	215	31.3	143	32.6	72	29.1	0.57
The median months of detention (25% 75%)	36	12-52	36	12-52	30.5	12-51.5	0.93

7.3. Evaluation of the Overall Satisfaction with the Opioid Substitution Therapy Service, Medical Service Needs, and the Quality of Life

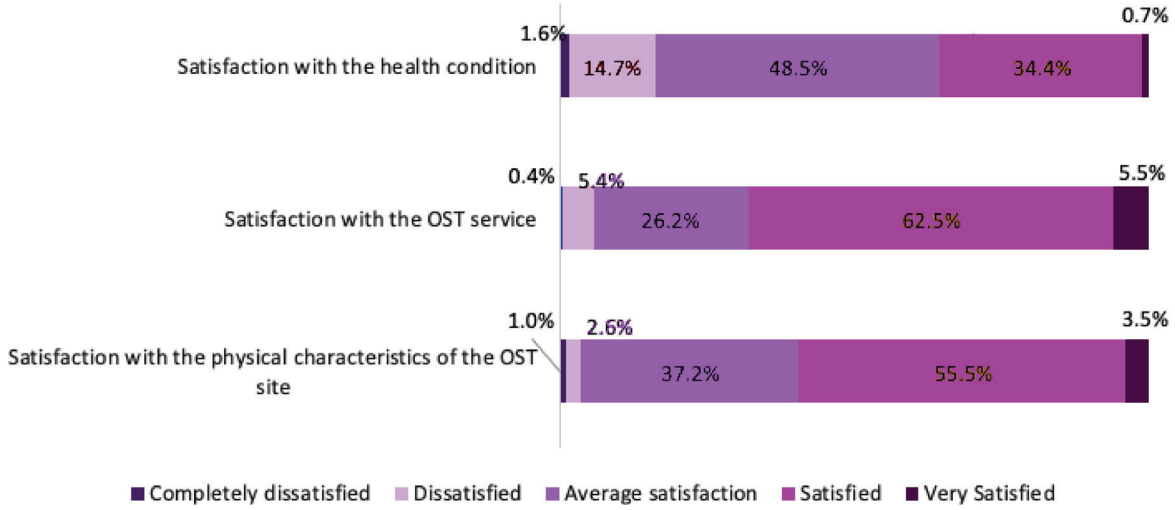
The majority of the study participants indicated satisfaction with opioid substitituion therapy services, 73.2% of them rated the OST services as good or very good. At the same time, only about a third of the respondents rated their own quality of life as good or very good, 32.1% and 0.3% respectively. The data distribution is presented on Figure 7.

Figure 7: Evaluation of the OST Services and of the Quality of Life of Respondents



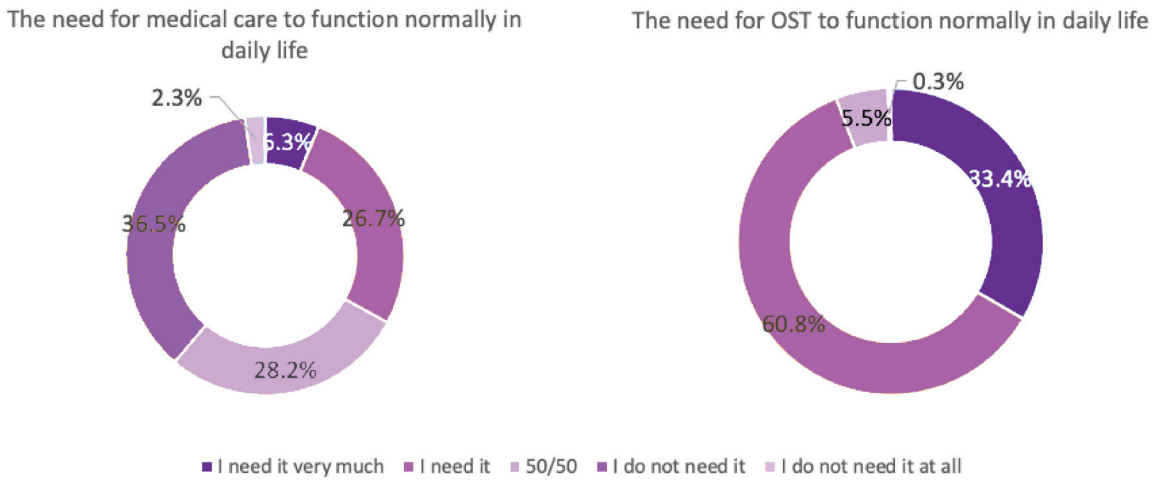
Slightly more than a third of the study respondents indicated that they were satisfied or very satisfied with their own health (35.1%). However, the number of respondents satisfied with OST service and its physical characteristics was higher (68% and 59%, see Figure 8).

Figure 8: Satisfaction with the Physical Characteristics of the OST Sites, OST Services and the Health of Respondents



The study assessed respondents' opinions on the need for the OST and other medical services for normal functioning in daily life, which is presented in Figure 3. The majority of respondents (94.2%) indicated that they needed OST service, while only slightly more than a third (33%) stated that they needed other medical services (see Figure 9).

Figure 9: Assessment of the Medical Care and of the Need for the OST



7.4. Evaluation of the Opioid Substitution Therapy Services

Research participants evaluated OST services by different criteria. More than half of the respondents indicated that it is convenient to commute to the OST site (60.7%) and that the OST site has a good medical quality (53.8%) and the information received from the site staff is sufficient (66.5%). Correspondingly – almost 40% of the respondents indicate that it is not convenient to commute to the OST site (39.3%), 46.2% are not satisfied with the medical quality of the OST site, and 33.5% consider that the information received from the site staff is not sufficient. The majority of the study participants rated the dose of the substitution drug as sufficient (90.5%), they also noted that the attentive attitude of the OST workers is important for continuing to participate in the program (69.9%), and 55.1% noted that the behavior of OST staff influence their decision to continue or to stop the participation in the program. Nearly half of the participants felt safe on the OST site (44.6%), while more than half (55.4%) does not feel safe. Even less, were satisfied with the psychosocial support on the site (37%) and at the same time 38.8% indicated that they expected to address the psychologist service on the site (see **Figure** 10).

Figure 10: Summary Data Related to the OST Programs

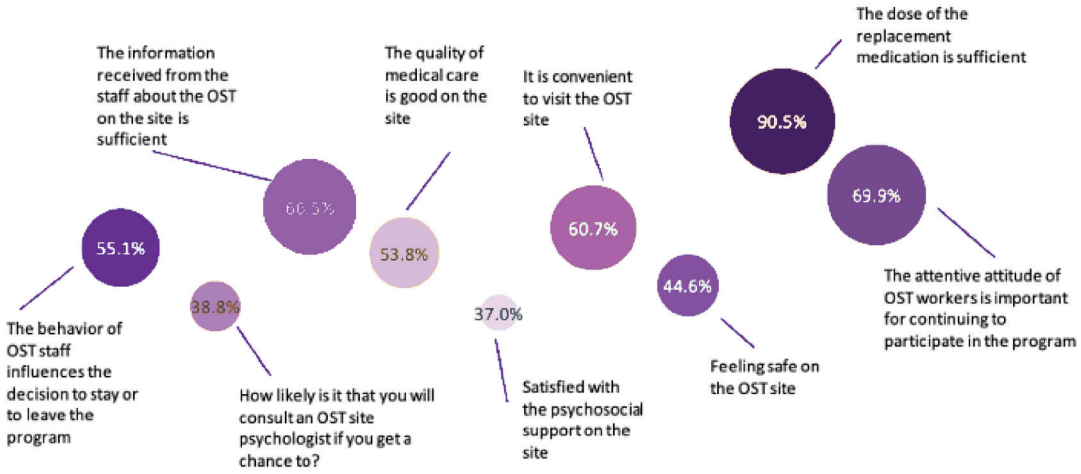
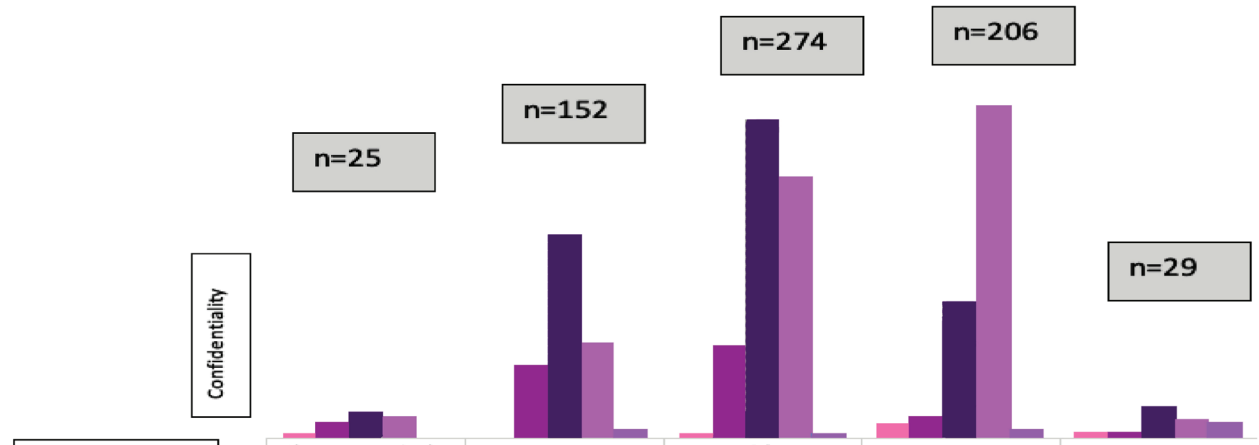


Figure 11, where data are presented in terms of safety and confidentiality, shows that 274 respondents were semi-convinced and 206 respondents were convinced of the confidentiality. The positive correlation between confidentiality and feeling safe was statistically significant (p value <0.01).

Figure 11: Perception of Confidentiality and Security



Feeling safe	I'm not entirely sure	I'm not sure	I am neither sure nor not sure	I am sure	I'm entirely sure
I do not feel safe at all	1	0	1	5	2
I do not feel safe	6	29	37	8	2
50/50	10	82	129	55	12
I feel safe	8	38	106	135	7
I feel very safe	0	3	1	3	6

7.5. Characteristics of OST Sites in Terms of Public and Private OST Programs

The research data were analyzed in the context of public and private OST programs. The analysis revealed that a smaller proportion of respondents, enrolled in the public program, were introduced to the program rules when enrolling (72.6% and 85.8%), as well as knew the exit rules than in the private program (76.4% and 91.1%) and this difference was statistically significant (p value <0 , 01). Only 1% of public program beneficiaries reported resistance by medical staff to exiting the program, which was also statistically significant (p value <0.01, see Table 3).

It should be noted that almost two-thirds of survey participants (62.2%) have never reached out for a social worker support and also three-quarters (75.6%) have never seeked psychological support during the last 6 months. About 8% of respondents reported that they were not informed about the possibility of either a psychological or a social support on the site. About 26% of the study participants applied to social workers' support one to three times, while, systematically, only 3.6% have applied during the last 6 months. Also, a low proportion (15%) from whole respondents reported that they applied one to three times, and only 1.5% systematically applied to psychological support services during the last 6 months. There was no statistically significant difference between public and private OST sites (see Table 3).

Table 3: **Characteristics of OST Program Sites by Type**

Characteristics	The Whole Sample		Public OST Program		Private OST Program		P- value
	#	%	#	%	#	%	
	688	100	441	100	247	100	
The rules of the program were introduced while enrolling in the OST program	**532**	**77.3**	**320**	**72.6**	**212**	**85.8**	**0.00**
The rules for leaving the program were introduced	**562**	**81.7**	**337**	**76.4**	**225**	**91.1**	**0.00**
The resistance of medical staff in attempts to leave the program	**4**	**0.6**	**4**	**0.9**	**0**	**0.0**	**0.00**
Service user satisfied with the duration of the treatment	567	82.4	372	84.4	195	78.9	0.09
Probability of writing a complaint in the future							0.17
Very unlikely	175	25.4	103	23.4	72	29.1	
Unlikely	317	46.1	199	45.1	118	47.8	
50/50	65	9.4	48	10.9	17	6.9	
Likely	110	16	75	17	35	14.2	
Very likely	19	2.8	14	3.2	5	2	
Social worker assistance during the last 6 months							0.06
Not informed about service availability	52	7.6	40	9.1	12	4.9	
There is no social worker on the site	2	0.3	2	0.5	0	0	
Never addressed	428	62.2	281	63.7	147	59.5	
Addressed one to three times	180	26.2	101	22.9	79	32	
Addresses systematically	25	3.6	16	3.6	9	3.6	
Assistance from a psychologist during the last 6 months							0.11
Not informed about service availability	53	7.7	41	9.3	12	4.9	
There is no psychologist on the site	1	0.1	1	0.2	0	0	
Never addressed	520	75.6	326	73.9	194	78.5	
Addressed one to three times	103	15	63	14.3	40	16.2	
Addresses systematically	10	1.5	9	2	1	0.4	

Data related to anxiety and depression were also analyzed in the context of the OST sites. 52.7% of respondents enrolled in the public OST program stated that they had not been able to stop or control their anxiety related worry for the past two weeks. From whole sample, 70.1% participants mentioned that they had little interest in doing things in the last two weeks, while the proportion of private program participants was about 18% and 16% less in both cases respectively (p value <0.01). A statistically significant difference was also observed with respect to self-assessed depression. 72.1% of the public program beneficiaries reported being in low spirits, hopeless, or depressed over the past two weeks, while the proportion of private program participants in this regards, was relatively low too 62.7% (p value <0.05, see Table 4).

The analysis revealed statistically significant difference in anxiety and depression self-evaluation between private and public OST site beneficiaries. The private OST program participants were more relaxed while being at the site (65 vs. 80) as well as while communicating with their doctor (63.5 vs.80) and nurse (65 vs.78, p value <0.01, see Table 4).

Table 4: Problems Associated with Anxiety and Depression during the Last Two Weeks

Characteristics	The Whole Sample		Public OST Program		Private OST Program		P- value
	N	%	N	%	N	%	
	685	100	438	100	247	100	
They felt nervous, anxious, or that they had gone to extremes during the last 2 weeks							0.20
Not at all	240	34.9	149	33.8	91	36.8	
For a few days	390	56.7	249	56.5	141	57.1	
More than half of the days	39	5.7	26	5.9	13	5.3	
Almost everyday	16	2.3	14	3.2	2	0.8	
They could not stop or control the worry during the last 2 weeks							**0.00**
Not at all	**366**	**53.2**	**206**	**46.7**	**160**	**64.8**	
For a few days	**292**	**42.4**	**208**	**47.2**	**84**	**34**	
More than half of the days	**21**	**3.1**	**18**	**4.1**	**3**	**1.2**	
Almost everyday	**6**	**0.9**	**6**	**1.4**	**0**	**0**	
They were in low spirits, feeling depressed, hopeless during the last 2 weeks							**0.03**
Not at all	**212**	**30.8**	**120**	**27.2**	**92**	**37.2**	
For a few days	**419**	**60.9**	**277**	**62.8**	**142**	**57.5**	
More than half of the days	**34**	**4.9**	**26**	**5.9**	**8**	**3.2**	
Almost everyday	**20**	**2.9**	**15**	**3.4**	**5**	**2**	
They had very little interest / little pleasure in doing things during the last 2 weeks							**0.00**
Not at all	**243**	**35.3**	**129**	**29.3**	**114**	**46.2**	
For a few days	**365**	**53.1**	**253**	**57.4**	**112**	**45.3**	
More than half of the days	**56**	**8.1**	**40**	**9.1**	**16**	**6.5**	
Almost everyday	**21**	**3.1**	**16**	**3.6**	**5**	**2**	
The median score of internal state while staying on OST site (on a scale from 1 = “tense, stressed / anxious” to 100 = “relaxed / calm”) (N=687, Npublic=440, Nprivate=247)	**70**	**55-89**	**65**	**50-83.75**	**80**	**61-93**	**0.00**
The median score of internal state when communicating with a nurse on the OST site (on a scale of 1 = “tense, stressed / anxious” to 100 =”relaxed / calm”) (N = 687, Npublic = 440, Nprivate = 247)	**70**	**56-88**	**65**	**52.25-85**	**78**	**61-90**	**0.00**
The median score of internal state when consulting a doctor on the OST site (on a scale of 1 =”tense, stressed / anxious” to 100 =”relaxed / calm”) (N = 687, Npublic = 440, Nprivate = 247)	**70**	**50-90**	**63.5**	**50-85**	**80**	**60-94**	**0.00**
The median score of internal state when consulting a social worker on the OST site (on a scale of 1 =”tense, stressed / anxious” to 100 =”relaxed / calm”) (N = 251, Npublic = 154, Nprivate = 97)	75	60-95	72.5	60-92.25	79	66-100	0.17
The median score of internal state when consulting a psychologist on OST site (on a scale of 1 = “tense, stressed / anxious” to 100 =”relaxed / calm”) (N = 128, Npublic = 80, Nprivate = 48)	83	70-98	84.5	69.5-98.75	77.5	70-98	0.27

Table 5 shows the presence of anxiety and depression problems in the last 2 weeks and the practice of receiving psychologist support during the last 6 months.

The analysis found that about half and more of the respondents who had never applied for a psychologist support during the last 6 months felt nervous and anxious for a few days (57.9%), could not control anxiety (43.3%), was depressed (61.7%) and had little interest in doing things (48.5%) in the last 2 weeks. Moreover, among those study participants who applied for psychologist support for one to three times during the last 6 months, about half and more (47.6% to 60.2%) experienced anxiety and depression problems in the last 2 weeks (see Table 5 for more details).

Table 5: Problems Associated with Anxiety and Depression during the Last Two Weeks and Assistance from a Psychologist during the Last 6 Months

Characteristics	Assistance from a psychologist during the last 6 months				
	Not informed about service availability	*There is no psychologist on the site*	*Never addressed*	*Addressed one to three times*	*Addresses systematically*
	n (%)	n (%)	n (%)	n (%)	n (%)
They felt nervous, anxious, or that they had gone to extremes during the last 2 weeks					
Not at all	25 (47.2)	0 (0)	186 (35.8)	25 (24.3)	4 (40)
For a few days	20 (37.7)	1 (100)	301 (57.9)	62 (60.2)	6 (60)
More than half of the days	1 (1.9)	0 (0)	26 (5)	12 (11.7)	0 (0)
Almost everyday	7 (13.2)	0 (0)	5 (1)	4 (3.9)	0 (0)
They could not stop or control the worry during the last 2 weeks					
Not at all	37 (69.8)	1 (100)	278 (53.5)	46 (44.7)	4 (40)
For a few days	12 (22.6)	0 (0)	225 (43.3)	49 (47.6)	6 (60)
More than half of the days	0 (0)	0 (0)	14 (2.7)	7 (6.8)	0 (0)
Almost everyday	4 (7.5)	0 (0)	1 (0.2)	1 (1)	0 (0)
They were in low spirits, feeling depressed, hopeless during the last 2 weeks					
Not at all	17 (32.1)	0 (0)	164 (31.5)	27 (26.2)	4 (40)
For a few days	29 (54.7)	1 (100)	321 (61.7)	62 (60.2)	6 (60)
More than half of the days	0 (0)	0 (0)	23 (4.4)	11 (10.7)	0 (0)
Almost everyday	7 (13.2)	0 (0)	10 (1.9)	3 (2.9)	0 (0)
They had very little interest / little pleasure in doing things during the last 2 weeks					
Not at all	26 (49.1)	0 (0)	174 (33.5)	38 (36.9)	5 (50)
For a few days	20 (37.7)	1 (100)	289 (55.6)	50 (48.5)	5 (50)
More than half of the days	1 (1.9)	0 (0)	46 (8.8)	9 (8.7)	0 (0)
Almost everyday	6 (11.3)	0 (0)	9 (1.7)	6 (5.8)	0 (0)

7.6. WHOQOL-Bref Domain Indicators for the Assessment of the Quality of Life in Terms of Different Characteristics of the Study Participants

Data analysis revealed that respondents' age, employment status, disability pension, HIV-positive status, and the presence of hepatitis C had a statistically significant association with the quality of life domain indicators. In particular, older respondents rated their own physical, psychological, social and environmental quality of life as lower than younger respondents. Similar to age, the mean scores of all four domains were lower among respondents who did not have a job, while for respondents who reported receiving a disability pension, only the quality of physical life had a statistically significant association and the mean score was lower. HIV-positive respondents also had a low quality of physical and psychological life, which was also in a statistically significant association with the mentioned domains. The presence of hepatitis C only had a statistically significant relationship with the social quality of life and their quality was also low (see Table 6).

It should be noted that a statistically significant association with the quality of life of the study participants was also found in terms of the OST site (public or private), the type of the medication (Methadone or Subuxone) and the frequency of going to OST site for medication (going to the site every day or once in 5 days). Namely:

- The average scores of the public OST service participants were lower than the scores of private OST service participants in self-assessment of both physical as well as psychological and social quality of life;
- The average scores of Methadone substitution therapy beneficiaries were lower than the scores of Subuxone substitution therapy beneficiaries in self-assessment of both physical as well as psychological and social quality of life;

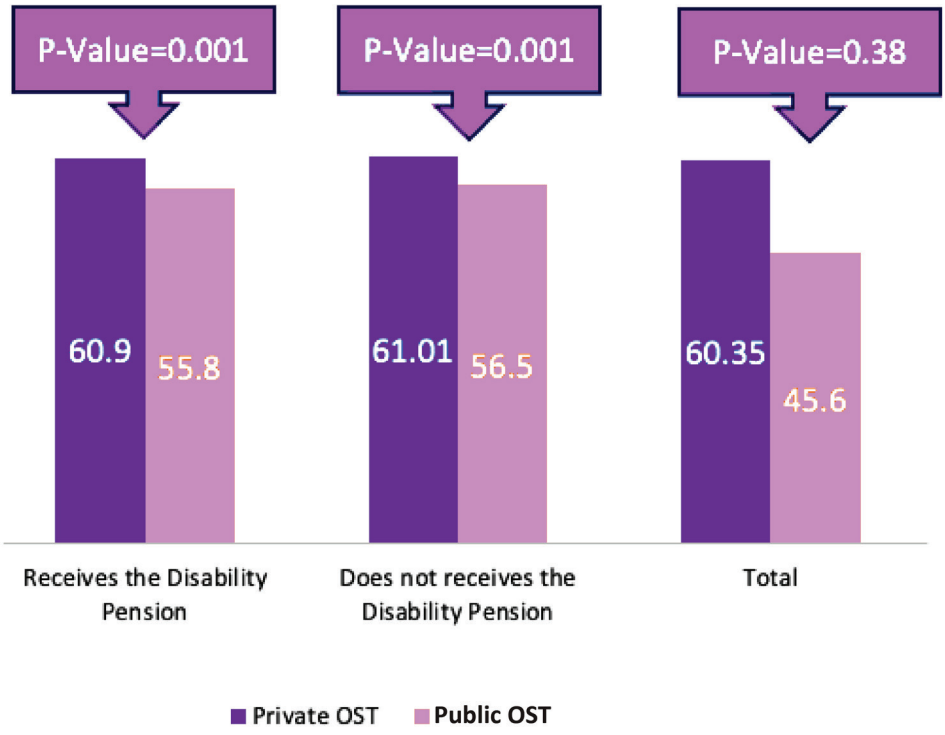
- And finally, less frequent going to the OST site for medication had a statistically significant association with low levels of psychological quality of life of the respondents (see Table 6).

Table 6: Mean and Standard Deviation of the Quality of Life in Terms of Different Characteristics (WHOQOL-Bref, 0-100 scale)

Characteristics	Physical	Psychological	Social	Environmental
Age				
<43	**60.93 (14.83)*****	**59.51 (10.25)*****	**70.25 (14.63)*****	**54.82 (11.85)*****
>=43	**54.88 (16.21)*****	**55.93 (10.63)*****	**65.3 (16.12)*****	**50.98 (12.34)*****
Sex				
Male	57.68 (15.87)	57.59 (10.59)	67.59 (15.62)	52.78 (12.27)
Female	66.07 (12.63)	62.5 (17.68)	75 (23.57)	50 (0)
Unemployed				
Yes	**53.98 (15.62)*****	**56.05 (10.54)****	**65.03 (15.4)*****	**51.17 (12.86)****
No	**61.14 (15.31)*****	**59.05 (10.46)****	**70 (15.48)*****	**54.25 (11.49)****
Receives Disability Pension				
Yes	**49.7 (18.83)***	54.4 (13.69)	64.12 (18.67)	50 (13.61)
No	**58.15 (15.57)***	57.78 (10.39)	67.81 (15.44)	52.93 (12.17)
Type of the OST site				
Public	**55.87 (16.78)****	**56.73 (11.28)***	**66.35 (16.56)****	52.03 (13.06)
Private	**60.99 (13.46)****	**59.18 (9.07)***	**69.88 (13.53)****	54.12 (10.56)
Medication				
Methadone	**55.53 (16.75)****	**56.52 (11.24)***	**66.05 (16.59)****	**51.86 (13.14)***
Buprenorphine	**61.39 (13.47)****	**59.44 (9.15)***	**70.26 (13.48)****	**54.33 (10.44)***
Goes to OST site for medication everyday				
Yes	58.95 (14.82)	**59.11 (10.12)****	68.93 (14.51)	53.51 (11.9)
No	57.24 (16.22)	**57.04 (10.73)****	67.12 (16.02)	52.5 (12.39)
HIV positive				
Yes	**42.86 (10.1)***	**47.92 (9.41)***	63.89 (16.39)	44.79 (8.54)
No / Does not know / Refuse to answer / Not tested	**57.84 (15.84)***	**57.69 (10.58)***	67.65 (15.63)	52.85 (12.27)
Hepatitis C				
Yes	55.82 (16.42)	56.71 (10.6)	**65.85 (16.62)***	51.66 (12.01)
No / Does not know / Refuse to answer / Not tested	59.64 (15.03)	58.53 (10.54)	**69.42 (14.34)***	53.92 (12.42)
***** P-value <0.01**	**** P-value <0,05**	***P-value <0,1**		

A statistically significant difference was found in the average scores of the physical domain of the quality of life in terms of disability pensions received by the users of private and public sites (see Figure 12).
The domain of the physical quality of life of the participants in the private OST program exceeded the average score of the respondents involved in the public program. A similar trend was observed in the entire sample, as well as in those respondents who received and did not receive the disability pension. It should also be noted that the physical quality of life of the latter group was slightly better for both types of OST service users, than for those receiving a disability pension.

Figure 12: Physical Domain of the Quality of life According to the Disability Pension Receipt and OST Site Type



As demonstrated above in the Table 3, 64% to 70% of the study participants felt nervous, anxious, or had gone to extremes, perceived themselves as hopeless, in low spirits, depressed, has had little interest in doing things in the last 2 weeks. About half of the respondents also mentioned that they could not stop or control their worry during the same period. We wondered if these factors were related to the self-assessed quality of life scores. The analysis showed that all four of these factors are statistically significantly related to lower scores of the quality of life in all the domains, physical, psychological, social, and environmental domains (see Table 7).

Table 7: Mean and Standard Deviation of the Quality of Life by Anxiety and Depression (WHOQOL-Bref, 0-100 scale)

Characteristics (during the last two weeks)	Physical***	Psychological***	Social***	Environmental***
They felt nervous, anxious, or that they had gone to extremes				
Yes	**54.63 (15.56)**	**56.36 (10.57)**	**65.88 (16.33)**	**50.35 (11.85)**
No	**63.63 (14.66)**	**60.08 (10.2)**	**71.2 (13.25)**	**57.44 (11.62)**
They could not stop or control the worry				
Yes	**52.49 (15.54)**	**55.41 (11.01)**	**65.36 (16.89)**	**49.58 (11.91)**
No	**62.4 (14.61)**	**59.62 (9.8)**	**69.82 (13.91)**	**55.67 (11.83)**
They were in low spirits, feeling depressed, hopeless				
Yes	**54.95 (15.8)**	**56.21 (10.54)**	**66.23 (15.99)**	**50.4 (11.79)**
No	**64.07 (14.01)**	**60.89 (9.99)**	**71.11 (13.87)**	**58.24 (11.5)**
They had very little interest / little pleasure in doing things				
Yes	**54.61 (15.82)**	**56.15 (10.87)**	**66.01 (16.27)**	**50.2 (11.73)**
No	**63.55 (14.15)**	**60.42 (9.46)**	**70.9 (13.52)**	**57.63 (11.71)**

We have explored the complaints of anxiety and depression, named by the respondents over the past 2 weeks, as the determinants of satisfaction with the OST service. Bivariate regression analysis revealed that each of

them had an effect on satisfaction and this was statistically significant. In particular, in those respondents who felt signs of anxiety and depression, the likelihood of being satisfied with OST services was lower than in those who did not feel the signs of anxiety and depression (see Table 8).

Table 8: Factors Associated with OST Services Satisfaction

Factors		**Odds Ratio (95% CI)**	**P value<0.01*** **
They felt nervous, anxious, or that they had gone to extremes			
Yes	*No*	0.42(0.29-0.61)***	0.00
They could not stop or control the worry			
Yes	*No*	0.42(0.3-0.58)***	0.00
They were in low spirits, feeling depressed, hopeless			
Yes	*No*	0.23(0.15-0.35)***	0.00
They had very little interest / little pleasure in doing things			
Yes	*No*	0.44(0.31-0.64)***	0.00

8. DISCUSSION

8.1. Identified Paradoxes

Research revealed a kind of paradox: on the one hand, about two-thirds of the respondents are satisfied with the OST programs, while on the other hand, about one-third of the respondents are satisfied with their quality of life and health. In particular, 73.2% of respondents rated the OST services as "good" or "very good", while only 32.1% of respondents rated their quality of life as "good" and 0.3% as "very good"; Satisfaction with their own health ("satisfied" and "very satisfied") was expressed by 35.1% of the respondents.

Such a mismatch between the general satisfaction with the program and one's own quality of life and health may be due to the fact that patients of the OST programs in western Georgia do not expect the program to improve their health and quality of life. Or, perhaps, such a discrepancy might indicate that there is no explicit communication between the program staff and the beneficiaries about the expected outcomes of the program / treatment and the indicators of the program's success. The latter situation is similar to the one described in Chapter 4 of this report, when there was a mismatch between the patient's expectations for treatment and the treatment goals set by the medical staff in two studies conducted in Georgia in 2006-2007 (Chirikashvili, 2007; Todadze and Lezhava, 2008).

The above-mentioned paradox may also be explained by the fact that the health state and the quality of life of the beneficiaries were even worse before joining the program. Due to the design of the study, we were not able to measure respondents' satisfaction with their quality of life and health and compare them at the different stages of treatment (e.g., before treatment, after half a year, after one year). This would allow us to assess changes in these variables as it was done for example in the prospective design research "Progression of the substitution therapy in the users of different types of opioids", which revealed positive dynamics in terms of the improvement of both physical health and the quality of life of the research participants (Todadze and Mosia, 2016). However, the results of our study allow us to conclude that in order to achieve a higher degree of satisfaction with the life and health of the study participants, beneficiaries need additional services − eg, more intensive and effective psychosocial support. According to the findings of our study, only 37% of the respondents are satisfied with the psychosocial support provided on the OST sites.

Similar to the results of our study, the discrepancy between, on the one hand, program satisfaction and, on the other hand, satisfaction with the quality of life and health was also revealed by the results of a similar study conducted in Ukraine in 2019. In particular, 72% of Ukrainian respondents were generally satisfied with the program, while 36% rated their quality of life as "good" and 2% as "very good", and a total of 35% were satisfied with their health (EHRA, 2020).

Another paradox revealed by the quantitative component of our research is that 90.5% of the respondents indicated that the dose of the substitute drug was sufficient for them (that was not a case in the qualitative component of the study where part of the respondents stated that the dosage of the substitution drug is not sufficient for them). At the same time, 39% of the respondents reported that they had used illegal substances in the last 30 days in parallel with the substitute drug. This may, on the one hand, indicate that the prescribed dose of the substitute drug is not enough for them but they do not realize this − which indicates the need for additional communication with the treating physicians on this issue. On the other hand, to explain the given paradox, we may suspect that motivation of the users to be in the program is not to refrain from using illegal drugs. In this case, it is advisable, instead of punishment[14] to work with them to increase their motivation to stop using illicit drugs - which is mainly the competence of a psychologist and a social worker. In this regard an interesting result was observed in the 2017 study by the *Partnership for Health Research and Development*, *Operational Research of Barriers and Facilitators to Harm Reduction Services for IDUs (including female IDUs)*,

14 In case if use of illegal drug is revealed, the OST programs strategy is as follows: for the first time the patient receives a warning, for the second time he/she will be dismissed from the program.

where providers named the insufficient dose of the medication as one of the reasons for the beneficiary dissatisfaction with the program (PRAH, 2017).

Another paradox revealed by the study is the following: As mentioned above, 90.5% of the respondents are satisfied with the dose of the substitute drug. At the same time, only 35.1% of respondents indicated that they were satisfied or very satisfied with their own health. This discrepancy may indicate other medical problems and the need to proactivate offer appropriate medical services (different types of examinations, referral to other programs of treatment if necessary) to the beneficiaries.

The following results of the study were also unexpected: it was revealed that those respondents who went to the OST site daily to get the substitution drug rated the psychological domain of the quality of life higher than those who went once in 5 days. In a qualitative study, the vast majority of the respondents rated the practice of taking home the substitution drug several day dosage (which was allowed due to a pandemic) as positive; At the same time, they noted that some beneficiaries prefer to take home only a dosage of three days as it becomes easier for them to manage a small dosage. However, none of the respondents reported that they prefer to visit the site every day instead of taking home a dosage of a few days. According to the results of the quantitative research, daily attendance gives beneficiaries some psychological comfort. This may be related to positive communication / socialization experiences with peers, and it might as well indicate the need for the group psychosocial activities to be implemented; or, this may be indicative of difficulties to manage an amount of substitutive drug corresponding to the 5-days doze among the program beneficiaries.

8.2. The Lack of Sense of Safety

The study found that less than half of the respondents – 44.6% feel safe on the site. In the case of Ukrainian respondents, this figure was relatively high – 65% (EHRA, 2020). The matter of data protection and confidentiality plays an important role here. It is noteworthy that only a third of respondents were assured of confidentiality (206 respondents were “sure” and 29 respondents were “completely sure”). Georgian respondents seem to be needing more communication and information from the program staff and management on confidentiality matters, potential risks, risk reduction strategies, and related issues.

8.3. Low Level of Satisfaction with Various Services

Overall, the following characteristics of the OST program were rated relatively high by the respondents: general quality of service (68%), physical characteristics of the sites (59%), ease of access to the OST site (60.7%), quality of the medical services on the OST site (53.8%), sufficient level of information received from the staff on the site (66.5%), sufficient dose of the substitute drug (90.5%). As the paradoxes described above have revealed, a high evaluation of various characteristics may not reflect the objective state of those characteristics and may as well be a function of low expectations from them.

Relatively few respondents are satisfied with the psychosocial services on the site (37%); Only 38.8% of respondents indicated that they would expect to seek help from a site psychologist if needed (44% for the respondents in the Ukrainian study). At the same time, research found a high prevalence of anxiety and depression symptoms in the surveyed population (64.7% of the entire sample felt anxious, 46.4% could not manage their worry, 68.7% were in low spirits, 62.5% had little interest in activities). At the same time, almost three-quarters of the study participants (75.6%) have never turned to a program psychologist for help in the last 6 months. Only 1.5% of the respondents received systematic assistance from a psychologist during the same period, while 15% received one to three consultations. 8% of the respondents were not informed about the availability of neither psychologist nor social worker services on the site. This situation indicates that even when the beneficiaries are suffering from mental health problems, they do not seek appropriate help. As it turned out, some of them (8%) are not aware of the possibility of such help. Some of them may not consult a specialist because of stigma, or because they do not have any experience of receiving quality service. Some

of them may not be aware of their own mental health problems. A similar problem was identified in a public mental health epidemiological study conducted in Georgia in one of the most marginalized groups – the war-affected population. This epidemiological study found that in a representative sample of study respondents, of the individuals with mental health problems, only 24.8% sought appropriate services; 19.6% realized that they had mental health problems but did not seek help for various reasons; 54.8% had pronounced mental health problems but were unaware of it (Chikovani et al., 2015)

High rates of anxiety and depression are statistically significantly associated with lower levels of satisfaction with the OST services, which speaks about a great need for full-fledged psychological and psychosocial services in the OST patients. The previous study, "Methadone substitution therapy among HIV-positive patients in Georgia" indeed indicates the high effectiveness of full-fledged psychological services, which showed that the self-assessment of depression, quality of life and anxiety significantly improved in the context of providing an intensive course of psycho-counseling for HIV-positive patients. The authors conclude that the combination of the MST, the ART, and the psychoconsultation significantly improves physical and psychosocial state, quality of life, and compliance with the treatment among HIV-positive people who inject drugs (Todadze and Kavtiashvili, 2012). Similar results were obtained in one of the earlier researches devoted to the study of the effectiveness of pilot programs of methadone substitution therapy in Georgia among the patients who received methadone substitution therapy and psychosocial support. The results of the study showed a significant improvement in patients' psychosocial status, namely: a reduction in depression and anxiety levels, and an increase in the quality of life compared to the measures taken before enrollment in the program (Todadze and Lezhava, 2008).

8.4. Poorer Condition of the Public OST Program Beneficiaries in Comparison with the Private OST Program Beneficiaries

Analysis of the quantitative research data shows that statistically significant differences were observed between the public and private program beneficiaries on a number of important issues.

The study found that beneficiaries of the public program have a lower socio-economic status (low rates of income and employment status) than patients in the private programs. Also, the average scores of physical, psychological and social quality of life of the public program beneficiaries were lower than those of the private program beneficiaries. Furthermore, symptoms of depression (being in low spirits 72.1%, little interest in activities 70.1%) and anxiety (65.6% felt anxious, could not manage their worry 52.7%) were higher among beneficiaries of the public OST services than among users of the private OST services (62.7%, 53.8% and 63.2%, 35.2%, respectively). Likewise, there was a statistically significant difference in the prevalence of injecting drug use, with a higher use among the beneficiaries of the public programs (42.6% and 32.8%, respectively).

Since the public program is free for the beneficiaries, we can assume that the socio-economic status of the persons benefiting from these services, their quality of life and, consequently, their state of mental health, were already worse before joining the program than of those receiving the private OST services. These variables may have been even lower before joining the program. It should be noted that according to the World Drug Report, low socio-economic status is associated with substance use and substance use disorders (UNODC 2020). This speaks about the need to intensify the role of a social worker and about the high necessity for psychosocial adaptation-habilitation-rehabilitation programs and, in particular, the employment promotion among the public program beneficiaries.

9. CONCLUSIONS AND RECOMMENDATIONS

- The study found a gap between, on the one hand, the level of general satisfaction with the OST programs among the clients of the programs and, on the other hand, the level of satisfaction with their own quality of life and their own state of health. Our recommendation to fill this gap is that the OST Implementing body (in our case, the Ministry of Internally Displaced Persons from the Occupied Territories, Labor, Health, and Social Affairs of Georgia) and the implementing agencies both public and private, take the following steps:
  - Consider the quality of life of the program beneficiaries as one of the key indicators of program effectiveness, and direct the work to improve this indicator, by implementing multidisciplinary approach and case management, setting appropriate goals for the individual treatment plan of each beneficiary addressing their biopsychosocial needs, by carrying out appropriate work to achieve these goals, and by monitoring the progress;
  - Collaborate with the program beneficiaries to establish the expectation to improve the quality of life as one of the key expectations of the program. To do this, a proper informing of the beneficiaries and exchanging information with them shall be implemented on a regular basis using effective methods of communication;
  - Implement the practice of routine measurement of the quality of life of program participants at different stages of enrollment in the program: before enrollment in the program, at the initial stage and afterwards routinely once every six months.

- There is a gap between, on the one hand, the level of satisfaction of the respondents with the dose of the substitute medication and, on the other hand, the satisfaction with their own state of health. This gap may indicate that beneficiaries of the OST programs do not see a link between the dose of the medication and their own health state and/or require other biopsychosocial services of which they have low awareness and therefore no demand. To fill this gap, we have the following recommendations:
  - It is desirable that the site staff engage more actively in communicating with the beneficiaries about the link between a substitute medication dose and their health state, using effective communication methods;
  - It is desirable that the site staff proactively offer beneficiaries biopsychosocial services and/or referrals to receive services relevant to the identified biopsychosocial needs, which will improve their health state and the quality of life.

- A large proportion of respondents (39.1% of the total sample) report the use of illicit injecting psychoactive substances (aka High Risk Drug Use), which may indicate low motivation to quit illicit drug use (a) and/or mental health problems that require appropriate care (b). We find the latter explanation plausible, as about two-thirds of respondents experience symptoms of depression and anxiety in public OST services and just under two-thirds in private services. To address this problem, we offer the following recommendations to the OST service implementing institutions:
  - Pay special attention to the mental health problems of the beneficiaries: routine screening for common mental health problems – depression, anxiety, post-traumatic stress disorder, and, if necessary, planning and implementing (or redirecting) appropriate interventions in the individual treatment plan;
  - Ensuring the quality of work of psychologists: providing psychologists with the opportunity for professional training in evidence-based methods of working with addictions and relevant modules; As well as providing psychologists with professional supervision;
  - Using the method of motivational interviewing, psychologists and social workers shall work with the

clients to increase their motivation to quit the use of illegal psychoactive substances. To this end, it is desirable to provide them with professional training opportunities in motivational interview evidence modules (SAMHSA, 2018);
- Identify the biopsychosocial needs of the beneficiaries and reflect, put into practice and monitor the implementation of appropriate measures to meet their needs in the individual plan.

- The majority of the program respondents (55.4%) do not feel safe on the site and are not sure that their personal information will be kept confidential (only 29.9% of respondents are fully assured in confidentiality, 39.8% are semi-assured). In this regard, we will have the following recommendation:

  - It is desirable to proactively and explicitly inform the program beneficiaries about ensuring confidentiality, first at the stage of involvement in the program - by the program management and the treating physician, but also later - by a social worker, regularly, using effective methods of communication;
  - It is desirable that a social worker raised the awareness of the beneficiaries about the protection of their own (patients') rights by using effective methods of communication. This will help the beneficiaries to build trust in the institution. For this, it is desirable to properly improve the qualifications of social workers.

- The study revealed a significant vulnerability of beneficiaries involved in state-funded programs compared to beneficiaries involved in private programs. This applies to income and employment status, as well as the quality of life, health (including mental health) and the use of illicit psychoactive drugs. Likewise, the results of the study show that the beneficiaries of the program rarely use services other than receiving substitution medicine, such as consulting a social worker to meet other needs beyond medical needs, although the results clearly show these needs in both mental health and social condition (symptoms of anxiety and depressed mood, unemployment or low income). Promoting and activating the psychosocial component will have a positive impact on the immediate goals of the program and the quality of life in general, especially as it is in line with the national law, which states, among other things, that substitution therapy is intended to improve the somatic and mental state of opioid dependent persons, to facilitate their social adaptation and reintegration into society (Ministry of Internally Displaced Persons from the Occupied Territories, Labor, Health and Social Affairs of Georgia, 2014). In terms of improving the enforcement mechanisms of this legislation, we will have the following recommendations for the organizations implementing public OST programs:

  - To focus greatly on the biopsychosocial, holistic multidisciplinary approach in the following way: real implementation of the case management method into the practice in order to take into account not only the medical-biological but also the psychological and especially the social needs of the program beneficiaries;
  - In order to facilitate the employment of program beneficiaries, it is necessary to think about advocating for workplaces for them – both at the level of the legislation and in actual practices. This should be done through collaboration with the community organizations of people who use drugs.

- The study revealed that only 85% of the sample was tested for HIV and hepatitis C, of which 6 respondents were HIV positive – 5 were on ART and 1 was not receiving adequate treatment. The prevalence of hepatitis C in the tested respondents was 59.8% and 17% of them were never treated. Majority of the sample (94.2%) stated that they need OST treatment while only 33% stated that they need other medical services, which reveals low awareness on own treatment needs among them. At the same time, research findings reveal that having viral diseases is in statistically significant association with lower level of life satisfaction. In this regards we will have the following recommendations for the treatment institutions providing OST:

  - It is desirable to maintain proactive communication with those OST patients who are not tested yet for viral diseases to motivate them for Voluntary Counselling and Testing (VCT), to be able to indicate and treat infectious diseases in the whole cohort of beneficiaries;

- It is desirable to proactively offer appropriate treatment or referral to those HIV and hepatitis C positive patients who do not receive treatment, and to help them to understand linkage between infectious diseases and quality of life.

- A third of the quantitative research respondents indicated that they had been in a detention facility, including temporary detention, for which the median number of months spent in a denetion facility was 36 (3 years). This is indicative of punishment oriented drug policies in the country and reveals necessity of drug legislation reform.

- The quantitative component of the study revealed that a smaller proportion of respondents, enrolled in the public program, were introduced to the program rules when enrolling (72.6% and 85.8%), as well as knew the exit rules than in the private program (76.4% and 91.1%). The respondents of the qualitative component of the study reported that in many cases, the patient may be in a state of withdrawal, or under the effect of a psychoactive substance during the first appointment with a doctor at a substitution therapy facility, which makes it difficult for them to comprehend information about therapy prior to treatment. Based on that we will recommend to maintain communication about the program rules during the treatment course regularly or at least at a point when patient is in a good enough condition to comprehend corresponding information.

- More focus on the individual approach is desirable during the treatment process, this will better meet the patient's needs. For example, before the pandemic beneficiaries were visiting site every day and no take-home doze was allowed; during the pandemic all beneficiaries are given 5-days doze to take home, while some of them, in the qualitative component of the study, explicitly stated that they do prefer to take home less than 5 days doze (i.e. 3 days doze). Depending on whether they feel the need to take home less amount of medication, or an additional medication, the appropriate dose shall be adjusted, or an additional treatment shall be prescribed.

- The qualitative component of the study revelaed that there are a lot of myths (misinformation) spread among the program beneficiaries about different aspects of OST programs (as are: nature and goal of OST programs, inclusion criteria, etc.). Many of these myths people heard from general population. This reveals necessity of elaboration of a communication strategy focused at rising awareness on OST not only among program beneficiaries but also among general public, via implying PR activities. This will contribute to overcoming stigma and discrimination towards program beneficiaries.

10. RESEARCH STRENGTHS AND LIMITATIONS

The strength of this research is that it implies community based participatory approach. Recruitment for the qualitative component of the study and the quantitative component of the study was conducted by representatives of the community of people who use drugs (community based organization) and the degree of trust from the respondents was high. This also came into view from the fact that a significant part of the respondents did not hesitate to admit that they had used an illegal psychoactive substance during the past month. The community of people who use drugs also provided valuable feedback on the questionnaire and final report, as well as participated in formulating the recommendations based on the study results.

The strength of the research is that the data was collected through the RedCap platform, which enabled immediate assessment of the quality of each questionnaire, feedback to the interviewer, and refinement of his or her performance.

Another strength of the research is that it was able to survey the representative sample of beneficiaries of the OST programs in western Georgia, and therefore, the results of the research can be generalized to the beneficiaries of the OST programs in the western region of Georgia.

Another strength of the study is that in addition to the OST service satisfaction and the quality of life, we studied the common mental health problems of respondents, such as symptoms of anxiety and depression, which allowed us to understand the results of the research in terms of biopsychosocial needs of the OST program beneficiaries and observe a statistically significant relationship between the low levels of satisfaction with the OST program services and the high levels of expression of mental health symptoms. This provides a clear vision of one of the most important areas for improving the OST services (paying more attention to managing the mental health state of the beneficiaries and strengthening psychosocial support and multidisciplinary care).

We can point out the following limits of the research:

The respondents of the study are hidden (so-called “marginalized”) population. Various studies findings report that women rarely enroll in the drug treatment programs, which can be attributed to stigma; but, there are other interesting findings as well: women are more likely to enroll in treatment, if they are able to access tailored programs (EMCDDA, 2006), which again points to the need of specialized services. In the quantitative component of our study, only 0.3% of the respondents surveyed in the study were female (2 respondents in total). Because of this, the study fails to reflect the needs of female beneficiaries and the experience of being in the substitution therapy. A separate research is necessary to study the degree of satisfaction of the female beneficiaries and it should be set as an immediate task.

Another limit of our study is: the research design and sampling methodology required the recruitment of every second beneficiary who arrived at the target site within 5 days; However, the extent to which this recruitment strategy was adhered to could not be monitored. Research monitoring capabilities were limited. For example, routine monitoring, such as writing down respondents’ telephone numbers and randomly calling them failed, as this would have prevented the participation of hidden population in the survey. Neither field monitoring was possible – due to a pandemic.

The following limitations of the qualitative component of the research should also be noted: Representatives of the community of people who use drugs organization recruited respondents for the qualitative component of the study (from various cities/sites in western Georgia), which made it easier to contact them; However, at the same time, such recruitment did not prevent recruitment bias characterized to studying the hidden

population (so-called “marginalized” groups) (EHRA, 2020). In addition, qualitative interviews were conducted in an online format, due to the pandemic - which made it difficult to observe nuances in the interview process such as body language, intonation, etc., making it difficult to assess the respondent’s sincerity, openness and the quality of sharing the authentic information.

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12. TABLES AND FIGURES

13. APPENDICES

Appendix I: Aim, Objectives and Questions of the Research

The aim of the research was to study the satisfaction of beneficiaries of the OST programs in Western Georgia with the programs, their quality of life and the factors affecting their satisfaction and the quality of life, and to develop recommendations for the program refinement based on the study.

The research objectives and questions were as follows:

- **Objective:** To assess the satisfaction with OST services among the beneficiaries of the OST programs in Western Georgia.

Research Relevant Questions:

- How satisfied are the beneficiaries with OST services in general?
- How satisfied are the beneficiaries with the medical services?
- How satisfied are the beneficiaries with psychosocial services?
- How satisfied are the beneficiaries with the physical conditions of the program?
- How safe do the beneficiaries feel in the program?
- What factors are related to satisfaction with the OST program?
- How do the beneficiaries of public and private OST programs differ in this regard?

- **Objective:** To identify the biopsychosocial needs related to the participation in the program and the level of satisfaction among the beneficiaries of the OST programs in Western Georgia.

Research Relevant Questions:

- What are the information needs of the beneficiaries and how satisfied are they?
- What are the medical needs of the beneficiaries and how satisfied are they?
- What are the mental health needs of the beneficiaries and how satisfied are they?
- What are the needs related to social assistance and how satisfied are they?
- What is the difference between the beneficiaries of the public and private OST programs in this regard?

- **Objective:** To determine the level of subjective satisfaction with the quality of life among the beneficiaries of the OST programs in Western Georgia.

Research Relevant Questions:

- What is the level of subjective satisfaction with the quality of life among the beneficiaries?
- What is the level of satisfaction with the physical domain of the quality of life?
- What is the level of satisfaction with the psychological domain of the quality of life?
- What is the level of satisfaction with the social domain of the quality of life?
- What is the difference between the beneficiaries of the public and private OST programs in this regard?

Appendix II: Informed Consent Form for the Qualitative Component

Welcome and please participate in the survey **"Study of the Satisfaction of Beneficiaries with the Substitution Therapy Services in Western Georgia".**

The aim of the study is to assess the degree of satisfaction of patients involved in the opioid substitution therapy (OST) program in western Georgia.

The study is conducted by Ilia State University *Institute of Addiction Studies*, in collaboration with the foundation *Global Initiative in Psychiatry - Tbilisi* and the community organization *"Rubicon*", with the support of the Eurasian Harm Reduction Association.

The study involves two stages: In the first stage, interviews are conducted with the beneficiaries of the OST program to identify the issues that play a role in their satisfaction with the OST program. Based on this first component of the study, a sophisticated quantitative questionnaire will be administered to a larger number of the OST program beneficiaries to obtain more detailed information.

We invite you to participate in the first stage of the research. It involves an online interview (with Skype platform) on service satisfaction issues, conducted by a member of a research team. In particular, questions will be asked on topics such as: since when did you join the OST program; What has changed in your life since joining the program; How satisfied are you with participating in this program and with what specifically; What can be improved, etc.? The duration of the interview will be about an hour and thirty minutes. To participate in the research, the respondent must be a beneficiary of the OST program in Western Georgia, and must be willing to participate in the study.

Consentaneity: Participating in the research is completely voluntary and you can discontinue the study any time - at any stage of the research. This will not cause you any problems.

Anonymity, Confidentiality and Data Protection: The study does not collect personal information about specific persons (name, surname, ID number, etc.), therefore, identifying a person based on a certain answer is impossible. Moreover: if in an online interview you prefer to have your face covered, there is a possibility of that as well. An audio recording will be made during the research so that the researcher does not miss the important messages spoken by the participants. The data (audio recording and its transcript) will be stored in a secure database and will not be accessible to anyone, except the research team. Anonymous data will be destroyed within one year of completing the research.

Personal Benefits: We are aware that the participants' time is valuable, therefore a symbolic gift of 12.60 GEL is provided as a personal profit to participate in the research, which will be given to you by the research coordinator, a representative of the non-governmental organization "Rubicon".

Social Benefits: The results of the study will also be beneficial for the OST program beneficiaries as they help us better understand the needs of the OST program beneficiaries and provide this information to decision makers for the maximal refinement of the existing services.

Your Rights: None of your rights will be violated by participating in the study. The study was approved by the Ethics Comity of Ilia State University, Faculty of Arts and Sciences. You have the right to request information that will help you understand the core of the research. If you have any doubts during the research process, in terms of protecting your rights, you can contact the Principal Investigator - Jana Javakhishvili (see the contact email below).

Expected Risk: The risk that the information collected during the study will be leaked outside the study is minimal, as the research data is stored on password-protected computers, which are not accessible to anyone outside the research team (see data storage and privacy above).

The likelihood that answering the questions will cause you any emotional discomfort is minimal. If at the time of completing the questionnaire you realize that you wish to seek help with the free mental health hotline,

the relevant contact information is provided at the end of the questionnaire.

Contacting the research team: In the future, if you have any questions about the study, or if you would like to learn more, you can contact us at the following email addresses:

Researcher: addictology@iliauni.edu.ge

Principal Investigator: darejan.javakhishvili.1@iliauni.edu.ge

Free Mental Health Service:

Hotline: 2 911 000

Thank you for participating!

I consent

- The study was described to me in an understandable language
  ☐ Yes ☐ No
- I understand what it means to participate in the study and I voluntarily agree to participate in the study
  ☐ Yes ☐ No
- I am aware that participating in the interview depends only on my desire to do so and it will be acceptable if I reconsider participating in the study any time
  ☐ Yes ☐ No
- I am aware that in this study my identity will not be revealed to anyone - the interview is confidential
  ☐ Yes ☐ No
- I am aware that any personal information I provide to the research will be kept confidential
  ☐ Yes ☐ No
- I am aware that I can contact the researcher at any time regarding the study and ask any questions
  ☐ Yes ☐ No

I agree to participate in this study

Respondent's signature: *(Write your initials)*

Signature of the person receiving the consent form:

Date ..... / ..... / .....

Appendix III: Qualitative Interview Guide

Tell us about yourself, your family, what do you do, where do you work, your substance-use experience…

How long have you been in the OST?

1. The needs and expectations regarding the treatment

Please, tell us how did you start treatment in the OST. What was happening at that moment in your life; How did you learn about the substitution therapy; Did you have any experience of taking the medication at the time, or experience of using a substitute medication for non-medical purposes before joining the program?

Have you had the need or experience of any other treatment than the OST before or in parallel?

Please, tell us in details how did you get involved in the program. Did anyone help you (relatives, friends, acquaintances, social workers, medical workers, etc.)?

What were your first impressions, what difficulties did you face, did anything happen that you did not expect (whether it is good or bad)?

Did your loved ones know that you were being involved in the program? How did your loved ones react to your involvement in the OST - did they support you or try to change your mind?
Do they know now? If they know - what is their attitude to it?

Did you have any expectations that your life would change and specifically how? E.g., labor-related expectations; Education expectations; Expectations of additional qualifications?

What has changed in your life specifically since joining the program?

2. Communication with the site staff and other patients

Please, tell us in details how do you take the medication; How do you get to the site; How do you interact with the site staff and other patients (medical workers, social workers, other patients); What do you do after taking the medication, and what do you want to do after taking it?

Please, tell us in detail how do you interact with nurses, doctors, social workers, psychologists on the site? Do you receive any other services on the site besides the medication?

Have you ever had any additional requests for the site staff? For social workers? What specifically? Have you heard of any patients having requested any additional services? What was it specifically? How did the site staff react?

Please, tell us how do you understand the OST treatment process. Has anyone told you how the treatment process goes? What are your prospects and approximate times for completion? What options are there for voluntary discontinuation of the treatment; Redirecting to other programs? What do you know about other programs?

3. Satisfaction / dissatisfaction during the treatment process

How satisfied are you with your involvement in the OST? What exactly are you satisfied with? What exactly are you dissatisfied with - what needs to be improved?

Please, tell us how was the dosage of the medication chosen. How satisfactory do you think it was then? How satisfactory is it now? Did you have a desire to change the medication or the way you administered it? If you have had such a request to the site staff – please, tell us about it in detail. If such a request was not fulfilled, what do you think - why? How did you solve this problem yourself; How do other patients solve similar problems?

Please, tell us how patients' behavior is being controlled on the sites; How difficult or easy it is to follow the existing rules. Why? Have you had any cases of breaking the rules? Please, tell us in more detail. Is there a formal list of the rules? And an informal listing?

Do you think the site staff is breaking any rules? Have you had the opportunity to seek external help on the site to solve your problems? Please, tell us in more detail.

4. The experience of participating in or refusing to participate in the specific OST programs

If this is not your first experience with enrolling in the OST program, please tell us about your experience of discontinuing the OST service. Was it your own decision or was it the decision of the site employee / management? Please, tell us how it happened. What happened next: did you go back to the street drug-use, stopped using them for a while, did you go through the rehabilitation, did you go back to the OST again? Do you think this experience of yours is unique or typical and many people face the same problems?

5. Changes in perceptions, expectations, and needs over the course of time related to the participation in the OST programs

How would you describe, on the whole, how well does your involvement in OST meet your initial expectations? Were your initial needs that you had when you joined the program met? Which needs of you were met and which were not? What new needs have arisen? Do you think the same story applies to other patients or their situation is different? If it is different - how?

What would you like to change in the program? What services would you add for you and for other patients?

Would you recommend becoming an OST patient to your opioid-dependent acquaintances, friends, relatives? Why? To whom would you recommend it and to whom would you not?

Appendix IV: Informed Consent Form for the Quantitative Component

Welcome and please participate in the survey **"Study of the Satisfaction of Beneficiaries with the Substitution Therapy Services in Western Georgia".** The aim of the study is to assess the degree of satisfaction of patients involved in the opioid substitution therapy (OST) program in western Georgia.

The study is conducted by Ilia State University *Institute of Addiction Studies*, in collaboration with the foundation *Global Initiative in Psychiatry - Tbilisi* and the community organization *"Rubicon"*, with the support of the Eurasian Harm Reduction Association.

The study involves two stages: In the first stage, interviews are conducted with the beneficiaries of the OST program to identify the issues that play a role in their satisfaction with the OST program. Based on this first component of the study, a sophisticated quantitative questionnaire will be administered to a larger number of the OST program beneficiaries to obtain more detailed information.

The second component of the study entails participating in the given survey, completing a questionnaire on a specially assigned tablet, with the help of our research team. It is with this form of informed consent that we invite you to participate in that survey.

In the questionnaire, you will be asked questions such as: your demographic data - age, income, etc., how long have you been using drugs, how long have you been involved in the OST program, how satisfied are you with the participation in the program and its specific components: medical services, regimes, psychologist services, social worker services, etc. There will also be questions about your quality of life - how well do you feel physically, psychologically, etc. The duration of the interview will be about an hour and thirty minutes. To participate in the research, the respondent must be a beneficiary of the OST program in Western Georgia, and must be willing to participate in the study.

Confidentiality and Data Protection: The study does not collect personal information about specific persons (name, surname, ID number, etc.). Instead, each respondent will be given a code to avoid duplication of the

data. Thus, identifying a person based on a certain answer is impossible. The data will be collected in a secure database, the RedCap, that complies with the ethical regulations for the protection of personal information collected during the research process. The collected data will be stored in the computers of the research team and no one except the research team will have access to it. Anonymous data will be destroyed within one year of completing the survey.

Expected Benefits: This research gives you a direct symbolic benefit: GEL 9.45, which will be given to you by the research coordinator, a representative of the non-governmental organization "Rubicon".

Social Benefits: The results of the study will also be beneficial for the OST program beneficiaries as they help us better understand the needs of the OST program beneficiaries and provide this information to decision makers for the maximal refinement of the existing services.

Consentaneity: Participating in the research is completely voluntary and you can discontinue the study any time - at any stage of the research. This will not cause you any problems.

Your rights: None of your rights will be violated by participating in the study. The study was approved by the Ethics Comity of Ilia State University, Faculty of Arts and Sciences. You have the right to request information that will help you understand the core of the research. If you have any doubts during the research process, in terms of protecting your rights, you can contact the Principal Investigator - Jana Javakhishvili (see the contact email below).

Expected Risk: The risk that the information collected during the study will be leaked outside the study is minimal, as the research data is stored on password-protected computers which are not accessible to anyone outside the research team (see the paragraph above).

As far as the questionnaire is concerned with sensitive topics, there is a small probability that answering the questions will cause you some emotional discomfort, however, this probability is minimal. If at the time of completing the questionnaire you realize that you wish to seek help with the free mental health hotline, the relevant contact information is provided at the end of the questionnaire.

Contacting the research team: In the future, if you have any questions about the study, or if you would like to learn more, you can contact us at the following email addresses:

Researcher: addictology@iliauni.edu.ge

Principal Investigator: darejan.javakhishvili.1@iliauni.edu.ge

Free Mental Health Service:

Hotline: 2 911 000

Thank you for participating!

I consent

- The study was described to me in an understandable language
  ☐ Yes ☐ No
- I understand what it means to participate in the study and I voluntarily agree to participate in the study
  ☐ Yes ☐ No
- I am aware that participating in the interview depends only on my desire to do so and it will be acceptable if I reconsider participating in the study any time
  ☐ Yes ☐ No
- I am aware that in this study my identity will not be revealed to anyone - the interview is confidential
  ☐ Yes ☐ No

- I am aware that any personal information I provide to the research will be kept confidential
  ☐ Yes ☐ No
- I am aware that I can contact the researcher at any time regarding the study and ask any questions
  ☐ Yes ☐ No

I agree to participate in this study

Respondent's signature: *(Write your initials)*

Signature of the person receiving the consent form:

Date ..... / ..... / .....

Appendix V: Quantitative Questionnaire

Date:

ID: Respondent code.

Site: To interviewer: Please indicate the location of the site where the research participant receives the OST service:

1. Kutaisi
2. Zugdidi
3. Senaki
4. Batumi
5. Zestafoni
6. Sachkhere

D6[15]. Program Type Online:

7. Public
8. Private

D7. What is the frequency of visiting the site to receive the substitute drug?

1. I visit the site daily
2. I go to the site once in 5 days
3. Other (please specify):

D8. OST drug:

1. Methadone
2. Buprenorphine

D1. Your gender?

- Female
- Male
- Other _____

15 The letters, numbering (and in some cases - acronyms) in front of the questions represent the question code and not the numbering.

D2. How old are you (number of full years)?

D3. How many times have you participated in the OST programs (except the current one)?

The next few questions will be about your health and the OST program. Please choose the answer that suits your feelings at the time of the interview:

W1. How would you rate your quality of life?
1. Too badly
2. Badly
3. Neither badly nor well
4. Well
5. Very well

O1. Overall, how do you rate the OST services?
1. Too badly
2. Badly
3. Neither badly nor well
4. Well
5. Very well

W2. How satisfied are you with your health condition?
1. Very dissatisfied
2. Dissatisfied
3. Neither dissatisfied nor satisfied
4. Satisfied
5. Very satisfied

O2. How satisfied are you with the OST service you receive?
1. Very dissatisfied
2. Dissatisfied
3. Neither dissatisfied nor satisfied
4. Satisfied
5. Very satisfied

W3. How hindering is your physical condition in performing your duties during the day?
1. Very hindering
2. Hindering
3. 50/50
4. Not hindering
5. Not hindering at all

O3. How much do you need the OST for normal functioning in daily life?
1. I need it very much
2. I need it
3. 50/50
4. I do not need it
5. I do not need it at all

W4. To what degree do you need various medical care (other than the OST) to function normally in daily life?

1. I need it very much
2. I need it
3. 50/50
4. I do not need it
5. I do not need it at all

W5. How satisfied are you with your life?

1. Completely dissatisfied
2. Dissatisfied
3. At an average rate
4. Satisfied
5. Very satisfied

W6. How meaningful is your life in your estimation?

1. Very meaningful
2. Meaningful
3. 50/50
4. Not meaningful
5. Completely meaningless

O4. How does the OST staff's behavior towards you influence your decision to continue or to stop being in the program?

1. Strongly influences
2. Influences
3. 50/50
4. Does not influence
5. Does not influence at all

O5. How important is the attentive attitude of the OST staff to you to continue participating in the program?

1. It is very important
2. It is important
3. 50/50
4. It is not important
5. It is not important at all

W7. How well can you concentrate?

1. I can not at all
2. A little
3. At an average rate
4. Mainly, I can
5. I can always

O6. How sufficient is the information you get from the staff about the OST on the site?

5. Completely sufficient
4. Sufficient
3. 50/50
2. Not sufficient
1. Not sufficient at all

W8. How safe do you feel in everyday life?

5. I feel very safe
4. I feel safe
3. 50/50
2. I do not feel safe
1. I do not feel safe at all

O7. How safe do you feel on the OST site?
5. I feel very safe
4. I feel safe
3. 50/50
2. I do not feel safe
1. I do not feel safe at all

To what extent do you agree with the following provisions regarding the OST site you visit / you are attached to:

O8. The site space (rooms) is quite capacious:
5. I completely agree
4. Mainly, I agree
3. I do not completely disagree
2. I agree more than disagree
1. I do not agree

O10. The site space is clean:
5. I completely agree
4. Mainly, I agree
3. I do not completely disagree
2. I agree more than disagree
1. I do not agree

O11. In the building / space where I take the medication, there is a place where I can sit down to consult a doctor and talk about my personal health problems in such a way that no one interferes (without a third person presence):
5. I completely agree
4. Mainly, I agree
3. I do not completely disagree
2. I agree more than disagree
1. I do not agree

O9. It is possible for patients to shut the door of the toilet:
1. Yes
2. No
98. I do not know

O9_1. Is there video surveillance installed on your site?
1. Yes
2. No
98. I do not know

O9_2. If there is video surveillance in the toilet, how much does it discomfort you?
0. Not applicable (there is no video surveillance in the toilet)
5. Causes me severe discomfort
4. Causes me discomfort
3. 50-50
2. Does not cause me discomfort
1. Does not cause me discomfort at all

O12. Overall, how satisfied are you with the physical characteristics of the site (the size of the building / the room, the possibility to lock the toilet door, the existence of the surveillance camera, waiting area, etc.)?

1. I am not satisfied at all
2. I am not satisfied
3. I am neither satisfied nor dissatisfied
4. I am satisfied
5. I am fully satisfied

W9. In general, how healthy do you think the environment in which you live is (e.g. buildings, roads, parks)?

5. Very healthy
4. Healthy
3. 50/50
2. Unhealthy
1. Completely unhealthy

Next part of the questions concerns your self-perception and the ability to perform certain functions during the last 4 weeks:

W10. Do you have enough energy for daily life?

5. Completely enough
4. Enough
3. 50/50
2. Not enough
1. Not enough at all

W11. Are you satisfied with your appearance?

5. Completely satisfied
4. Mainly satisfied
3. 50/50
2. More dissatisfied than satisfied
1. Not satisfied

W12. Do you have enough money to meet different needs of yours?

5. Completely enough
4. Enough
3. 50/50
2. Not enough
1. Not enough at all

W13. How accessible is the information that you need in your daily life? (any information you need)

5. Easily accessible
4. Sufficiently accessible
3. 50/50
2. Insufficiently accessible
1. Completely inaccessible

W14. How sufficient are your means to relax and have fun?

5. Completely sufficient
4. Sufficient
3. 50/50
2. Insufficient
1. Completely insufficient

O13. Is the substitute medication dose you are taking sufficient for you?

5. Completely sufficient
4. Sufficient
3. 50/50
2. Insufficient
1. Completely insufficient

W15. How easily can you reach (commute to) the places you need?

5. Very easily
4. Easily
3. 50/50
2. Not easily
1. Not easily at all

O14. How convenient is it for you to visit the OST site?

5. Very convenient
4. Convenient
3. 50/50
2. Inconvenient
1. Completely inconvenient

O15. How do you rate the quality of medical services on the site?

1. It is too bad
2. It is bad
3. It is neither bad nor good
4. It's good
5. It is very good

O16. How often have you contacted the OST site social worker for assistance in the last 6 months?

98. I am not informed about the availability of such a service
97. There is no social worker on the site
0. I have never contacted
1. I contacted one to three times
2. I systematically contact them

O16_1. How often have you consulted the OST site psychologist in the last 6 months?

98. I am not informed about the availability of such a service
97. There is no social worker on the site
0. I have never contacted
1. I contacted one to three times
2. I systematically contact them

O17. How satisfied are you with the psychosocial support you receive on the site?

1. I am not satisfied at all
2. I am dissatisfied
3. I am neither dissatisfied nor satisfied
4. I am satisfied
5. I am very satisfied

Please note, that the following questions are about your satisfaction with various aspects of your life during the last four weeks:

W16. How satisfied are you with your sleep?
1. I am completely dissatisfied
2. I am dissatisfied
3. I am neither dissatisfied nor satisfied
4. I am satisfied
5. I am completely satisfied

W17. How do you assess your coping skills for your day-to-day duties?
1. I am completely dissatisfied
2. I am dissatisfied
3. I am neither dissatisfied nor satisfied
4. I am satisfied
5. I am completely satisfied

W18. How satisfied are you with your work productivity?
1. I am completely dissatisfied
2. I am dissatisfied
3. I am neither dissatisfied nor satisfied
4. I am satisfied
5. I am completely satisfied

W19. How satisfied are you with yourself?
1. I am completely dissatisfied
2. I am dissatisfied
3. I am neither dissatisfied nor satisfied
4. I am satisfied
5. I am completely satisfied

Please note, that the following questions are about your satisfaction with other people over the past four weeks:

W20. How satisfied are you with the relationships you have?
1. I am completely dissatisfied
2. I am dissatisfied
3. I am neither dissatisfied nor satisfied
4. I am satisfied
5. I am completely satisfied

W21. How satisfied are you with your sex life?
1. I am completely dissatisfied
2. I am dissatisfied
3. I am neither dissatisfied nor satisfied
4. I am satisfied
5. I am completely satisfied

W22. How satisfied are you with the support you receive from your acquaintances and friends?
1. I am completely dissatisfied
2. I am dissatisfied
3. I am neither dissatisfied nor satisfied
4. I am satisfied
5. I am completely satisfied

O19. How satisfied are you with your relationship with your acquaintances?

1. I am completely dissatisfied
2. I am dissatisfied
3. I am neither dissatisfied nor satisfied
4. I am satisfied
5. I am completely satisfied

O18. How satisfied are your acquaintances with your participation in the OST?

1. They are completely dissatisfied
2. They are dissatisfied
3. They are neither dissatisfied nor satisfied
4. They are satisfied
5. They are completely satisfied

Please note, that the following questions are on how satisfied you are with the availability of the infrastructure and services over the last four weeks:

W23. How satisfied are you with the living conditions of the place where you live now?

1. I am completely dissatisfied
2. I am dissatisfied
3. I am neither dissatisfied nor satisfied
4. I am satisfied
5. I am completely satisfied

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

1. I am completely dissatisfied
2. I am dissatisfied
3. I am neither dissatisfied nor satisfied
4. I am satisfied
5. I am completely satisfied

W25. How satisfied are you with the transport you use?

1. I am completely dissatisfied
2. I am dissatisfied
3. I am neither dissatisfied nor satisfied
4. I am satisfied
5. I am completely satisfied

O20. On a scale of 1 to 10, where 1 means “tense, stressed / anxious” and 10 means “relaxed / calm”, which score best describes your inner state while on the OST site?

1 2 3 4 5 6 7 8 9 10

O21. On a scale of 1 to 10, where 1 means “tense, stressed / anxious” and 10 means “relaxed / calm”, which score best describes your inner state when communicating with a nurse on the OST site?

1 2 3 4 5 6 7 8 9 10

O22. On a scale of 1 to 10, where 1 means “tense, stressed / anxious” and 10 means “relaxed / calm”, which score best describes your inner state when consulting a doctor on the OST site?

1 2 3 4 5 6 7 8 9 10

O23_SW. Is there a social worker on your site?

2. Yes and I have addressed him/her
1. Yes, but I have not addressed him/her
0. No.
98. I do not know

O23. On a scale of 1 to 10, where 1 means “tense, stressed / anxious” and 10 means “relaxed / calm”, which score best describes your inner state when consulting a social worker on the OST site?

1 2 3 4 5 6 7 8 9 10

O23_1_psy. Is there a psychologist on your site?

2. Yes and I have addressed him/her
1. Yes, but I have not addressed him/her
0. No.
98. I do not know

O23_1. On a scale of 1 to 10, where 1 means “tense, stressed / anxious” and 10 means “relaxed / calm”, which score best describes your inner state when consulting a psychologist on the OST site?

1 2 3 4 5 6 7 8 9 10

The following questions are about how often you have experienced various states during the last four weeks:

W26. Over the past 4 weeks, how often have you had negative feelings, eg, bad mood, despair, anxiety, depression?

1. Never
2. Sometimes
3. Quite often
4. Very often
5. Always

O24. How likely is it that you will consult an OST site psychologist if you have a chance?

1. Very unlikely
2. Unlikely
3. 50/50
4. Likely
5. Very likely

O25_1. Are you aware of the possibility of filing a complaint if you are not satisfied with the service?

1. Yes
0. No

O26. If needed, how likely is it that you will file a complaint?

1. Very unlikely
2. Unlikely
3. 50/50
4. Likely
5. Very likely

O25. Have you ever formally sued an OST site (e.g., writing a formal complaint or otherwise)?

1. Yes
0. No

O27. Were you informed about the rules of the program when you last registered for the OST program? Even if this is your first time enrolling in the program:
1. Yes
0. No / I do not know
98. I refuse to answer

O28. If you were a user of the OST program more than once, did you leave the program at least once by your decision?
1. Yes
0. No / I do not know
98. I refuse to answer

O29. If you were a user of the OST program more than once, did you leave the program at least once at the request / decision of the program staff?
1. Yes
0. No / I do not know
98. I refuse to answer

O30. Are you satisfied with the duration of treatment in the OST program?
1. Yes
0. No

O30_1. If you are not satisfied, what do you prefer - to get treatment for a shorter or a longer period of time?
0. A shorter period
1. A longer period

O31. Do you know the rules for leaving the OST program?
1. Yes
0. No.

O32. If you have tried to quit the program, did the medical staff resist you in quitting the program?
1. Yes
0. No / I do not know
98. I refuse to answer

O33. How confident are you that the personal information you disclose to the OST workers is confidential (it will not be given to a third party)?
1. I'm not sure at all
2. I'm not sure
3. I am neither sure nor unsure
4. I'm sure
5. I'm absolutely sure

O33_1. On a scale from 1 to 10 how much do you trust the following stuff?
1. Nurse
2. Laboratory assistant
3. Guard
4. Head of the institution
5. Social worker
6. Psychologist

D4. Approximately how old were you when you first used opiates / opioids (non-injectable or injectable). Please, specify the year.

D5. When was the last time you joined the OST program (even if this is your first-time enrollment)? Please, indicate approximately if you do not remember the exact date.

D6_2. How much does it cost you per month to participate in the OST program (including buying tests, buying cups, etc., transportation costs excluded) (in GEL)?

D5_1. How long did the process take from the first visit to the start of dose selection (including being on a waiting list, taking tests and medical consulting)? Please, indicate the number of days, for example, there are on average 30 days in 1 month, 60 days in 2 months, and so on.

D8_1. What is the current dosage you are taking (mg)?

D9. Do you take any additional medications prescribed by a doctor (psychiatrist, narcologist)?
1. Yes
0. No / I do not know
98. I refuse to answer

D9_1. If yes, indicate which:
1. Antidepressant
2. For sleeping
3. Analgesic
4. Tranquilizer
5. Other

D9_1_other. If other, please specify:

D10. Have you ever been tested for HIV / AIDS?
1. Yes
0. No / I do not know
98. I refuse to answer

D11. What was the test result?
0. I was told that I do not have HIV / AIDS
1. I was told that I have HIV / AIDS
2. I was told that the result is unclear
3. I do not know
98. I refuse to answer

D12. When did you first learn about HIV / AIDS diagnosis? Please, indicate approximately if you do not remember the exact date.

D13. Are you currently receiving antiretroviral (medication for AIDS) treatment?
1. Yes
0. No / I do not know
98. I refuse to answer

D14_1. Do you know what viral load do you have?
1. Yes
0. No / I do not know
98. I refuse to answer

Please, indicate the amount of the virus in 1 ml of blood:

D15. Have you ever been tested for hepatitis C?
1. Yes
0. No / I do not know
98. I refuse to answer

D16. What was the result?
0. I was told that I do not have hepatitis C
1. I was told that I have hepatitis C
2. I was told that the result is unclear
3. I do not know
98. I refuse to answer

D17. Have you ever taken medication to treat hepatitis C?
0. Question is not applicable for me (I am not receiving treatment)
1. Yes, I am currently receiving treatment
2. Yes, for the last 3 years
3. Yes, I was receiving treatment more than 3 years ago
97. No, I have never taken medication to treat hepatitis C
4. I do not know
98. I refuse to answer

D18. Which of the following conditions currently apply to you (please, select all relevant options):
1. Hepatitis B
2. Tuberculosis
3. Pancreatitis
4. Gastric / peptic ulcer
5. Teeth problem
6. Vein problem
7. Severe headaches
8. Diabetes
9. None

D19. Which answer suits the current state of your employment (please, select all relevant options)?
1. Permanent work, full-time (40 or more hours per week)
2. Permanent work, part-time
3. Periodic or seasonal work (includes daily work and waiting period)
4. Unemployed
5. I can not work (disability)
6. Housewife / household carer (caring for children and / or other family members)
7. Student
8. Retired
9. Other
98. I refuse to answer

D19_1. If other, please specify:

D20. Do you receive a disability pension?
1. Yes
0. No

D21. Have you ever been to a detention facility (including a temporary detention facility)?
1. Yes
0. No
98. I refuse to answer

D22. How old were you when you first ended up in a detention facility (including a temporary detention facility)?

D23. Approximately how many times have you been in a detention facility (including a temporary detention facility)?

D24. Overall, how long time did you spend in the detention facility (including temporary detention)? Please indicate the number of months. For example: 1 year = 12 months, 2 years = 24, 10 years = 120, etc.

D25. When was the last time you were released? Please, indicate an approximate date if you do not remember.

D26. For how many days have you injected any illegal drug in the last month?

D27. Are you taking any additional drug **without a doctor's prescription**?
1. Yes
0. No

D28. If yes, please indicate:
1. Antidepressant
2. For sleeping
3. Analgesic
4. Tranquilizer
5. Other:

D28_other. If other, please specify:

D29. Education level:
1. Incomplete secondary education
2. Secondary education
3. Specialized education
4. Incomplete higher education
5. Higher education

D 30. What is your income:
1. Less than 300 GEL
2. Between 300 and 1000 GEL
3. 1000 GEL
4. From 1000 to 3000 GEL
5. More than 3000 GEL

D 31. Marital status:
1. I am married
2. I am divorced
3. I am not married but I have a partner
4. I am not married, I do not have a partner

Over the past 2 weeks, how often have you had the following problems:

PHQ_1. I felt nervous, anxious, or that I had gone to extremes
0. Not at all
1. A few days
2. More than half of all days
3. Almost every day

PHQ_2. I could not stop or control my worry

0. Not at all
1. A few days
2. More than half of all days
3. Almost every day

PHQ_3. I was in low spirits, depressed, hopeless

0. Not at all
1. A few days
2. More than half of all days
3. Almost every day

PHQ_4. I had little interest / little pleasure in doing things

0. Not at all
1. A few days
2. More than half of all days
3. Almost every day

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