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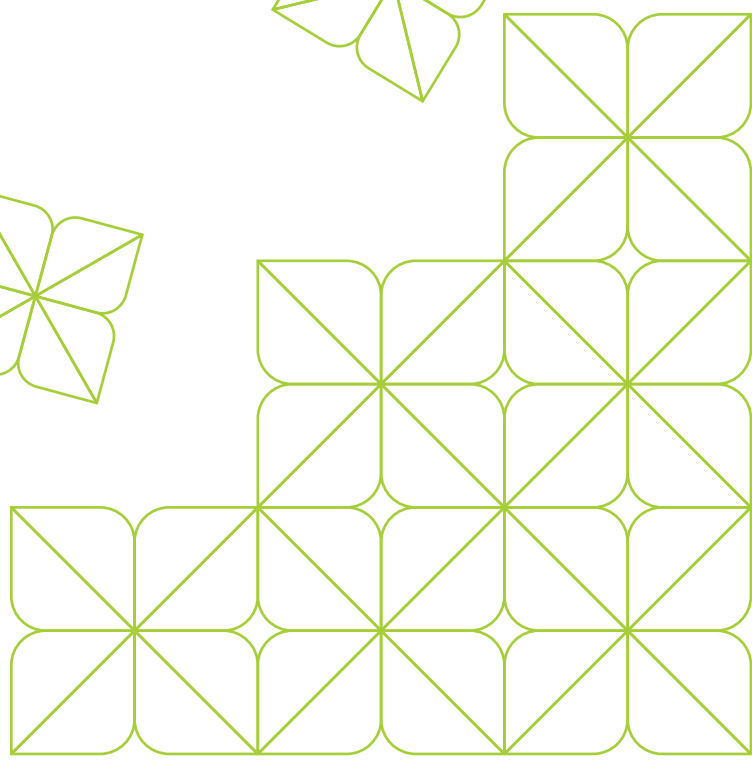
EVALUATION OF THE IMPLEMENTATION OF THE BEHAVIORAL INTERVENTION FOR PEOPLE LIVING WITH HIV AND USING INJECTION DRUGS



STEPS TOWARDS HEALTH

SUMMARY OF THE ANALYTICAL REPORT

KIEV – 2017



BACKGROUND

People who inject drugs (PWID) demonstrate the highest levels of HIV prevalence and morbidity in the country compared to other key populations. In 2015, HIV prevalence among PWID increased to 21.9%, as compared to 19.7% in 2013, which is in contrast to the recent reductions in prevalence¹. HIV positive PWID face numerous problems, which make it impossible to ensure effective treatment. This population experiences significant losses throughout the entire cascade of HIV services due to low adherence to the services². Routine monitoring data in Ukraine demonstrates that one third to half of HIV positive people identified through lab screening are not enrolled in medical care³.

This research was aimed at assessing implementation and effectiveness of a behavioral intervention targeting people who live with HIV and use injection drugs (PLHIV-PWID) *Steps to Health*.

INTERVENTION

Steps towards Health is a cognitive behavioral intervention aimed to enhance consistency to the medical services in PLHIV who use injection drugs. The intervention is aimed at prevention of HIV/STIs/viral hepatitis among people who actively use injection drugs. The intervention involves the target population, individual counseling and comprehensive case management. Besides the prevention of HIV in PLHIV-PWID, the goal of the Steps to Health is to develop adherence to the medical service, including HIV related medical

care. The target of the intervention is HIV positive people who use injection drugs and do not visit an AIDS center or an ART site.

The Steps towards Health intervention is based on the Seven Steps intervention⁴; it is also based on the results of the researches carried out by the Central Caribbean University, School of Medicine and Puerto Rico Narcological Research Center with the support of the US National Institute on Drug Abuse (NIDA)⁵. Uniqueness and effectiveness of the Steps to Health is grounded in the approach based on continuous interaction between a client and the team members: a consultant/social worker and a project manager.

Steps towards Health Intervention was designed by the USAID RESPOND Project in March of 2015 at the request of and in partnership with the All-Ukrainian Charitable Foundation All-Ukrainian Network of People Living with HIV. The intervention was piloted for one and a half years (March 2015 to September 2016) in two organizations: Vse Vozmozhno (Everything is Possible) a charitable foundation in Melitopol, Zaporizhzhia region, and the Kryvy Rih branch of the Charitable Foundation All-Ukrainian Network of People Living with HIV (Kryvy Rih, Dnipro Region). The results of the pilot were presented in the guidelines Steps towards Health. Case Management for PLHIV Who Use Injection Drugs⁶.

During the three month pilot period, intervention participants underwent an introductory session and five individual sessions on behavior change with a case management component. The sessions were carried out by the facilitators (project coordinators, social workers) who worked in the NGOs and underwent a special training on implementation of the Steps towards Health intervention. Between the

¹ Барська Ю., Сазонова Я. (Baska Yu., Sazonova Ya.). Моніторинг поведінки та поширеності ВІЛ серед людей, які вживають ін'єкційні наркотики, та їхніх статевих партнерів (Monitoring of behavior and HIV prevalence in people who use injection drugs and their sexual partners). – К.: МБФ «Альянс громадського здоров'я», 2016. – Р. 130.

² Mann, B. et al. Improved adherence to modern antiretroviral therapy among HIV-infected injecting drug users. *HIV medicine*, 2012. 13(10): p. 596–601.

³ ВІЛ-інфекція в Україні. Інформаційний бюлетень (HIV infection in Ukraine. News-letter) / Держ. установа «Український центр контролю за соціально небезпечними хворобами Міністерства охорони здоров'я України», Держ. установа «Інститут епідеміології та інфекційних хвороб імені Л.В. Громашевського Національної академії медичних наук України». – № 45. – К., 2016.

⁴ Сім кроків. Когнітивно-поведінкове втручання для зниження інфікування ВІЛ, ППСІ та вірусними гепатитами серед споживачів ін'єкційних наркотиків з використанням індивідуального консультування та кейс-менеджменту. Посібник із впровадження (Seven Steps. The Cognitive Behavioral Intervention to Reduce HIV, STI and Viral Hepatitis Prevalence in People Who Inject Drugs Using Individual Counseling and Case Management. Implementation Guidelines). – К., 2015. – 216 p.

⁵ Rafaela R. Robles, (Ed.D.), Juan C/Reyes, (Ed.D.), Hector M.Colon, (Ph.D.), Hardeo Sahai, (Ph.D.), C. Amalia Marrero, (M.P.H), Tomas D. Matos, (M.S.), Jose M. Calderon, (M.S.), Elizabeth W. Shepard, (M.P.H). Effects of combined counseling and case management to reduce HIV risk behaviours among Hispanic drug injectors in Puerto Rico: A randomized controlled study // *Journal of Substance Abuse Treatment*, 27(2004): p. 145-152.

⁶ Кроки до здоров'я: Соціальний супровід ЛЖВ, які вживають ін'єкційні наркотики. Посібник із впровадження (Steps to Health. Case Management for PLH Who Use Injection Drugs. Implementation Guidelines). – К., 2015. А. Бойко, Н. Дмитришина, Н. Тюленева. – К.: «Поліграф плюс», 2016. – 364 p.

sessions, the facilitators talked to the participants on the phone to be certain that they abide by all the recommendations and received the social and medical services they had been referred to.

The intervention covered 390 persons, of them, 301 person underwent all five counseling sessions.

METHODS

The research was designed as a randomized longitudinal experiment. An intervention arm was compared to a control arm. The intervention arm received a standard service package from the NGOs (syringe exchange, free condoms and lubricants, consultations from the experts and referrals). The participants of this arm did not receive the counseling aimed toward affecting changes in behavior but they had access to regular counseling provided by a social worker or a psychologist. The standardized package of services offered to the control arm did not include case management or physical escort to the AIDS center.

The research component included three interviews: a baseline interview and a three and six month follow up interview. The research sample was 300 participants, with 150 PLHIV-PWID in each of the arms. The eligibility criteria were as follows: at least 18 years of age or older; confirmed HIV diagnosis as measured by registration at the AIDS center; use of injection drugs during the last six months; at the time of enrollment in the research are not on ART; did not visit the AIDS center during the last six months; have the ability to, and agree, provide two form of contacts for the participants that can be used to get in touch with them; and readiness to provide a written consent to participate in the study.

The data collection period was March 2015 to November 2016.

In the study, both qualitative and quantitative methods were used. The qualitative component included focus groups with the intervention coordinators and social workers (the facilitators of

the counseling sessions) regarding the obstacles to implement this intervention in Ukraine.

Data analysis included assessment of fidelity, feasibility and effectiveness of the intervention. Indicators of the intervention effectiveness included renewed follow-up, the success of referrals to the social and medical services, improved knowledge on HIV, and reduction of risky behavior. To assess intervention impact, multiple regression analysis was used, in particular logistic regression and Poisson regression. Conformity of the research with the ethical standards was established by the Ethical Committee of the Ukrainian Institute on Public Health Policy.

RESULTS

Sociodemographic Profile of the Participants

Average age of the PLHIV-PWID participants is 39 years. Approximately one-third (37%) were women. A majority of the participants (55%) completed vocational training; a share of people had unfinished or completed higher education (only seven percent). Over a half of the PLHIV-PWID (51%) have a long-term partner of a husband/wife. Most of the research participants lived in their own permanent residences (58%) or with their parents or friends and did not pay rent (28%). The level of income is rather low: 27% informed researchers that they did not have any personal income while 37% earned up to UAH 1,500 per month. More than a half of PLHIV-PWID (53%) had an incarceration experience prior to their participation in the research. Most of the research participants used opioids, in particular - opium extract ('shirka').

Fidelity and Feasibility⁷

Of the five percent of intervention sessions monitored and assessed, all included five key elements as defined by the intervention (Table 1). The facilitators were in most cases successful in keeping in touch with the participants in-

⁷ Results of assessment of the indicators regarding the intervention arm, by two data sources: external monitoring of the intervention participants, who participated in the research, conducted by the Ukrainian Institute on Public Health Policy (150 persons), and internal monitoring of all intervention participants (390 persons).

between the sessions. Eighty-three percent of the participants from the intervention arm had this experience. What turned out to be a challenge was ensuring full length of the counseling sessions. In accordance with the results of the

analysis, 68% of the sessions were as long as it was recommended, namely 45 to 60 minutes long. 77% of the intervention participants underwent all five mandatory sessions.

Table 1

Evaluation results of the intervention implementation: fidelity and feasibility

Indicator	Calculation methods	The result received	Target indicator
Recruiting index	Numerator: a number of the participants who underwent the zero session and provided an informed consent to participate in the intervention.	Among the intervention participants: 390 out of 469 persons (83%)	100%
	Denominator: a number of the participants invited to participate in the intervention.		
Retention index	Numerator: a number of the participants who underwent all 5 sessions.	Among the intervention participants: 301 out of 390 persons (77%)	80%
	Denominator: A total number of the participants covered by the intervention.		
A share of the clients with whom the intervention staff kept in touch between the sessions*	Numerator: a number of the participants covered by the facilitators after each session by means of personal outreach contact.	Among the intervention participants who participated in the study: 124 out of 150 persons (83%)	100%
	Denominator: A total number of the participants covered by the intervention.		
A share of the intervention sessions which covered all 5 key elements**	Numerator: A share of the intervention sessions which, according to the monitoring, covered all 5 key elements.	100%	100%
	Denominator: a total number of sessions assessed during the monitoring.		
Average length of the sessions	Numerator: Average length of the sessions assessed during the monitoring.	Among the intervention participants: 49.0 minutes	45 min.
	Denominator: a total number of sessions assessed during the monitoring.		
A share of the intervention sessions 45 to 60 minutes long	Numerator: A number of the sessions that were 45 to 60 minutes long.	Among the intervention participants: 68%	100%
	Denominator: a total number of sessions assessed during the monitoring.		

* Data for this indicator was collected only by external monitoring among the intervention participants who participated in the study (150 persons).

** This indicator was calculated on the base of the results of analysis of 5% of the sessions that the intervention participants, who participated in the study, underwent (150 persons).

Intervention Effectiveness

Compared to the standard services, the intervention is more effective regarding renewal of active enrollment in care (visits to an infection disease doctor, CD-4 screening) and initiation or continuation of treatment (Table 2). Among the participants in general, 25% of the intervention arm and 12% of the control arm initiated ART during the research (Fig. 1).

Based on the research results, a short-term impact of the intervention on a number of successful referrals as well as short-term and long-term impact on reduction of risky sexual practices (not using a condom during the last sexual intercourse and irregular use of condoms with the long-term partners) was demonstrated (Table 2).



Table 2

Results of the assessment of efficacy of the Steps to Health intervention for PLHIV-PWID

	Assessment, in 3 months			Assessment, in 6 months		
	C	E	OR / RI (95% CI)	C	E	OR / RI (95% CI)
Visited the infection disease doctor	65/142 (46%)	105/140 (75%)	3,89 (2,24–6,74)	72/141 (51%)	115/141 (82%)	4,76 (2,65–8,56)
Did CD-4 test	-	-	-	70/141 (50%)	112/141 (79%)	4,16 (2,36–7,31)
Initiated ART	-	-	-	18/141 (13%)	38/141 (27%)	2,62 (1,35–5,08)
Received at least one medical or sociopsychological services that they were referred to during the last 3 months	109/111 (98%)	133/136 (98%)	0,82 (0,13–5,15)	109/112 (97%)	126/129 (98%)	1,42 (0,27–7,54)
Median number of the medical or sociopsychological services received through the referral during the last 3 months	3	5	1,33 (1,16–1,52)	4	4	1,23 (0,07–1,42)
Correctly identify the modes of HIV transmission and prevention	96/142 (68%)	98/140 (70%)	1,01 (0,59–1,74)	107/141 (76%)	118/141 (84%)	1,60 (0,83–3,08)
Used a sterile needle and a syringe last time they used injection drugs	108/109 (99%)	88/88 (100%)	-	114/114 (100%)	87/87 (100%)	-
Made an injection using a syringe that was used by another person to inject, during the last 30 days	7/109 (6%)	4/88 (5%)	0,69 (0,20–2,45)	11/115 (10%)	0/87 (100%)	0,10 (0,01–0,78)
Did not use a condom during the last sexual intercourse	63/129 (49%)	37/116 (32%)	0,51 (0,29–0,90)	61/123 (50%)	34/107 (32%)	0,52 (0,28–0,95)
Did not regularly use a condom with the long-term partners, during the last 30 days	72/129 (56%)	34/116 (29%)	0,29 (0,15–0,56)	70/123 (57%)	31/107 (29%)	0,32 (0,17–0,61)
Did not regularly use a condom with the casual or commercial partners, during the last 30 days	4/129 (3%)	1/115 (1%)	0,27 (0,03–2,47)	5/123 (4%)	2/105 (2%)	0,45 (0,09–2,37)

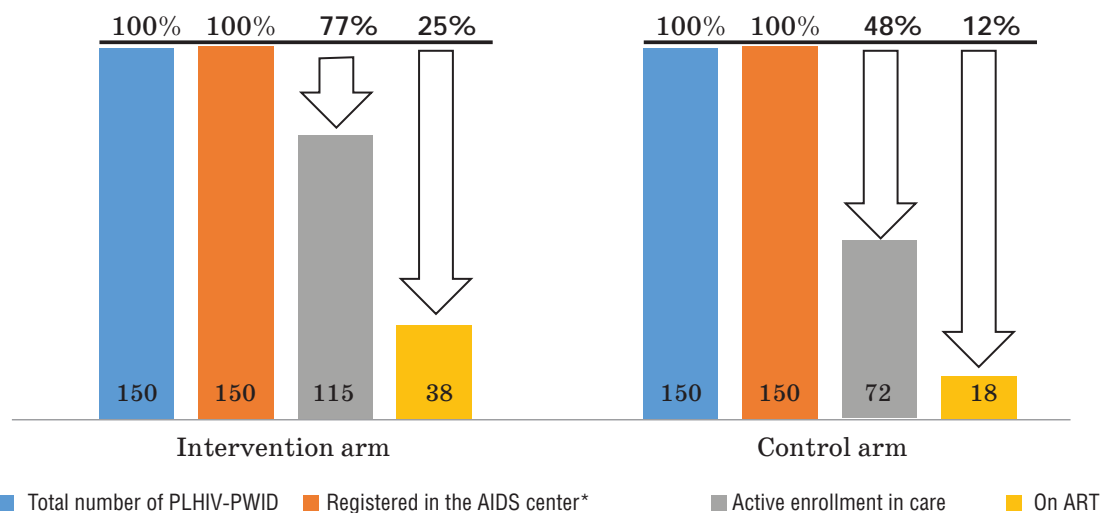
C – the control arm

E – the intervention arm

OR – odds ratio Odds ratio is adjusted using the sociodemographic characteristics for all indicators beside the indicators of the injection practices and irregular use of condoms with the casual partners.

RI – ratio of incidence rates of the effective referrals; calculated only for the indicator of a number medical or sociopsychological services received as a result of a referral.

CI – confidence interval



* Registration in the AIDS center was one of the eligibility criteria of the research.

Figure 1. HIV Treatment Cascade among the research participants: final assessment in 6 months

CONCLUSIONS AND DISCUSSION

Steps to Health intervention has proven its efficacy regarding visits to the infection disease doctors (OR 4.76; 95% CI: 2.65–8.56 – assessment in 6 months); CD4 screening (OR 4.16; 95% CI: 2.36-7.31 – assessment in 6 months); initiation or renewal of ART (OR 2.62; 95% CI: 1.35-5.08 – assessment in 6 months); reduction of sexual practices without use of condom during the last sexual intercourse (OR 0.51; 95% CI: 0.29-0.90 – assessment in 3 months; OR 0.52; 95% CI: 0.28-0.95 – assessment in 6 months); and irregular use of condom with the long-term partners during the last month (OR 0.29; 95% CI: 0.15-0.56 – assessment in 3 months; OR 0.32; 95% CI: 0.17-0.61 – assessment in 6 months).

A short-term impact of the intervention on a number of successful referrals to the social and medical services was proven; however, there is no long-term impact (RI 1.33; 95% CI: 1.16-1.52 – assessment in 3 months; RI 1.23; 95% CI: 0.07-1.42 – assessment in 6 months). A hypothesis of higher efficacy of the intervention (compared to the standard package) in improving knowledge on HIV infection was not proven (OR 1.01, 95% CI: 0.59-1.74 – assessment in 3 months; OR 1.60; 95% CI: 0.83-3.08 – assessment in 6 months).

Due to low popularity of the practice of use of non-sterile injection tools and a small share of the participants who had casual sexual partners, the sample size was insufficient to provide evidence of effectiveness of the behavioral intervention regarding reduction of such risks as use of non-sterile needles and syringes and irregular use of condoms with casual and commercial partners.

In spite of higher efficacy of the intervention compared to the standard services in a number of indicators, significant losses were identified in the HIV service cascade in the number of the participants from both arms; however, such losses were smaller among the participants of the intervention arm. One quarter of the recruited PLHIV-PWID (25%) out of people who participated in the behavioral intervention and 12% of PLHIV-PWID, who received the standardized care, initiated treatment during the research.

The key obstacles for successful implementation of the intervention identified by the participants during the focus group interviews can be divided into two categories: organizational problems (stigma and discrimination in the health care facilities, high prices for medical services, limited package of services for PLHIV-PWID, in particular, lack of job placement assistance) and individual problems (feeling sick, drug use, being busy at work, lack of time). The participants identified positive attitude of the consultants towards the client («as if we were peers»), simplicity of presentation of information

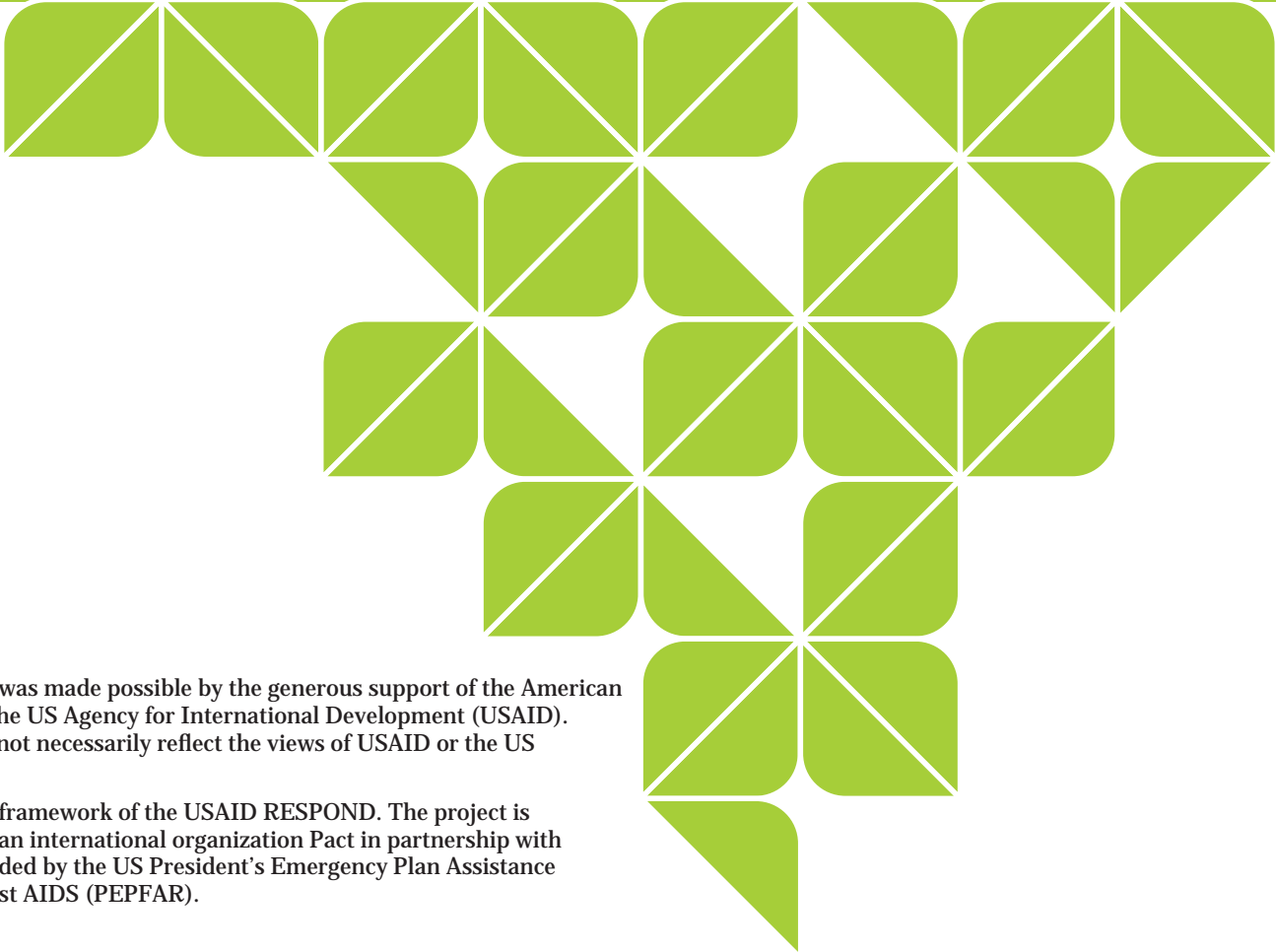
and escorting the clients to the services as the factors, which influenced effectiveness? of the intervention. According to the intervention staff, the key obstacle to shape adherence to the services of AIDS centers was lack of CD-4 and viral load tests as well as shortage of the ART medications. PLHIV-PWID who returned to the AIDS center could not receive the necessary services and this fact significantly weakened their motivation for further visits. In the second half of 2015 (the intervention was launched in July 2015) the research sites experienced a shortage of the CD4 and VL tests, which were a prerequisite for the therapy prescription in cases when there were no clinical indications in accordance with the clinical ART protocol that was in force in 2015⁸.

Limitations of the research include lack of collection of clinical data about date of visit to the AIDS center, screenings, ART prescriptions and dispensing the medication using the patient's record in the AIDS center; systemic mistakes related to memory that could arise in self-assessment of the behavioral practices; and comparatively short time when the intervention impact was followed-up (six months).

In spite of the limitations of the research, it is necessary to identify its *advantages*. This is one of the first in Ukraine randomized experimental trials in PLHIV-PWID that were lost for follow-up. A major advantage is assessment of a significant number of resulting variables, in particular, studying the behavioral intervention not only from the viewpoint of return to care but also from the viewpoint of risky behavior, knowledge and successfulness of the referrals. Besides, the research provides a possibility to assess the HIV treatment cascade in PLHIV-PWID; in the framework of routine monitoring in the AIDS centers the treatment cascade of this key population is not assessed.

Taking into consideration the proven fidelity, feasibility and effectiveness, the *Steps towards Health* behavioral intervention can be recommended for implementation in Ukraine. Further efforts should be aimed at assessing the intervention impact over a longer period of time, using the interviews with the participants alongside the clinical data collection from the patients' records as well as at studying the intervention effectiveness regarding the risky injection behavior and risky sexual behavior with casual partners.

⁸ The amendments to the Clinical protocol of ART of HIV infection in adults and adolescents recommending early start of ART for the risk population irrespectively of the results of CD-4 and VL screening was approved on December 22, 2015 (Order of the MOH of Ukraine as of Dec. 22, 2015, #887 «On approval of the amendments to the Clinical protocol of ART of HIV infection in adults and adolescents»). – [Electronic resource]. – Available at: http://moz.gov.ua/docfiles/dn_20151222_0887dod.pdf.



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