Published in final edited form as:
Addiction. 2009 November ; 104(11): 1864–1873. doi:10.1111/j.1360-0443.2009.02660.x.

Interventions with Injection Drug Users in Ukraine

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Abstract

Aims—To assess the effectiveness of a brief HIV testing and counseling intervention compared to a more time-consuming and expensive street-based intervention with injection drug users (IDUs).

Design—Crossover experimental design in which 600 IDUs were recruited, followed by a "wash out" period with no recruitment, a reversal of intervention assignment areas and an additional recruitment of 600 IDUs with baseline and six-month follow-up assessments.

Setting—Kiev, Odessa and Makeevka/Donesk Ukraine.

Participants—1,798 IDUs.

Measurements—HIV testing and audio-computer assisted self-interview (ACASI) data on socio-demographics, drug use and injection and sex-related risk behaviors.

Findings—Participants in both conditions significantly reduced their injection and sex risks, however, there was little difference in outcomes between conditions. IDUs who knew they were HIV infected at baseline were significantly more likely to practice safe sex than those unaware or HIV negative; those who first learned they were infected at baseline changed their safe sex practices significantly more than those who already knew they were infected at baseline and those who were HIV negative. Younger IDUs and those injecting for a shorter period of time reported higher injection and sex risk behaviors following interventions.

Conclusions—Awareness of HIV infection by street-recruited drug injectors is associated with reduced sex risks. Additional interventions are required for younger IDUs and those injecting for shorter periods of time.

Keywords

Injection drug users; Ukraine; HIV testing and counseling

INTRODUCTION

In 2007, an estimated 1.63% of the adult population in Ukraine was living with HIV/AIDS, or 440,000 citizens, up from 1.46% in 2005 (1), yet as late as 1995 WHO characterized Ukraine as a low prevalence country (2). Evidence suggests that the epidemic most likely

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There are no conflicts of interest.

began that year and spread rapidly thereafter. By 1996, all 25 regional capitals in Ukraine reported HIV cases, primarily among drug injectors (3). The epidemic continues to grow at an alarming rate, with annual diagnoses more than doubling each year since 2001, reaching 16,094 in 2006 (4). Unfortunately, the majority of infections are among those in the most active reproductive age (20 – 34), contributing to the decline in Ukraine's population from 47,000,000 in 2004 to 45,986,000 in 2006 (5). Some project the population to decrease up to 40% by 2050 (6). The World Bank and the International HIV/AIDS Alliance in Ukraine estimate that as many as 820,400 will be infected by 2014 (7) and that 140 Ukrainians will die each day, 75% between 20 and 34 years of age and half women (8). This perception is due largely to an increase in sexually transmitted new infections from IDUs to non-injectors. In the last decade, the epidemic began to spread rapidly through heterosexual transmission (9). In Odessa and Donetsk, two of the cities included in this proposal, 55–60% of new infections in 2005 were due to unprotected sex (10).

Many attribute the epidemic to the social and economic disruption that followed the collapse of the Soviet Union in 1991 (11 – 13). With the withdrawal of the Soviet Union, police controls lagged and drugs became more available (14 – 16). Locally produced opiates and amphetamines flourished (17) and the number of registered drug users increased rapidly, as did new cases of drug dependence (11). Following the rise in injection drug, new cases of HIV began to appear as well. The injecting practices of IDUs in Ukraine also likely had a role in the epidemic (18 – 20). Opiates, already liquefied, are typically purchased in pre-loaded syringes from Roma selling in open-air markets or from drug dealers who are usually IDUs (21). Dealers prepare enough drug solution for themselves and 6–10 others. The solution is withdrawn from a jar or cup with the user's needle/syringe, or front or back loaded with the dealer's needle/syringe (21, 22). Amphetamines, purchased in the form of pseudo-ephedrine from pharmacies, also involve using shared drug mixing containers (15, 23). When injecting ephedrine-based solutions, IDUs typically inject in groups and share not only the drug solution but also needles/syringes (15, 24).

As recently as 2005 Ukraine had no public health information service, no HIV prevention policy or substance abuse treatment, no sex education in schools, and no dissemination strategy to address the HIV/AIDS epidemic (25). Also lacking was funding necessary to provide comprehensive HIV testing and counseling. The present investigation was designed to compare a brief structured HIV testing and counseling intervention against a more intensive model that included repeated one-one-one contacts between outreach workers and IDUs focusing on assessing risk behaviors and, using a hierarchy, developing strategies to move to lower risk positions.

METHODS

Beginning in June 2004, participants in both arms were recruited by former drug users serving as outreach workers, a procedure shown to provide appropriate samples for this type of research (26, 27). The research was conducted by non -government organizations (NGOs) in three Ukraine locations, Kiev, Odessa and Makeevka/Donesk. The NGOs were in areas with high concentrations of IDUs and HIV prevalence rates, they had experience working with IDUs and they had expressed prior interest in HIV prevention. Using a cross-over design (28), half of the cohort was recruited, followed by a "wash out" period with no recruitment, a reversal of intervention assignment areas and recruitment of the remaining cohort. Participants at each site received either a NIDA-developed standardized HIV Counseling and Education intervention, (C & E; 29), or the C & E plus an individualized risk reduction intervention, the Indigenous Leader Outreach Model (ILOM; 30). The C & E was a manually-driven intervention that consisted of HIV pre-test counseling, a blood draw to test for HIV, and post-test counseling. When first developed, there was no rapid HIV test

and post-test counseling sessions were conducted approximately 14 days after the blood draw. In Ukraine, however, a finger stick rapid test was available, the HIV I + II One-Step Test (Orgenics, Ltd., Yavne, Israel), with results available within approximately 20 minutes. In the pre-test counseling session, a series of cue cards describing basic information about AIDS and how to reduce risk of HIV were discussed with the participant. The content of the cue cards was slightly modified from the original C & E model based on the injection practices of Ukraine IDUs (21). Participants rehearsed how to clean injection equipment and use a condom with an anatomical model. At the post-test session, test results were provided and additional cue cards presented based on the results of the test. Those testing positive were provided a list of HIV service agencies in the area and referred to the AIDS Centre in their city for confirmation of test results.

The ILOM was an intervention approach we have employed since 1987 and one found effective in reducing needle-related risk behaviors (31, 32). In the model, former drug users serve as outreach workers to access the target population, gain rapport, describe the study's purpose, conduct an initial eligibility assessment and schedule the research interview. Those interested in participating are informed of the project's eligibility requirements and an interview is scheduled. Following the baseline interview and over the course of the next five months, outreach workers conduct repeated interventions with study participants to assess individual risk behaviors, offer a hierarchy of high risk alternatives, reinforce risk reduction and encourage prevention advocacy.

Approximately 20 participants were recruited monthly from two distinct areas at each site over a 15 month period; one where recruits were assigned to the C & E only arm and the other where participants were assigned the C & E plus ILOM condition, for a total of 150 per arm. Areas targeted for recruitment were determined based on the NGOs' knowledge of where IDUs congregated. Following a three month "wash out" period where no recruitment occurred, intervention assignment areas were reversed and recruitments continued over the next 15 months. Recruitment took place in street settings and, to obtain a more representative sample, occurred in 28 of the 30 districts across the three cities. Eligibility criteria included: self-reported drug injection in the previous 30 days; at least 18 years of age; and able to provide informed consent. Drug injection was verified by interviewers through visual inspection for signs of recent venipuncture. All participants provided informed consent and were compensated the equivalent of $5.00 for their initial interview and $6.00 for their six-month follow-up interview. Following the interview, participants were provided free HIV testing. After the baseline assessment, those in the C & E + ILOM condition received five months of interventions. No intervention contacts were to occur between months five and six to reduce bias at the six-month interview. Participants assigned to the C & E only arm received no further intervention after the HIV post-test counseling session. All study procedures were approved by the Institutional Review Board (IRB) of the University of Colorado Denver, which served as the IRB of record through a Federal-wide Assurance of Protection for Human Subjects as there was no IRB available in Ukraine at the time the study began, and were in accord with the ethical standards of the Helsinki Declaration of 1975.

Interviews were conducted by staff comfortable with drug injectors and familiar with the research protocol. An audio computer-administered self-interview (ACASI) schedule, adapted from the Risk Behavior Assessment (RBA) developed by a grantee consortium of NIDA was utilized. It assessed demographics, health history, drug use and injection and sex-related risk behaviors. Reliability and validity assessments of the RBA support its use with IDUs for this purpose (33, 34). The instrument was modified slightly based on the drug use patterns of IDUs in Ukraine discovered during a series of focus groups with users and dealers and a review by NGO staff (21). Translation into Russian was provided by an IRB-

certified translator in Denver and verified by the project's CO-Investigator (Dvoryak) and Project Manager (Sinitisyna), both of whom were fluent in Russian and English.

Independent variables used in the analyses included demographics, drug use and testing positive for HIV (at the baseline interview). Dependent variables were collected at the 6-month follow-up and included drug use and needle and sex risk behaviors. Injection and sex risk composite measures were also computed and dichotomized according to weather any risk behavior was reported. The needle risk composite included injecting drugs drawn from a common container used by other IDUs, front/backloading, injecting with a used needle/syringe without cleaning ("dirty" needle/syringe) and sharing cotton, cooker or water. The sex risk composite included having more than one sex partner, sex with an IDU, sex with an HIV-infected partner or one of unknown status and unprotected vaginal or anal sex. The risk period for both baseline and follow-up assessments was the 30-day period prior to the interview.

Participants in the C & E and the C & E + ILOM conditions were compared on demographics, HIV status, drug use and needle and sex risk behaviors. Continuous variables (age, years injected, and times injected in the last 30 days) were assessed using t-tests; all other variables (dichotomized or ordinal) were compared using a χ^2 statistic. Changes in needle and sex risk behaviors from baseline to follow-up were evaluated separately for C & E and C & E + ILOM groups using McNemar's χ^2 statistic for matched pairs or a paired t-test (for mean times injected). In addition, repeated measures analyses were computed in order to test for the group by time interaction, which indicates differential pre/post change between the two intervention groups. ANCOVA was computed for the continuous outcome (times injected) and categorical models fitted for binary outcomes. Categorical models act much like the ANCOVA model, testing for group and time main effects and the group by time interaction, but are appropriate for binary outcomes and use a chi-square rather than an F-test. The ANCOVA and the categorical models also incorporated dummy codes for city as covariates. Relationships between needle and sex risk outcome behaviors and selected predictor variables measured at baseline were evaluated using a χ^2 statistic for dichotomous predictor variables or a t-test for continuous predictor variables. Finally, stepwise multiple logistic regressions were computed for dichotomous needle and sex risk behaviors, including the composite measures, using the baseline measure and dummy codes for city as control variables and adding intervention assignment and other predictor variables that had univariate relationships with the outcome variable of $P < .10$. The adjusted odds ratio (OR), 95% confidence interval (CI), and p-value of the OR for predictor variables are reported.

Follow-up Rates and Baseline Comparisons

Baseline assessments were completed by 1,798 respondents at the three sites, 600 in Odessa and 599 each in Kiev and Makeevka/Donesk, with 900 assigned to C & E only and 898 to the C & E + ILOM conditions. Overall, 1571 were successfully re-interviewed at 6-months for a completion rate of 87%. Of those not contacted at follow-up, 5% were incarcerated, hospitalized or had died, 2% had moved out-of-the area and 6% could not be found. Thus, 94% of those interviewed at baseline were located at follow-up. Follow-up rates did not differ significantly by intervention arm, site or on any of the demographic, drug use, needle or sex risk variables. There were, however, significant differences between sites on several variables. More than half (53%) of the participants from Odessa tested positive for HIV, compared to 34% in Kiev and 20% in Makeevka/Donesk ($P < .001$). Opiate injection was highest in Makeevka/Donetsk (55%), followed by Kiev (50%) and Odessa (48%; $P < .05$), while Makeevka/Donetsk had the lowest percentage of opiate/sedative mix injectors (28% versus 48% and 49% in Kiev and Odessa, respectively; $P < .001$). Stimulant injection was lowest in Odessa (33%) and highest in Kiev (67%; $P < .001$). Subsequently, repeated measures analyses and logistic regressions controlled for city.

There were also several differences at baseline between intervention arms. In terms of drug use and injection risks, participants in the C & E arm were more likely to have injected an opiate/sedative mix (45% vs. 39%; $P<.05$) and to have reported at least one risk behavior on the needle risk composite measure (95% vs. 92%; $P<.05$). According to sex risks, the C & E + ILOM group was more likely than those in C & E to have had an IDU sex partner (44% vs. 38%; $P<.05$), sex without a condom (56% vs. 50%) and at least one risk reported on the sex risk composite measure (76% vs. 71%; $P<.05$). It is difficult to account for these differences in risk behaviors between the two conditions since participants were recruited from the same locations over the course of the study. Subsequent analyses, however, controlled for baseline differences between sites as well as intervention arms.

Participant Characteristics

The majority of those recruited were male (76%), 30% were married or living as married and the average age was 29.5 years (SD = 7.8). Half had completed some post-secondary education and only 13% had not completed secondary school. They had been injecting drugs for an average of 10.8 years (SD =7.2). Nearly two-thirds (63%) had been arrested in their lifetime, 14% were aware they were HIV positive, and 35% tested positive for HIV following the baseline interview. In the 30 days prior to their interview, participants averaged 28.5 injections (SD = 32.2), 53% had injected stimulants, 51% opiates (liquid poppy straw) and 42% an opiate/sedative mixture. In terms of injection-related risk behaviors, 33% reported injecting drugs drawn from a common container, 85% front/backloaded, 18% injected with a dirty needle/syringe, 30% shared cotton, cooker or water and 93% engaged in at least one of these risks. According to sex risks, 26% reported multiple sex partners, 41% sex with an IDU, 36% sex with an HIV-infected partner or one of unknown status, 53% unprotected vaginal or anal sex and 73% reported one or more of these behaviors.

RESULTS

Table 1 shows baseline and follow-up data on drug use and needle risk behaviors separately for the C & E and C & E + ILOM intervention groups. Changes from baseline to follow-up were examined within the two arms and results showed there were statistically significant reductions on all behaviors assessed. Repeated measure ANCOVA results (for mean times injected) and repeated measures categorical models (for binary outcomes) revealed there were significant time effects on all variables. The group by time interaction was not significant on any outcome measure, however, indicating no differential effects between the two conditions.

Reductions were found for injection frequency as well as for injection risks. In order to further examine the relationship between reductions in injection frequency and injection risks, we grouped subjects into three groups based on changes in injection frequency and compared the pre-post change on injection risks within each of these three groups. The first group increased their injection frequency from baseline to follow-up by 6 or more times (N=187) and showed slight increases in 5 of the 8 injection risk indicators, with an increase in front/back loading of 9.1% being the only statistically significant change. A second group did not change in injection frequency by more than 5 times in the previous 30 days (N=767) yet showed statistically significant decreases for all injection risk indicators ranging from 3.1% to 15.5%. The third group decreased their injection frequency by 6 or more times in the previous 30 days (N=615) and showed the largest decreases in injection risk indicators, ranging from 12.1% to 31.2% reductions, all statistically significant at $p < .001$.

Table 2 presents baseline and follow-up data for sex risk behaviors for the C & E and C & E + ILOM groups. Overall, 80% reported vaginal or anal sex, including 26% who had sex with

more than one partner. There were significant reductions on all outcomes for those in both arms, with the exception of sex with an IDU among participants in the C & E. Results of the repeated measures categorical models analyses indicated that the time effect was significant on all sex risk variables. The interaction of intervention condition by time was significant for multiple partners ($P<.05$) and sex with an IDU ($P<.05$). Those in C & E had a greater reduction in sex with multiple partners over time (from 27% to 19%; $P< .001$) than those in C & E + ILOM (from 25% to 21%; $P<.05$), while sex with an IDU decreased more for the C & E + ILOM group (from 44% to 37%; $P<.01$) than C & E group (from 38% to 36%; NS).

The change analyses showed that the proportion of respondents engaged in each of the drug, needle and sex risk behaviors assessed was reduced significantly from baseline to follow-up, and that this change was generally consistent across the two intervention groups. Further analyses were conducted to examine predictors of needle and sex risk outcomes. A set of predictors measured at baseline, including demographics, drug use and testing positive for HIV were examined in relation to needle (Table 3) and sex risk behaviors (Table 4) at follow-up.

Results presented in Table 3 show that being younger, having a shorter injection career, and injecting more frequently were significantly associated with higher levels of each of the needle risk behaviors (with the exception of age and front/back loading; years injecting and front/back loading and the needle risk composite). Injecting stimulants was associated with higher levels of needle risk for all behaviors except front/back loading; injecting opiates was associated with a higher likelihood of front/back loading and the needle risk composite; and injecting an opiate/sedative mix was associated with a higher probability of front/back loading and the needle risk composite. Finally, testing positive for HIV was significantly associated with not using dirty works.

Predictors of sex risk outcomes are shown in Table 4. Males were more likely than females to have reported multiple sex partners, however, females were more likely to have had sex with an IDU, sex with an HIV+ (or don't know) partner, unprotected vaginal or anal sex and score higher on the sex risk composite measure. Younger participants and those with fewer years injecting were more likely to have had multiple partners, unprotected sex and at least one behavior on the sex risk composite. Frequency of injection was positively associated with having multiple partners and sex with an IDU. Stimulant injectors were more likely than those who did not inject stimulants to engage in all of the sex risk behaviors with the exception of sex with an HIV+ (or don't know) partner. Injectors of an opiate/sedative mix were less likely to have reported unprotected sex and score on the sex risk composite. Injecting opiates was not significantly associated with any of the sex risk variables. Finally, those who tested positive for HIV were less likely than those who tested negative to have had multiple partners, unprotected sex and one or more behavior on the sex risk composite measure, but were more likely to have sex with an HIV+ (or don't know) partner.

Logistic regression equations were computed for each of the needle and sex risk outcomes. For each behavior, the baseline measure of risk, as well as dummy codes for city (Makeevka and Odessa), were forced into equations as control variables. Additional predictors were then selected in a stepwise fashion and included intervention assignment and the predictor variables from Tables 3 and 4 that had relationships of $P< 0.10$ with the outcome variable. Greater times injecting in the 30 days prior to the baseline interview was a significant predictor of all needle risk behaviors (OR range from 1.19, 95% CI = 1.04–1.37; $P<.02$ for sharing cotton, cooker or water to 1.62, 95% CI = 1.33–1.97; $P<0.001$ for using a dirty needle/syringe). Injecting stimulants was a significant risk factor for drawing from a common container (OR = 1.52, 95% CI = 1.14–2.03; $P<.01$) and sharing cotton, cooker or

water (OR = 1.79, 95% CI = 1.31–2.44; $P < 0.001$), and injecting opiates was a risk factor for front/back loading (OR = 1.29, 95% CI = 1.02–1.63; $P < 0.05$) and the needle risk composite (OR = 1.31, 95% CI = 1.03–1.67; $P < 0.05$).

For sex risk outcomes, female gender was significantly related to reduced risk for having multiple partners (OR = 0.63, 95% CI = 0.43–0.92; $P < .02$) but increased risk for having sex with an IDU (OR = 3.55, 95% CI = 2.71–4.67; $P < 0.001$), unprotected vaginal or anal sex (OR = 1.55, 95% CI = 1.18–2.03; $P < 0.01$) and the sex risk composite measure (OR = 1.70, 95% CI = 1.28–2.27; $P < 0.001$). Greater years injecting was associated with decreased risk for having multiple partners (OR = 0.97, 95% CI = 0.94–0.99; $P < 0.01$) and the sex risk composite (OR = 0.97, 95% CI = 0.96–0.99; $P < 0.01$). In addition, increased times injecting in the last month (OR = 1.01, 95% CI = 1.00–1.01; $p < 0.001$) and injecting stimulants (OR = 1.41, 95% CI = 1.09–1.81; $P = 0.01$) were risk factors for having sex with an IDU partner.

Testing positive for HIV was associated with reduced risk of unprotected sex (OR = 0.55, 95% CI = 0.43–0.71; $P < 0.001$) and the sex risk composite measure (OR = 0.78, 95% CI = 0.60-.99; $P < .05$), but an increased probability of having sex with an HIV+ partner or someone of unknown HIV status (OR = 2.69, 95% CI = 2.08–3.47; $P < 0.001$). Additional analyses were conducted to examine whether IDUs were likely to change unsafe sex behaviors after testing positive for HIV. Results are shown in Table 5. Three groups were compared: 1. IDUs who tested HIV negative at baseline (N = 1,011); 2. those who tested positive at baseline and were unaware of being positive (N = 338); and 3. those at baseline who were aware of being HIV+ (N = 201). At baseline, 57% of the HIV negative and 52% of the HIV+ unaware groups engaged in unprotected vaginal or anal sex, compared to 38% of HIV+ aware IDUs ($P < .001$). At follow-up, 49% of HIV negatives reported unprotected sex compared to 32% of the HIV+ unaware and 27% of the HIV+ aware groups ($P < .001$). Thus, at baseline, IDUs who were aware of being HIV+ were less likely to engage in unprotected sex than were those who were either HIV negative or not aware of their HIV+ status. Although all three groups showed statistically significant reductions in unprotected sex, the greatest change at follow-up was among those who learned at baseline that they were HIV positive; the least change was reported by those who tested HIV negative at baseline.

DISCUSSION

Results of this study demonstrate that it is feasible to implement HIV prevention interventions in community-based settings in Ukraine and suggest that such interventions are effective in reducing HIV-related risk behaviors. Nearly 1,800 drug injectors were recruited from three sites and nearly 90% were successfully re-interviewed six months later. Findings revealed that this sample of IDUs were at very high risk of HIV transmission through both injection and sex risk behaviors. Yet, from baseline to follow-up, significant reductions were observed on all drug injection and needle risk variables assessed for each intervention condition. This may be a reflection of the interventions' emphasis on the importance of reducing both drug injecting and injection-related risk behaviors and, as injection frequency declines, there is less opportunity for related risks to occur. However, we also observed a substantial number of injection drug users who did not reduce their injection frequency but did reduce injection risks, although not at the magnitude of those who also reduced their injection frequency. Similar results were noted for sex risks with one exception (i.e., having an IDU sex partner for those in the C & E only arm).

Of interest was the relative lack of difference found in risk behavior change between intervention conditions. Overall, the C & E only intervention was as effective as the more expensive and involved C & E + ILOM. Studies of in-treatment populations of IDUs have

also reported no differences in outcomes between minimal and enhanced interventions (35, 36), including waiting lists with no intervention (37), although others have found enhanced interventions to be associated with greater reductions in risk behaviors (38). Studies of out-of-treatment IDUs have also tended to not support enhanced over standard interventions in accounting for behavioral change (39 – 43).

The finding that HIV testing and counseling alone was as effective as an individually-focused intervention that involved repeated encounters with the target population on the street has important implications for Ukraine. The C & E model is manually-based, the training involved in its use relatively simple and short, and it is inexpensive. In a country such as Ukraine, where the majority of people infected with HIV have not been tested (44) and the provision of HIV-related prevention services is minimal (25), such an approach may have appeal. Voluntary testing and counseling (VTC) of IDUs in this region of the world has been strongly recommended by the WHO (45). Moreover, the use of a rapid test helps assure that those tested receive their results. The acceptability of an HIV rapid test has been demonstrated, not only in the present study, but in rural and urban areas of the United States as well as in China and Costa Rica (46).

Supporting this recommendation were the findings that those who knew they were HIV infected at baseline were the least likely to practice unprotected sex in the prior 30 days, both at baseline and follow-up, and that those who newly discovered they were HIV infected at baseline changed the most in unprotected sex at follow-up. In a randomized clinical trial conducted with narcology hospital inpatients in St. Petersburg, Russia, Samet and colleagues (47) found that those who received the intervention were significantly more likely to report engaging in safe sex (i.e., protected) than those in the control group. The intervention was very similar to the C & E used in the present study. It included two safe sex counseling sessions and the provision of skills-building on HIV-related sex and injection risk behaviors delivered by skilled and well-trained personnel, as did the C & E. Both the Samet study and the present one, as well as a recent meta-analysis of sex risk behaviors in persons who were either aware or unaware they were HIV positive (48), offer evidence that knowledge of HIV infection reduces unsafe sex.

This study also found that younger IDUs and those with fewer years injecting engaged in greater drug and sex risk behaviors than those who were older and who had injected longer. Given the sharp increase in HIV in recent years (4), and findings we reported previously that younger IDUs were significantly less likely to be HIV infected (20), these findings may foreshadow a worsening epidemic in Ukraine. To further compound the problem, with the exception of having more than one sex partner, females were at greater risk in their sex behaviors than males, including unprotected vaginal or anal sex. Our earlier work found that females had significantly higher rates of HIV than males (49).

There are several limitations to this study that should be considered before drawing inferences from the findings. With the exception of HIV status, the results reported were based on self-report and participants could not be blinded as to intervention status, leaving open the possibility of social desirability, as well as recall errors. We did attempt to overcome these factors through the use of an ACASI and a short, 30-day, recall period. In addition, previous studies have shown that drug users' self-report is sufficiently valid for the type of research reported here (50, 51). The sampling plan was designed to access street-recruited IDUs from locations throughout each city in order to generalize to the population of drug injectors in those locations. While this approach is preferable to convenience sampling, it is not known how representative the samples were of IDUs in each city. Outreach workers, however, reported few refusals to participate and recruitment took place in nearly every district in each city. In addition, some of the findings reported could have

been the result of regression to the mean, a frequent occurrence in intervention research. Finally, the management of the study from the U.S. presented several challenges in monitoring recruitment, intervention and follow-up efforts. We attempted to minimize fidelity issues through training in Good Research Practices, quarterly monitoring visits by the U.S investigators and bi-monthly monitoring by our Ukrainian research coordinator.

In summary, the results produced by this study are both discouraging as well as encouraging. The high rates of HIV observed as well as the extent of risk behaviors, particularly by younger drug injectors, point to the continued escalation of HIV in Ukraine. On the other hand, the study showed it is feasible to implement prevention interventions in Ukraine, that HIV testing and counseling is as effective as more expensive and time-consuming approaches, and that knowledge of HIV infection reduces sex risk behaviors.

Acknowledgments

The authors would like to acknowledge the dedicated NGO staff and Directors who participated in this project. These include Elena Teryayeva with Health of Nation in Makeevka/Donetsk, Olga Kostyuk and Tatiana Semikop with Faith, Hope and Love in Odessa and Oxana Gorbach with the Substance Abuse and AIDS Prevention Foundation in Kiev. Their commitment to preventing the further spread of HIV in their country is inspiring. We are also indebted to the drug users who agreed to participate and gave their time that allowed us to conduct this study. We wish to thank Christina Schmitt for her editorial assistance. Finally, we acknowledge the thoughtful suggestions of the anonymous reviewers of the original manuscript. This study was supported by the U.S. National Institute on Drug Abuse (RO1 DA17620).

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Table 1

Ukraine Needle Risk Behaviors – Baseline to 6 month change for CE-only and CE+ILOM

	CE Only				CE + ILOM			
Variable	**Baseline**	**6 month FU**	**Test Statistic**	***p*-value**	**Baseline**	**6 month FU**	**Test Statistic**	***p*-value**
Mean times injected (std) *	28.3 (32.3)	21.6 (26.9)	13.75	<0.001	28.6 (32.1)	20.4 (28.7)	14.74	<0.001
Inj stimulants last month	53.1	44.5	26.27	<0.001	53.2	44.2	26.63	<0.001
Inj opiates last month	50.6	39.8	31.01	<0.001	51.2	39.5	34.94	<0.001
Inj opiate/sed mix last month [1]	44.5	35.8	26.89	<0.001	39.2	30.1	28.16	<0.001
Use common container	34.2	25.5	19.59	<0.001	32.4	25.6	12.27	<0.001
Front/back load (any)	86.6	70.7	65.60	<0.001	83.3	69.7	47.61	<0.001
Use a dirty syringe	16.4	10.5	15.67	<0.001	19.4	7.7	48.21	<0.001
Use dirty cooker, cotton, water	31.5	17.5	51.55	<0.001	29.1	16.9	38.08	<0.001
Needle risk composite [2]	94.8	74.0	131.52	<0.001	91.5	74.0	92.46	<0.001

* The log of number of times injected was used in the statistical analysis.

[1] CE-Only group significantly differed from CE+ILOM at baseline and at follow-up at $p < 0.05$.

[2] CE-Only group significantly differed from CE+ILOM at baseline but not at follow-up at $p < 0.05$.

Table 2

Ukraine Sex Risk Behaviors – Baseline to 6 month change for CE-only and CE+ILOM

	CE Only				CE + ILOM			
Variable	**Baseline**	**6 month FU**	**Test Statistic**	***p*-value**	**Baseline**	**6 month FU**	**Test Statistic**	***p*-value**
Multiple Partners[1]	26.6	18.9	27.27	<**0.001**	24.6	21.1	5.03	**0.025**
Sex with an IDU[1, 2]	37.8	36.3	0.70	0.403	44.0	36.5	14.89	**0.001**
Sex with HIV+ partner or dk	34.3	26.7	18.00	<**0.001**	38.3	30.4	16.54	<**0.001**
Unsafe (without condom) sex[2]	49.6	40.0	24.02	<**0.001**	56.4	43.5	41.04	<**0.001**
Sex risk composite[2]	70.8	62.9	19.41	<**0.001**	75.8	67.1	21.27	<**0.001**

[1]The Intervention Group by Time interaction was statistically significant at $p < 0.05$..

[2]CE-Only group significantly differed from CE+ILOM at baseline but not at follow-up at $p < 0.05$.

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Table 3

Predictors of Needle Risk Outcomes at 6 months

	N	Common Container	Front/back load	Dirty Syringe	Dirty works	Needle Risk Composite
City		***p* < 0.001**	***p* < 0.001**	***p* < 0.001**	***p* < 0.001**	***p* < 0.001**
Makeevka	516	15.7%	67.1%	10.5%	20.7%	72.9%
Kiev	552	54.5%	83.5%	14.3%	26.1%	87.7%
Odessa	503	3.8%	58.8%	2.2%	3.8%	60.0%
Gender		*p* = 901	*p* = 0.269	*p* = 0.338	*p* = 0.999	*p* = 0.347
Male	1187	25.5	70.9	8.8	17.2	74.6
Female	384	25.8	68.0	10.4	17.2	72.1
Mean age		***p* < 0.001**	***p* = 0.058**	***p* < 0.001**	***p* < 0.001**	***p* = 0.001**
Yes on outcome		27.5 (6.4)	29.2 (7.6)	27.1 (6.1)	27.0 (6.3)	29.1 (7.5)
No on outcome		30.1 (8.1)	30.1 (8.3)	29.7 (7.9)	30.0 (8.0)	30.6 (8.4)
Mean years injected		***p* < 0.001**	*p* = 0.565	***p* = 0.007**	***p* < 0.001**	***p* = 0.066**
Yes on outcome		9.2 (5.8)	10.7 (7.0)	9.5 (5.9)	8.9 (5.9)	10.6 (6.9)
No on outcome		11.3 (7.6)	11.0 (7.8)	10.9 (7.3)	11.2 (7.4)	11.4 (8.0)
Mean Times injected		***p* < 0.001**	***p* < 0.001**	***p* < 0.001**	***p* < 0.001**	***p* < 0.001**
Yes on outcome		42.2 (39.1)	31.7 (33.3)	47.3 (41.5)	35.2 (38.6)	31.5 (33.6)
No on outcome		23.7 (28.0)	20.7 (27.9)	26.4 (30.5)	27.0 (30.6)	19.7 (26.0)
Inj stimulants		***p* < 0.001**	*p* = 0.103	***p* < 0.001**	***p* < 0.001**	***p* < 0.001**
No	736	17.4	68.2	6.4	9.9	69.7
Yes	835	32.7	72.0	11.7	23.6	77.7
Inj opiates		*p* = 0.359	***p* = 0.001**	*p* = 0.405	*p* = 0.563	***p* = 0.006**
No	772	24.5	66.3	8.6	17.7	70.9
Yes	799	26.5	74.0	9.8	16.6	77.0
Inj Opiate/sedative		*p* = 0.200	***p* < 0.001**	***p* = 0.055**	*p* = 0.133	***p* = 0.009**
No	913	24.3	66.4	8.0	18.4	71.5
Yes	658	27.2	75.5	10.9	15.5	77.4
HIV positive test		*p* = 0.103	*p* = 0.895	*p* = 0.698	***p* = 0.003**	*p* = 0.686
No	1021	26.8	70.0	9.3	19.2	74.2
Yes	543	23.1	70.3	8.7	13.3	73.3

Table 4

Predictors of Sex Risk Outcomes at 6 months

	N	Multiple Partners	Sex with IDU	Sex with HIV+/dk	Unsafe Sex	Sex Risk Composite
City		$p = 0.271$	**$p = 0.053$**	**$p < 0.001$**	**$p < 0.001$**	**$p < 0.001$**
Makeevka	516	18.2%	35.3%	20.9%	60.6%	74.4%
Kiev	552	22.1%	40.2%	24.8%	34.3%	61.6%
Odessa	503	19.6%	33.3%	40.4%	31.8%	59.4%
Gender		**$p < 0.001$**	**$p < 0.001$**	**$p = 0.009$**	**$p = 0.002$**	**$p < 0.001$**
Male	1187	22.6	27.9	26.8	40.0	62.3
Female	384	12.1	62.7	33.8	48.9	73.8
Mean age		**$p < 0.001$**	**$p = 0.085$**	$p = 0.698$	**$p < 0.001$**	**$p < 0.001$**
Yes on outcome		28.1 (6.6)	29.0 (7.2)	29.6 (7.1)	28.5 (7.2)	28.7 (7.2)
No on outcome		29.8 (8.0)	29.7 (8.1)	29.4 (8.1)	30.2 (8.2)	30.8 (8.7)
Mean years injected		**$p < 0.001$**	**$p = 0.063$**	$p = 0.227$	**$p < 0.001$**	**$p < 0.001$**
Yes on outcome		9.5 (6.1)	10.3 (6.6)	11.1 (6.5)	9.9 (6.7)	10.0 (6.6)
No on outcome		11.1 (7.4)	11.0 (7.5)	10.6 (7.4)	11.4 (7.5)	12.2 (8.0)
Mean Times injected		**$p = 0.032$**	**$p < 0.001$**	$p = 0.468$	**$p = 0.090$**	$p = 0.489$
Yes on outcome		31.8 (34.5)	33.2 (35.5)	29.3 (33.2)	26.8 (29.9)	28.0 (31.4)
No on outcome		27.5 (30.6)	25.6 (28.8)	28.0 (30.9)	29.6 (33.7)	29.1 (33.4)
Inj stimulants		**$p = 0.007$**	**$p < 0.001$**	$p = 0.583$	**$p < 0.001$**	**$p < 0.001$**
No	736	17.1	30.7	27.8	37.5	60.2
Yes	835	22.6	41.3	29.1	46.3	69.5
Inj opiates		$p = 0.830$	$p = 0.629$	$p = 0.667$	$p = 0.362$	$p = 0.617$
No	772	19.8	37.0	29.0	41.0	64.5
Yes	799	20.2	35.8	28.0	43.3	65.7
Inj Opiate/sedative		$p = 0.392$	$p = 0.121$	$p = 0.523$	**$p < 0.001$**	**$p < 0.001$**
No	913	20.7	38.0	27.9	46.2	68.8
Yes	658	19.0	34.2	29.4	36.6	59.9
HIV positive test		**$p = 0.005$**	$p = 0.194$	**$p < 0.001$**	**$p < 0.001$**	**$p < 0.001$**
No	1021	22.2	35.3	19.1	48.7	68.6
Yes	543	16.2	38.7	46.3	30.2	58.9

Table 5

Unsafe Sex at Baseline and Follow-up by HIV Status

N	HIV Negative N = 1,011	Unaware Positive N = 338	Aware Positive N = 201	p[1]
Unsafe sex at baseline	56.5%	52.0%	38.1%	< 0.001
Unsafe sex at 6-month	49.0%	32.1%	26.9%	< 0.001
Change	7.5%	19.9%	11.2%	
p[2]	< 0.001	< 0.001	< 0.001	

[1]Probability is based on χ^2 statistic comparing the three HIV groups on unsafe sex at baseline or 6-month follow-up.

[2]Probability is based on a McNemar χ^2 statistic assessing change from baseline to 6-month follow-up within each HIV group.