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Research paper

Feasibility of buprenorphine and methadone maintenance programmes among users of home made opioids in Ukraine

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ABSTRACT

Background: Opioid substitution therapy (OST) in the Ukraine was not provided until 2004. Methadone maintenance therapy only became available in May 2008. Injecting drug users in Ukraine are predominantly injecting self-made opioid solution ('Shirka'). A feasibility study on buprenorphine and methadone maintenance treatment was conducted in 2008.
Methods: A total of 331 opioid dependent patients were given buprenorphine ($n = 191$) or methadone ($n = 140$) as a substitute, and a survey of substance use, HIV transmission risks, and legal and social status was conducted at baseline and at six months follow-up.
Results: Illegal substance use, illegal activities, incomes and HIV related transmission risks were highly reduced, whereas employment rates and psychiatric problems improved. Retention was comparatively high among the patients in buprenorphine (84.8%) and in methadone maintenance treatment (85.0%) after six months of treatment.
Conclusion: These data show the successful implementation of OST in the Ukraine among drug users who were predominantly injectors of self-made opioid solutions. Continuing scale-up of OST in the Ukraine is therefore both feasible and highly recommended.

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Background

Opioid substitution treatment (OST) has been shown to achieve similar positive outcomes in numerous low- to high-income countries, including the reduction of heroin and other illicit opioid use, the reduction of HIV risk behaviours associated with injection drug use, the decrease of criminal activities, and the improvement of physical and mental health and well-being (Lawrinson et al., 2008). According to a recent WHO estimation (Kruglov et al., 2008; Raykhert et al., 2008; UNAIDS, 2008), there are approximately 325,000–425,000 injection drug users (IDUs) in Ukraine, of whom 144,000 are estimated to be HIV positive.

Despite the large prevalence of IDUs, drug treatment programmes relied on detoxification and abstinence based rehabilitation in so called 'narcological centres' until 2004 (Bruce, Dvoryak, Sylla, & Altice, 2007). Due to political and clinical mistrust towards OST, buprenorphine was the only medication available for OST between 2004 and 2007. Cost-effectiveness estimations of OST in Ukraine were undertaken to examine the socio-economic and health advantages of country-wide provision of harm reduction interventions (Vickerman et al., 2006). In collaboration with the World Health Organization (Regional Office for Europe), the International HIV/AIDS Alliance, the Ukrainian Institute for Public Health Policy and the management and staff of existing treatment sites, six buprenorphine maintenance treatment (BMT) sites started in 2006 (Schaub, Subata, Chtenguelov, Weiler, & Uchtenhagen, 2009). In June 2007, methadone was approved by the Ukrainian Ministry of Health and became available for maintenance treatment in May 2008. By the end of 2008, through the huge investment and efforts in HIV prevention, the Global Fund to fight AIDS, Tuberculosis and Malaria grant, which was initially managed by Ukrainian government and then by the HIV/AIDS Alliance, 2202 IDUs were enrolled in OST. However, not less than 60,000 IDUs are still estimated to be in need of OST (International HIV/AIDS Alliance, 2009). In addition to the low availability of agonist maintenance in Ukraine, access to antiretroviral therapy (ART) for IDUs is low, and clinicians have tended to refuse ARTs to active IDUs, believing that they would be poorly adherent (Bruce et al., 2007).

A particularity of opioid use in Ukraine is that most IDUs do not use heroin but a self-made opioid called 'shirka', which is prepared from poppy straw in a container shared among several users. A contaminated needle can result in contaminating the 'shirka'

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and infecting other users. Also, ready-made 'shirka' is available in preloaded unsterile syringes that tend to be used first by the drug dealers themselves (Booth, Kennedy, Brewster, & Semerik, 2003; Booth et al., 2006). Some policy makers and clinicians in Ukraine have contested the applicability of international evidence on the effectiveness of OST in the context of predominant "shirka" use.

This publication reports the first six months of treatment data from the buprenorphine (Kiev City AIDS Centre and Sociotherapy Clinic, Donetsk Narcological Dispensary, Odessa Oblast Narcological Dispensary, AR Crimea Republican Narcological Dispensary, Dnijpropetrovsk Narcological Dispensary, Mykolaiv Narcological Dispensary, Ivano-Frankovsk Oblast Narcological Dispensary, Sumy Oblast Narcological Dispensary) and methadone treatment sites in Ukraine (Kiev City AIDS Centre, Donetsk Oblast Narcological Dispensary, Dnijpropetrovsk City AIDS Centre, Mykolaiv Oblast Narcological Dispensary, Vinnytsya Oblast Narcological Dispensary, Kherson Oblast Narcological Dispensary).

Methods

Study population

Patients were asked if they were willing to start BMT or methadone maintenance treatment (MMT) over a two- to three-month recruitment period. BMT prescription was possible at six treatment sites and MMT prescription at a further four sites, two of which were HIV/AIDS centres. A further two sites provided both BMT and MMT prescription. At the beginning of recruitment, these two new treatment possibilities were demanded by almost every patient ($n = 356$). A patient recruitment list documented basic characteristics of persons applying for OST, their eligibility and their eventual admittance to the programme by treatment staff. Patients were excluded from the study if they showed signs of severe cognitive impairment, behaviour disturbances or psychotic symptoms or if they were expecting a period of hospitalisation or imprisonment. In order to be eligible for participation in the study, patients had to fulfil dependence diagnosis for opioids according to ICD-10, be at least 18 years old and be living in a permanent residence within commuting distance of the OST or AIDS clinic. They also had to consent to treatment and treatment regime, including blood testing, and to participate in the study follow-up interview. Initially 333 patients were recruited for the OST programme but two declined consent, leaving a total of 331 patients.

Patients had to ingest their individual dose of buprenorphine or methadone at the OST site on a daily basis. According to the Ukrainian treatment protocol for BMT, higher buprenorphine doses were prescribed at the beginning of treatment to suppress withdrawal symptoms (typically 12–14 mg). Then the doses were gradually reduced and the maintenance dose tended to be from 2 to 8 mg, usually at the initiation of the patient, who often planned to leave the programme in the long run due to daily-supervised intake causing difficulties for their job situation. Methadone doses were prescribed in line with the Ukrainian treatment protocol, recommending doses ranging from 80 to 120 mg a day. The methadone doses at the beginning of the prescription were as follows: 20–30 mg (plus optional 5 mg in 4 h) on the first day, 30–40 mg on the second day, 35–50 mg on the third day, 40–50 mg on the fourth day, reaching 60 mg a day by the end of the first week. Patients who started to feel unwell either reduced or increased (rapid metaboliser) their dose. The final MMT prescription range at six months of follow-up was between 25 and 210 mg a day.

Patients were also tested for HIV in the first two weeks of the study. For financial reasons, HCV and HBV status were taken from medical records and patients were asked if they knew their status. Care was provided to sero-positive patients by AIDS centres (HIV testing at six months follow-up, as well as further testing, laboratory monitoring, and ART provision). All OST and HIV/AIDS services were free of charge. The study protocol was approved by the institutional ethical and review board of the All-Ukrainian Narcology Association.

Treatment staff and monitoring

At all sites, relevant professions (doctors, psychiatrists, nurses, psychologists, and social workers) were represented in the team to take care of the somatic, psychiatric, psychological and social needs of patients. Competence to work with drug dependent persons was assured by regular training in the Ukrainian guidelines for good practice in BMT and MMT, as well as by supervision on request. The monitoring and evaluation protocol was developed at the Research Institute for Public Health and Addiction at Zurich University, in consultation with the WHO Office for Europe, the International HIV/AIDS Alliance, the OST programme managers and the Ukrainian Institute of Public Health Policy.

Data collection

Patient descriptions and baseline and follow-up data were collected by use of a clinical record form. At both baseline and follow-up an external interviewer assessed history and patterns of substance use with the Addiction Severity Index ASI (McLellan, Kushner, Metzger, & Peters, 1992) and determined risk behaviours using the Blood-borne Virus Transmission Risk Assessment Questionnaire BBV-TRAQ (Fry & Lintzeris, 2003). Data on status, regime, treatment received, adverse events, compliance, and termination of treatment were entered on a daily basis by OST treatment staff into standardised patient records prepared by the same institute. Patients who dropped out of the study were contacted, if possible, in order to find out about their reasons for dropping out and to motivate them to participate in the follow-up interview. Reasons for dropout were noted on the patients' clinical report forms.

Data management and analyses

Data were transferred electronically to the Ukrainian Institute of Public Health Policy and entered into a relational database. All patients data were coded and recorded anonymously. Differences between baseline and follow-up were tested by repeated-measures analysis of variance test statistic for those patients who stayed in treatment. In the case of categorical variables, applicable data percent were specified and Chi-square tests for dependent and independent samples were applied, respectively. The reasons why patients dropped out of the study were reported on the clinical report form. Finally, two Cox regression analyses for MMT and BMT treated patients were performed separately for months in treatment, to investigate effects of baseline characteristics, mean OST dose, baseline HIV status, and baseline ASI and BBV-TRAQ scores as predictors for treatment retention. P values <0.05 were considered statistically significant. All data were analysed with the statistical software package SPSS, version 15.

Results

Sample characteristics

Seventy-nine percent of patients in BMT were male (MMT: 82.9%), patients had an average age of 35 years ($\pm$7.6) (MMT: 33.9 ± 7.3), declared on average 10.7 ($\pm$1.9) years (MMT: 10.3 ± 1.4 years) of education, and 1.7 ($\pm$1.9) years (MMT: 2.2 ± 2.1 years) of professional education. More than half of patients were married

(BMT: 55.0%, MMT: 56.4%). A minority said that they lived in unsatisfactory housing conditions (BMT: 4.7%, MMT: 0.0%), and many reported having a legally paid job (BMT: 44.0%, MMT 29.3%). By far the longest history of substance use related to "other opioids", which was almost exclusively 'shirka' (BMT: 11.5 ± 8.3 years, MMT: 13.0 ± 7.0 years), followed by cannabis use (BMT: 5.8 ± 8.3 years, MMT: 6.5 ± 7.4 years) and poly-drug use (BMT: 4.9 ± 6.0 years, MMT: 5.7 ± 6.6 years). In contrast, the use of other substances, especially heroin, was more recent. Although, patients reported a longer history of use of sedatives, tranquillisers (BMT: 2.6 ± 4.4 years, MMT: 4.0 ± 5.8 years) and barbiturates (BMT: 1.7 ± 3.4 years, MMT: 2.7 ± 3.8 years) of more than 2–4 years, respectively.

The large majority of former treatments were received for drug problems, with an average of 4.8 (±5.6) treatments in BMT and 4.7 (±5.4) per patient in MMT. Previous treatments for alcohol problems (BMT: 0.3 ± 1.1 episodes, MMT: 0.1 ± 0.4 episodes) and psychiatric problems (BMT: 0.3 ± 1.1 episodes, MMT: 0.1 ± 0.6 episodes) were much less frequent. Of all patients, 72.7% in BMT and 57.9% in MMT had been arrested at least once and 18.3% in BMT and 8.6% in MMT had been participating in groups for alcoholics anonymous or narcotics anonymous.

More than half of all patients (BMT: 48.2%, MMT: 60.7%) were found to be HIV positive at entry to the programme. In regard to their infection stage, clinical AIDS (stage 4 of HIV disease) was diagnosed in 5.2% of patients in BMT and in 2.1% of patients in MMT. HCV seropositivity was reported in 14.7% (17.2% missing data) of patients in BMT and the rate for HBV seropositivity was 3.7% (14.7% missing data). As two HIV/AIDS centres provided MMT, there were less missing data on patients' infectious disease status. HCV seropositivity was reported in 16.4% (2.1% missing data) of patients in MMT and the rate for HBV seropositivity was 7.9% (2.1% missing data). In BMT, 7.3% (18.3% missing data) of patients tested positive for tuberculosis and for MMT the figure was 5.7%.

Treatment outcomes

For both BMT and MMT, the use of other opioids (last 30 days) decreased significantly between baseline and six-month follow-up (see Table 1 for detailed treatment outcomes). Meanwhile, the mean buprenorphine dosage slightly decreased and the mean methadone dosage increased. The prescription of ART medication stayed approximately the same in BMT as in MMT. The occur-

Table 1
Percents, means, standard deviations and repeated measure analysis for baseline and six months follow-up of buprenorphine (BMT) and methadone maintenance therapy (MMT).

	Buprenorphine maintenance therapy			Methadone maintenance therapy		
	Baseline	Six months follow-up	*F*/Chi-square	Baseline	Six months follow-up	*F*/Chi-square
Number of patients *n* (*n*% total)	191 (100.0)	162 (84.8)	–	140 (100.0)	119 (85.0)	–
Medication						
Buprenorphine/methadone dosage (M; SD)	11.6 ± 4.2	10.9 ± 4.6	3.203**	66.6 ± 29.3	79.6 ± 38.0	5.349***
BMT/MMT treatment regime change (%)	–	10.2	–	–	9.2	–
Antiretroviral medication (%)	15.2	19.3	3.769	7.9	11.7	0.111
Substance use last 30 days						
Heroin use (M; SD)	0.8 ± 0.6	0.0 ± 0.0	2.801	0.8 ± 4.3	0.0 ± 0.2	4.114*
Other opioid use (M; SD)	14.3 ± 13.5	0.2 ± 1.2	176.896***	26.2 ± 8.1	0.7 ± 3.9	917.022***
Sedative use (M; SD)	4.2 ± 8.5	2.3 ± 6.2	5.206*	7.6 ± 12.3	2.4 ± 5.1	23.809***
Alcohol intoxication (M; SD)	0.5 ± 3.3	0.6 ± 3.6	0.117	1.7 ± 5.0	0.1 ± 0.6	12.943***
Cocaine use (M; SD)	0.2 ± 1.6	0.0 ± 0.0	1.475	0.0 ± 0.0	0.0 ± 0.0	–
Amphetamines use (M; SD)	0.4 ± 2.8	0.1 ± 0.8	2.145	1.5 ± 4.3	0.0 ± 0.1	125.752***
Inhalants use (M; SD)	0.0 ± 0.0	0.0 ± 0.0	–	0.0 ± 0.0	0.0 ± 0.0	–
ASI score alcohol (M; SD)	0.1 ± 0.1	0.0 ± 0.1	13.047***	0.0 ± 0.1	0.0 ± 0.0	12.301**
ASI score drugs (M; SD)	0.2 ± 0.1	0.1 ± 0.1	91.586***	0.2 ± 0.1	0.1 ± 0.1	347.440***
Somatic disorders						
Normal weight (%)	53.4	60.8	3.630	55.7	75.0	11.000**
Trophic ulcer (%)	8.9	4.2	7.000**	10.0	3.3	3.769
Digestion problems (%)	29.3	14.5	12.100**	33.6	22.5	4.592*
Urination problems (%)	11.0	1.8	12.250***	11.4	5.0	3.556
Sexual problems (%)	12.0	8.4	0.333	6.4	12.5	2.000
HIV positive (%)	48.2	50.0	1.000	60.7	60.0	–
ASI score medical (M; SD)	0.3 ± 0.3	0.3 ± 0.3	2.757	0.2 ± 0.3	0.1 ± 0.2	7.252**
Risk taking behaviour (BBV-TRAQ)						
Injecting score (M; SD)	9.9 ± 11.3	1.6 ± 5.7	69.723***	5.0 ± 8.4	1.7 ± 3.8	15.007***
Sexual score (M; SD)	7.2 ± 7.8	4.4 ± 6.4	22.338***	3.1 ± 5.1	4.6 ± 6.6	4.355*
Skin penetration score (M; SD)	2.2 ± 3.0	1.4 ± 2.7	7.252**	1.3 ± 2.3	1.2 ± 2.3	0.146
Psychiatric problems (ASI score)	0.3 ± 0.2	0.1 ± 0.2	58.084***	0.1 ± 0.1	0.1 ± 0.2	0.554
Employment and legal status						
Paid working days last 30 days (M; SD)	9.0 ± 11.4	13.3 ± 11.5	24.335***	6.9 ± 11.6	14.8 ± 13.3	26.140***
ASI score employment (M; SD)	0.8 ± 0.2	0.7 ± 0.3	16.573***	0.8 ± 0.3	0.7 ± 0.3	4.783*
Criminal activity last 30 days (M; SD)	3.2 ± 7.9	0.2 ± 1.4	24.114***	2.8 ± 7.4	0.0 ± 0.2	16.341***
ASI score for legal problems (M; SD)	0.1 ± 0.2	0.1 ± 0.1	29.333***	0.2 ± 0.2	0.0 ± 0.1	68.908***
Persons with illegal income last 30 days (%)	25.3	7.8	1.984	25.7	5.0	2.500
Family problems						
ASI score family (M; SD)	0.2 ± 0.2	0.2 ± 0.2	0.157	0.2 ± 0.2	0.1 ± 0.1	7.303**
Emotional abuse (last 30 days) (M; SD)	1.3 ± 0.5	1.2 ± 0.4	11.674**	1.3 ± 0.5	1.2 ± 0.4	9.953**
Physical abuse (last 30 days) (M; SD)	1.1 ± 0.3	1.0 ± 0.2	4.579*	1.1 ± 0.3	1.0 ± 0.2	5.537*

F: repeated-measures analysis of variance test statistic; Chi-square: Friedman test statistic; M: mean; SD: standard deviation
* $p < 0.05$.
** $p < 0.01$.
*** $p < 0.001$.

Table 2
Reasons for treatment drop out for patients in BMT and MMT.

	Buprenorphine maintenance therapy		Methadone maintenance therapy	
	n	*n*%	*n*	*n*%
Number of patients at baseline	191	100.0	140	100.0
Reasons for drop out				
A lot of non-attendance	7	3.7	14	10.0
Changing of place of residence	5	2.6	2	1.4
Due to imprisonment	7	3.7	3	2.1
Became abstinent	1	0.5	0	0.0
Due to detoxification in hospital	0	0.0	1	0.7
Change of OST substance (MMT vs. BMT)	0	0.0	1	0.7
Enter into 12 steps program	2	1.0	0	0.0
Treatment regime violation	2	1.0	0	0.0
Died	4	2.1	0	0.0
Reason unknown	1	0.5	0	0.0
Total drop outs	29	15.2	21	15.0

rence of somatic disorders decreased for trophic ulcer, digestion problems and urination problems in BMT. In MMT normal weight increased significantly, while digestion problems and the mean ASI medical score increased slightly. In both BMT and MMT there were considerable decreases in injection virus transmission risk behaviours and somewhat less pronounced for sexual virus transmission risks. The BBV-TRAQ skin penetration scores changed over the six-month period for BMT but not for MMT. Psychiatric problems, as measured by the ASI, were less frequent in BMT than MMT. Employment and legal status improved consistently for both BMT and MMT. Family problems did not improve in BMT but improved in MMT, while emotional and physical abuse decreased for both groups.

Dropouts

A total of 29 (15.2%) patients receiving BMT and 21 (15.0%) patients receiving MMT dropped out of the study after the six-month follow-up. The reasons for drop out are listed in Table 2.

The Cox regression for months in treatment revealed no significant effects on patients in BMT (Chi-square(191;18) = 22.277, n.s.) and MMT (Chi-square(140;18) = 27.601, n.s.) who dropped out for the covariates age, sex, age of first drug use, years of use of the assessed substances and poly-drug use, years of previous drug treatments, average and baseline buprenorphine/methadone dose, baseline HIV status, all baseline ASI domains and BBV-TRAQ scores.

Discussion

Study outcomes for the first six months of BMT and MMT among a group of IDUs using predominantly self-made opioid solution ('shirka') were impressive and comparable to those observed among mainly heroin IDUs in other countries. In both groups there were reductions in illegal and non-prescribed substance use, illegal activities, illegal income and risk taking behaviours. Further, the patients' employment rates increased and their psychiatric problems decreased compared to baseline.

This revealed that the target group of chronic Ukrainian opioid ('shirka') users were willing to enter OST and that the great majority remained in treatment during a six-month observation period. Almost all patients consented to participate in the evaluation study.

However, daily-supervised intake at the OST sites restricted patients' freedom to work and their relaxation time during weekends and vacations. Some patients planned to leave the programme in the long run because of this daily inconvenience and reduced their buprenorphine or methadone doses accordingly. We recommend that take-home doses should be available as soon as possible.

Treatment retention was comparatively high (Lawrinson et al., 2008) in both the BMT and MMT groups. Six-month treatment retention rates were similar to those found in an earlier Ukrainian study of BMT (Schaub et al., 2009), and there were fewer patients dropping out of treatment because OST could not be continued after admission to hospital. Assuring the continuation of OST after hospital admission would help to improve retention rates. The second most frequent reason for drop was imprisonment. Thus a next step for the implementation of OST in Ukraine would include its availability in prisons.

A direct comparison between BMT and MMT was not possible using the current study design, however there were few differences in results between these groups. Some minor differences were found in terms of reduction in episode of alcohol intoxications, where the MMT patients showed better outcome, and in psychiatric problems and risk taking behaviours (BBV-TRAQ) where BMT patients showed more distinct improvements. Thus the arguments of many Ukrainian politicians and clinicians against the use of MMT appear unfounded.

As one third of the patients in MMT were treated in HIV/AIDS centres, differences in somatic disorders domains between MMT and BMT are difficult to interpret. However, the current results support further scale-up of OST in Ukraine using buprenorphine and methadone.

It seems likely that not all patients recruited from HIV/AIDS, who would profit from ART medication, actually received it. Between 50 and 60% of IDUs were HIV positive at baseline, however, ART medication increased only slightly in the following six months of OST. It is also likely that HBV and HCV seropositivity was under-reported. Prevalence rates found in treatment centres in Russia (Sadikova et al., 2006) – an adjacent country which is similar to Ukraine in many respects – were much higher (HBV: 11.7%, HCV: 83.1%).

The current study involves the first systematic data collection on the feasibility of OST by BMT and MMT in Ukraine, These data are collected from a comparatively large sample of shirka' users. However, there were some limitations of this study: first, there was a reliance on self-report when assessing frequency of substance use, as urine testing would have been too expensive; second, patients were recruited from different kinds of treatment sites which could have led to selection biases; and third, there were some language restrictions (e.g. the ASI and the BBV-TRAQ had to be translated into Ukrainian but could not be validated as part of the current study). Nonetheless, the described standardised protocol for OST evaluation has been repeatedly applied in Ukraine since 2006 and has helped to assess differences in effectiveness over time, across sites and between different treatment modalities.

In consideration of the current study results we conclude that a successful and adequate implementation of OST in Ukraine

with buprenorphine and methadone is feasible. Both substitution substances led to equal improvements in numerous problematic aspects related to opioid dependence. Continuing scale-up of OST in Ukraine is highly recommended.

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Conflicts of interest

There are no conflicts of interests by any of the authors.

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