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Outcome evaluation of a "common factors" approach to develop culturally tailored HIV prevention interventions for people who inject drugs

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JO conceptualized the research question and prepared the first draft of the manuscript. TN developed the analysis strategy. TN and AM performed statistical analyses. SD, OF, PA, TZ, RA, and AM assisted with interpretation of the findings. All authors reviewed and approved the final version of manuscript.

Conflict of Interest

The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Abstract

Background: Current models of HIV prevention intervention dissemination involve packaging interventions developed in one context and training providers to implement that specific intervention with fidelity. Providers rarely implement these programs with fidelity due to perceived incompatibility, resource constraints, and preference for locally-generated solutions. Moreover, such interventions may not reflect local drug markets and drug use practices that contribute to HIV risk.

Purpose: This paper examines whether provider-developed interventions based on common factors of effective, evidence-based behavioral interventions led to reduction in drug-related HIV risk behaviors at four study sites in Ukraine.

Methods: We trained staff from eight nongovernmental organizations (NGOs) to develop HIV prevention interventions based on a common factors approach. We then selected four NGOs to participate in an outcome evaluation. Each NGO conducted its intervention for at least N=130 participants, with baseline and 3-month follow-up assessments.

Results: At three sites, we observed reductions in the prevalence of both *any risk in drug acquisition* and *any risk in drug injection*. At the fourth site, prevalence of *any risk in drug injection* decreased substantially, but the prevalence of *any risk in drug acquisition* essentially stayed unchanged.

Conclusions: The common factors approach has some evidence of efficacy in implementation, but further research is needed to assess its effectiveness in reducing HIV risk behaviors and transmission. Behavioral interventions to reduce HIV risk developed using the common factors approach could become an important part of the HIV response in low resource settings where capacity building remains a high priority.

Keywords

HIV prevention; Implementation Science; Common Factors; Ukraine; Drug Use

1.0 Introduction

HIV infection among people who inject drugs (PWID) remains a significant public health problem, despite the existence of effective strategies to reduce HIV transmission among this population. Harm reduction programs such as needle and syringe exchange programs (NSP) and medication-assisted treatment (MAT) for the treatment of opioid use disorder, and the provision of antiretroviral therapy (ART) to people living with HIV (PLWH) have demonstrated effectiveness at reducing HIV incidence (Anglemyer et al., 2011; Aspinall et al., 2014; Metzger et al., 2015). Research and modeling studies indicate that widespread coverage of these “three pillars” of HIV prevention—NSP, MAT, and ART—in high HIV prevalence areas can prevent HIV infections and HIV-related deaths (Cepeda et al., 2018; Degenhardt et al., 2014). However, efforts to scale up these interventions have faced significant challenges, particularly in low and middle income (LMIC) countries such as Ukraine. While NSP coverage in Ukraine is currently estimated to be about 37% (Barska and Sazonova, 2015), MAT and ART coverage lag significantly, with only an estimated

2.7% of PWID on MAT (Makarenko et al., 2016) and only 52% of PWID in HIV care and 38% on ART, and 28% are virally suppressed (Sazonova and Saliuk, 2018). Other studies suggest that certain subgroups of PWID in Ukraine have lower ART coverage (Mazhnaya et al, 2018). These coverage shortfalls can be attributed to negative attitudes toward MAT among PWID and providers (Bojko et al., 2015), lack of funding for ART and MAT expansion (Bojko et al., 2013, 2015), and structural barriers such as law enforcement targeting o PWID who visit MAT sites and poor location of facilities (Mazhnaya et al., 2016).

In the context of these challenges, HIV prevention interventions that promote behavior change can be an important tool that complements structural and policy interventions. As Rhodes (2009, 2002) argues, the production of HIV risk is multifaceted and requires multi-level response. Behavioral interventions can reduce injection risk behaviors such as sharing needles/syringes and injecting frequency compared with control interventions such as education-only (Booth et al., 2011; Copenhaver et al., 2006; Gilchrist et al., 2017; Latkin et al., 1996). In addition, these interventions can often serve as important conduits for enrolling clients in other programs offered by nongovernmental organizations (NGOs) or health care providers, including drug treatment and HIV care. Also, because these programs often require implementing agencies to continually enroll new clients into on-going programs, they can also serve as an important strategy for reaching new populations that may not have received harm reduction services previously.

As Rotheram-Borus et al. (2009) proposed, many efficacious, behavior change HIV prevention interventions are based on common principles and processes that they coined “common factors” that transcend individual interventions (Rotheram-Borus et al., 2009). Common factors are broad constructs that support behavior change and can be incorporated into a variety of EBIs. According to this framework, successful interventions provide participants with a framework for understanding their HIV risk behavior and opportunities for change; build cognitive, affective, and behavioral skills; foster social support; include tailored, behavior-specific content; and address environmental barriers to behavior change. They typically include multiple sessions in a small group format led by skilled facilitators; incorporate HIV/AIDS information and risk identification, use peer group discussion, demonstration, modeling, and role-playing to build participants skills related to engaging in safer behaviors and communicating with peers and partners about HIV risk reduction.

However, the current dominant model of HIV prevention intervention dissemination is based on the development of interventions and the “core elements.” In contrast to common factors, core elements are understood to be integral components of an intervention thought to be responsible for its effectiveness, and that must be retained in order for HIV risk reduction to occur (Helitzer et al., 2008; Zvoch, 2009). These interventions developed in one context are then packaged, and providers are trained to implement that specific intervention. Within implementation science, numerous studies have demonstrated that implementing interventions with high degrees of fidelity will lead to great program success (Bopp et al., 2013; Hansen, 2013). At the same time, research has *also* shown that implementing agencies rarely implement interventions with complete fidelity (Dusenbury et al., 2003; Galbraith et al., 2008). They may expand interventions to new populations, eliminate activities or

sessions, add elements that were not included in the original intervention, or combine them with other programs (Galbraith et al., 2008; Harshbarger et al., 2006; Palinkas et al., 2008; Prather et al., 2006).

While implementation fidelity can be improved (Horner et al., 2006), the focus on fidelity does not address underlying assumptions about whether this model of research-to-practice is the most effective way to engage frontline service providers in the development and implementation of evidence-based interventions. Several problems with this model exist, including the research-to-practice time lag (Somerville et al., 2006) under development and utilization of provider capacity (Pfeiffer, 2013), and potential resistance by local experts who may view pre-packaged programs as undermining their locally generated solutions and professional training and experience (Dworkin et al., 2008; Ogden et al., 2003; Palinkas et al., 2008). In addition, solutions developed to overcome shortcomings in the research-to-practice transfer process, including guidelines about how to select and purposefully adapt existing interventions, have their own potential limitations such as lack of rigorous evaluation themselves and uneven application in practice (Craig Rushing, 2016; Gaglio et al., 2013; Govindasamy et al., 2014; Khumsaen and Stephenson, 2017). Moreover, an emphasis on core elements may diminish the importance of incorporating intervention components that address local drug mark characteristics, drug use practices, and risk environments that shape HIV risk for PWID in specific contexts (Burris et al., 2004; Ciccarone, 2005; Koester et al., 2005). Finally, the research-to-practice time lag and dependence of community organizations on the expertise of researchers may lead to delays in the development of effective interventions in the context of rapidly changing drug use contexts.

This paper examines whether provider-developed interventions based on common factors of effective, evidence-based behavioral interventions led to reduction in drug-related HIV risk behaviors at four study sites in Ukraine.

2.1 Materials and Methods

2.1.1 Study Sites.

This study took place in Ukraine between 2012 and 2016. In a 2013 intervention inventory of HIV prevention interventions targeting key populations in Ukraine, USAID concluded that around 60% of the interventions implemented in Ukraine lacked sufficient evidence of effectiveness, and only 12% of interventions focused specifically on behavior change and 6% focused on skill-building (RESPOND et al., 2013). Given high rates of HIV transmission through intravenous drug use (UNAIDS, 2010), we focused on developing interventions for PWID.

As described in detail elsewhere (Owczarzak et al., 2016, 2014), in Phase I of the project we trained service providers from eight nongovernmental organizations (NGOs) that work in HIV prevention from regions with the highest rates of HIV and epidemics concentrated among PWID, to develop interventions based on a “common factors” approach that also reflected their local HIV and drug use contexts, organizational resources, and clients. All study agencies worked in urban areas from a harm reduction perspective and provided a

range of services that included HIV and hepatitis C testing, psychosocial support, case management, and community centers. Agencies varied in size, from a small NGO primarily staffed by volunteers to a large organization staffed by paid professionals. All agencies served diverse populations that included PWID, people living with HIV, youth, and commercial sex workers. At the conclusion of Phase I, all participating agencies successfully developed a manualized intervention based on a common factors approach (Owczarzak et al., 2016). Phase II involved an outcome evaluation of four of the eight NGOs' intervention. The decision to evaluate the interventions of four agencies (rather than all eight) was built into the original study design. Resource constraints (financial, human, logistical) limited the number of sites we could work within the evaluation component of the study. Decision-making around which four agencies to continue working within Phase II was informed by 1) our understanding of the realities of staff turnover and agency and stability, based on our previous experience working with NGOs and in this region; 2) a goal of having agencies and interventions that represented diverse geographic regions, intervention content, and target populations among the final four agencies; and 3) selecting agencies whose interventions most consistently reflected the common factors training. To select the four agencies for evaluation, we systematically reviewed each agency's intervention (intervention manual and video recordings of one complete cycle of each site's intervention); reflected on our experiences working with the agency in Phase I; and comparison of the intervention content, geographic regions, and target populations across sites. For example, two agencies developed interventions primarily aimed at women. While both agencies developed strong interventions that reflected the common factors approach, we selected to work with the agency with the most stable funding and staffing. We did not select another agency for Phase II because it was located in AR Crimea, which was annexed by Russia and continuing to work there would have been logistically infeasible.

Each NGO that was selected to continue in Phase II was provided with resources to conduct full cycles of its intervention for at least N=130 participants (total N=520) with baseline and 3-month follow-up assessments. Each NGO combined strategies of direct contact, participant referral, and street-based outreach to recruit individuals to participate in the intervention. Inclusion criteria included being at least 18 years of age and having injected drugs within the last 30 days. Eligible participants provided oral informed consent. Study participants included both existing and new clients recruited through outreach and participant referral.

2.1.2 Description of NGO-Developed Interventions.

The four NGOs whose interventions included the largest number of common factors and most closely reflected the content of the training in their programs were selected to continue in the effectiveness evaluation component of the study (see Table 1). Within their interventions, all agencies targeted behavioral determinants related to five theoretical concepts: (1) risk perception and appraisal, (2) self-perception, (3) emotion and arousal, (4) relationships and social influences, and (5) environmental and structural factors. Reflecting the principles of "common factors," each NGO's intervention was unique in terms of specific target population, intervention content, and program structure (e.g., number and length of sessions) (see Table 2).

Site 1 chose to target clients of harm reduction services who were older (>35 years) and had some knowledge about HIV risk and access to clean needles but continued to practice injection risk behaviors. Examples of targeted behaviors include developing and applying planning strategies to always have and use clean syringe, boiling drug solution bought in already pre-filled syringe, and negotiating clean syringe and condom use. Intervention activities included role playing, self-assessment, group discussions, video informational materials, and small lectures, as well as skills building for goal setting and planning drug use. Intervention facilitators included professional pedagogical staff (N=2) and a peer who was an employee of the agency.

Site 2 targeted PWID between 18 and 30 years old who injected stimulants and such behaviors as goal setting to reduce risky behaviors, developing strategies to access available services for PWID, cleaning syringes and needles, changing group norms regarding clean syringe and paraphernalia use, negotiating to buy drugs using own clean syringe, and using condoms with partners. Intervention sessions consisted of motivational interviewing, group discussions, small lectures, goal setting exercises, skills building for cleaning syringes and needles, and building negotiation skills through role playing. Experienced addiction treatment specialist facilitated the sessions. A separate session for women was facilitated by female social worker from the agency.

Site 3 targeted their intervention toward heterosexually active women between 25 and 45 years old who inject drugs and have children. Within their intervention, the team targeted lack of knowledge about HIV, hepatitis, and sexually transmitted infections; low perceived risk of infection; low priority for preserving and maintaining health; lack of skills to access health services; maintaining safe injection and sex practices; and controlling emotion and arousal. Information sessions, skills building, group discussions, risk self-assessment, role playing, goal setting, planning and strategizing were utilized to achieve intervention goals. Intervention sessions were conducted by two female facilitators (a psychologist and a social worker).

Site 4 targeted PWID between 25 and 35 years old who use two or more type of substances (for example, opiates and stimulants) simultaneously or successively for more than 1 year. Low self-risk perception, prevalent myths about HIV risk, lack of knowledge and skills regarding safer injection and sexual practices, overdose prevention, and control of emotions, as well as lack of skills to change group norms were main targets of the intervention. Information sessions, video lectures, self-assessment, group discussions, skills building, identification of barriers, and role playing were the main strategies employed to achieve intervention goals. The sessions were conducted by an experienced (seven years of fieldwork) social worker.

2.1.3 Data and Study Design.

Participants at all sites completed a baseline assessment and a follow-up assessment 90 days after the last intervention session. The assessment instrument was based on Risk Behavior Assessment (RBA) and included basic sociodemographic characteristics (age, sex, education, marital status, income, housing situation), health history, drug use, and injection and sex-related risk behaviors, psychosocial constructs believed to mediate or moderate

risky behaviors (HIV risk reduction behavioral intentions, HIV-related vulnerability beliefs, HIV risk reduction skills, HIV-preventive behavioral skills self-efficacy), and participants' experiences in the intervention. In order to minimize social desirability bias that could result from having an interviewer ask the questions about the effects of an intervention they developed and implemented, the instrument was self-administered in Russian through a web-based online platform at the NGO venue in a private environment. NGO staff was available during the assessment to troubleshoot technical problems with the instrument. Participants were compensated 120 UAH (~5 USD) for completing the baseline assessment, and 180 UAH (~7USD) for completing the follow-up assessment. Additionally, agencies could use program support funds for intervention participation incentives (e.g., lunches and transportation cost). Intervention participants in Sites 1 and 2 were provided food and a small financial incentive. Site 3 participants were provided hygienic kits as a small gift for attending the intervention. Site 4 participants did not receive a financial incentive by the agency to attend the intervention.

Study protocol and materials were reviewed and approved by the Institutional Review Board at Johns Hopkins Bloomberg School of Public Health and the Ethics Committee of the Sociological Association of Ukraine.

The current paper focuses on the main outcomes of interest to the study: drug injection related HIV risk behaviors. We consider these behaviors in two broad groups: those related to drug acquisition and those related to injection itself. Drug acquisition risks included buying drugs in a preloaded syringe or giving one's syringe to a drug dealer, a middle person, or an injecting partner to get drugs. Injection- related risks included using a common drug container shared by other people; using a drug cooker, water or cotton that has been used by someone else; or frontloading (drawing drugs into the syringe through the needle) or backloading (removing the plunger to fill the syringe) one's syringe from a dealer's syringe. Based on these data, our analyses use as outcomes three combined variables in binary form: *any risky behavior in drug acquisition* (based on behaviors in the first group); *any risky behavior in drug injection* (second group); and *any risky behavior in drug acquisition and/or injection* (both groups). The time frame for these behaviors is the previous 30 days. Our current goal is to investigate differences between baseline and 3-month follow-up in the prevalence of these behaviors.

It is important to note that we did not employ a randomized controlled trial (RCT) design. RCTs are often considered the gold standard for generating the highest level of evidence regarding an intervention's effectiveness, but may not be appropriate or even feasible in some community settings such as the context in which this study took place (Rosen et al., 2006; Sanson-Fisher et al., 2007). It was not an option to randomize sites given only four sites with unique interventions developed for different contexts. Randomization of clients within each site was not accepted by the frontline service providers with whom we work because they believed that all people who desired to participate in the intervention should receive it and that participants would not want to be randomized (West et al., 2008). In addition, even if randomization had been more acceptable, contamination between intervention arms would have been hard to prevent given interaction among clients at each site. As the study uses a pre-post design without a comparison group, we will carefully

discuss factors other than the intervention that may have contributed to an apparent outcome prevalence change, or the lack of one.

2.1.4 Analysis Strategies.

Analyses were conducted separately for each site because the four sites are diverse, and the interventions are site specific. For each outcome at each site, the objective was to estimate (i) the pre-intervention outcome prevalence, (ii) the post-intervention outcome prevalence, and (iii) the pre-to-post outcome prevalence change (the difference between (ii) and (i)).

In this context of community-based interventions with hidden populations, some loss to follow-up was anticipated, especially at Site 1 where the client body tends to be transient due to migration and housing instability (see below). Our approach was (i) to estimate outcome prevalence and prevalence change on the whole group of people enrolled in the study at each site (as if there was no loss to follow-up), using multiple imputation to deal with missing follow-up outcome data; and (ii) to conduct a sensitivity analysis leaving out the individuals lost to follow-up if they make up more than 10% of the original sample.

As outcome variables are each coded based on several behavior specific items, an outcome variable may be missing because component behavior items are missing (e.g., ‘any risky behavior in drug injection’ is missing if a person answered ‘no’ to some items and did not answer the remaining items in this behavior group). Our strategy was to impute the detailed items before combining them into the three outcome variables (Rubin, 1987). We conducted multiple imputation (in Mplus) using a joint modeling approach (treating categorical variables as manifestations of underlying continuous variables). In addition to letting the various specific risk behaviors inform one another, the imputation model incorporates auxiliary variables including baseline participant characteristics and types of drugs injected, among others. The number of imputations (100) was picked based on White et al.’s (2011) recommendation that the number of imputations should be at least equal 100 times the fraction of missing information (FMI) for the parameter being estimated, and FMI is always smaller than 1 (or 100%).

This means the analysis for each site was based on the combination of the imputed datasets. Each imputed dataset provides a set of estimates for the parameters of interest – pre-intervention prevalence, post-intervention prevalence, and pre-to-post prevalence change, of each of the outcomes. We used bootstrapping to estimate variance. Specifically, from each imputed dataset, we resampled the individuals to draw 2000 bootstrap samples, which we used to estimate the covariance matrix of the parameter estimates. Thus, from each imputed dataset we have a set of point estimates and an estimated covariance matrix. These were pooled across the 100 imputed datasets based on Rubin’s (1987) combining rules (which hold in the current situation where the estimands are sample means), using the R package mitools (Lumley, 2014) to compute the final point estimate and confidence interval for each parameter. This bootstrapping procedure with multiply imputed data is called “MI boot”; see technical details in Schomaker and Heumann (2018). For each risk behavior at each site, we conducted a permutation test of the null hypothesis that there is no difference between baseline and follow-up – using 10,000 permutations of the measurements’ baseline/follow-up labels to establish the null sampling distribution.

3.1 Results

3.1.1 Sample Descriptions.

Table 3 presents the characteristics of study participants at baseline. As expected, the sites are quite diverse. While participants in Sites 1, 2, and 4 were mostly men, with about between 22% and 29% women, all participants in Site 3 were women. Participants in Site 2 were more likely than those at other sites to have some employment. Unstable housing was rare for participants in Sites 2 and 3, but not rare for the two other sites, and was common for those in Site 1. About 20% of participants in Sites 2 and 4 reported being HIV positive; the number of participants reporting being HIV positive in Site 1 was much smaller (7%), and none reported being HIV positive in Site 3. This may reflect differences in HIV prevalence, the degree to which participants were aware of their HIV status, and recruitment and screening strategies. Across sites, approximately 47% of participants exchanged syringes in the previous 3 months, with Site 1 indicating the lowest level of syringe exchange (35%) and Site 4 the highest (66%). National data indicate that 37% of PWID received syringes from NGOs in 2015 (Barska and Sazonova, 2015).

The loss to follow-up proportion is highest in Site 1 (23.8%), followed by Site 2 (8.7%), Site 4 (5.3%) and Site 3 (3.8%). Discussion with the partner organization at Site 1 indicated that high drop out at this site may be attributed to higher rates of unstable and transitory housing, exacerbated by the migration of internally displaced people fleeing conflict in eastern Ukraine. Based on our analysis strategies, this indicated the need to do a sensitivity analysis leaving out individuals without post-treatment data for Site 1.

A questionnaire skip-pattern error resulted in missingness in two items (giving syringe to middle person or partner to acquire drugs): 58% pre-intervention and 36% post-intervention for Site 1 (leaving out those lost to follow-up), 25% and 26% for Site 2, 13% and 14% for Site 3, and 37% and 41% for Site 4; with Site 3 least affected. The other items had lower missing rates that are more similar across sites, ranging between 5.6 and 27.7% across sites and questions. We conducted multiple imputation as described above. Table 4 provides a detailed report of missing rates in the specific risky behavior variables, and the corresponding missing rates in the composite outcome variables This table also shows the degree to which the variance of a prevalence or prevalence change estimate (for composite outcome variables) is inflated due to missing data; these variance inflation factors were estimated using the fmi function in the R package semTools (Jorgensen et al., 2018).

3.1.2 Outcome Prevalence Pre- and Post-Intervention, And Pre-To-Post-Intervention Change.

Table 5 presents the estimated prevalence of each of the three outcome variables pre- and poster-intervention (first and second numeric columns) and the corresponding pre-to-post-intervention prevalence changes (third numeric column), for each site. Despite variance inflation due to missing data (see Table 4), the standard errors are not substantial -- between 0.7% and 3.9% for the prevalences and between 1.1 and 4.3 percentage points for the prevalence changes.

There was variation in pre-intervention risk behavior prevalences across sites. Overall, these prevalences tend to be higher in Sites 2, 3 and 4 (mostly in the seventies and eighties range, in percentage terms) relative to Site 1 (in the fifties and sixties range). There was also a substantial difference in prevalence between the two types of risk behavior at Site 3, where risk behavior in drug injection (53.2%) is much less prevalent than risk behavior in drug acquisition (89.4%); such feature was not seen at other sites.

Regarding pre-to-post-intervention change in outcome prevalence, at Sites 1, 2, and 4, we observed reductions in the prevalence of both *any risk in drug acquisition* and *any risk in drug injection*, with the largest reductions (about 30+% for both behaviors) in Site 2, about double those at Sites 1 and 4. In Site 3, interestingly, the behavior with lower baseline prevalence (*any risk behavior in drug injection*, 53.2% at baseline) was reduced by a substantial 17.1 (CI=14.1,19.2) percentage points down to a prevalence of 36.1% (CI=34.7,37.6) post-intervention; yet the more prevalent behavior (*any risk in drug acquisition*, 89.4% at baseline) essentially stayed unchanged.

The sensitivity analysis for Site 1 leaving out those lost to follow-up gave similar results.

4.1 Discussion

Reductions in drug use-related HIV risks were observed among study participants in the NGO-developed interventions. The degree of decrease is similar to that reported in evaluations of other behavior change risk reduction interventions in Ukraine (Booth et al., 2011) and elsewhere (Copenhaver et al., 2006), although the ranges in this study were broader. Three of the four sites demonstrated risk reduction for both drug acquisition and drug injection, whereas one site demonstrated decrease in drug injection risk only.

The intervention developed by Site 3 did not demonstrate the same decreases in drug acquisition risks as other sites. Site 3 general services targeted women specifically, including those who engage in sex work, and built their intervention using knowledge acquired from working with this population. The intervention addressed gender-specific aspects of HIV risk through sex and drug use, including negotiating condom use, communication, power imbalances, building safe injection skills such as negotiating to not use dirty syringes. Based on follow-up conversations with agency staff at Site 3, the organization of the drug market may have shaped the extent to which intervention participants could change their acquisition-related risk behaviors. Clients typically purchased their drugs through a courier, who would deliver the ordered amount in a disposable syringe (i.e., prefilled syringe). There may be no other alternatives for procuring drugs in this region, and therefore reflects a dimension of HIV risk over which intervention participants felt they had little control. Further research on the underlying HIV risk mechanisms for women who use drugs and engage in sex exchange is warranted.

Both the “common factors” training and the interventions developed by the agencies narrowly focused on drug use related risk behaviors, although some agencies did address condom use in their programs. In addition, this study did not address other outcomes such as entry into treatment and frequency of drug use that can lead to reduced HIV risk or use

biomarkers such as HIV status to demonstrate efficacy. Interventions also did not have an explicit HIV testing and counseling component, although all study sites offered HIV testing and counseling as part of their standard package of services. Future studies and interventions developed using a “common factors” approach could incorporate more comprehensive trainings and interventions that address multiple HIV risks faced by PWID (i.e., both drug and sex related risks), models of intervention, and outcomes.

In designing this study, we accounted for the realities that many NGOs face when conducting their work. Staff turnover, funding uncertainties, and shifting public health priorities can undermine organizational viability and sustainability. We purposefully included more organizations in Phase I (intervention development) than we could support in Phase II (evaluation). Participating agencies understood at the outset of the study that not all organizations would continue into the evaluation component. The “common factors” approach attempts to address a particular aspect of implementation science—how to build the capacity of local organizations to create their own locally-relevant public health programs. Further research and innovation are necessary to address issues of sustainability, particularly for NGOs that depend on international donors for financial viability, and to simultaneously provide strong scientific evidence and correspond to the real-world circumstances in which programs are implemented.

We attempted to minimize reporting bias (e.g., over reporting at baseline and underreporting at follow up) by using self-administered assessment. Temporal trends are another threat to validity of a pre/post study that might account for part of the changes we observed. Throughout the study and at its conclusion, we had extensive conversations with NGO staff about this possibility and did not note any changes services or drug acquisition and use practices that would account for the changes.

The common factors approach would benefit from an RCT that rigorously establishes causal effects. Such a research project would require a sustained and deep collaboration between researchers and NGOs, a kind of collaboration that facilitates co-learning and enables NGO staff to become more familiar with research principles and concepts and allows researchers to better understand what is needed for real world frontline interventions. This collaboration would need to benefit both researchers and service providers. Harmonization between these two interests requires long-term and genuine understanding and partnership, as well as investment of financial and other resources.

Finally, in addition to an RCT, a reasonable next step for understanding the common factors approach would be additional process evaluation studies that would advance implementation science. An evaluation using an implementation science framework such as RE-AIM or other process models and evaluation frameworks (Nilsen, 2015) would provide important information needed to scale up the common factors approach such intervention costs, participant and implementing staff characteristics, and program maintenance at the individual and organizational levels.

5.0 Conclusion

Improving the ways in which research evidence is used and decreasing the knowledge-to-practice gap is a critical step in the implementation of evidence-based programs by frontline service providers. The “common factors” model proposes a new way of approaching how knowledge is generated and shared between researchers and practitioners. It shares the basic principles of what makes an intervention effective with those who will implement an intervention and uses the experience-based knowledge and skills of the implementers to develop contextually relevant programs that respond to the needs and circumstances of the implementing community. Moreover, behavioral interventions to reduce HIV risk among PWID that are developed using the common factors approach could become an important part of the HIV response in low resource settings where capacity building remains a high priority. A common factors approach can bring together research-generated knowledge with local knowledge, creativity and solutions. Finally, the common factors approach is highly flexible and potentially transferrable to other approaches in addition to behavioral interventions. All intervention strategies--including MAT, ART, and NSP programs--require local buy-in and the creation of local programs that fit local contexts, rather than a “one size fits all” model. A common factors approach can be used in the development of these programs as well.

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Highlights

- Current interventions may not reflect local drug use practices that lead to HIV risk.
- A “common factors” approach can empower providers to develop effective programs.
- All NGO-developed interventions in this study reduced drug use-related HIV risks.
- This approach can help frontline providers respond to local drug use contexts.

Table 1:

Characteristics of Participating NGOs

	Site 1	Site 2	Site 3	Site 4
Region	Southern	Central	Southern	Eastern
Clients	PWID (80%), CSW, prisoners, street children	PWID (60%), prisoners, PLWHA, youth	PWID (70%), CSW, youth, PLWHA	PWID (60%), CSW, PLWHA, TB patients, street children
Years in existence (at project start)	13	12	12	12
# of PWID served/6 months	~4,000	2,824	~2,000	2,039
Annual budget (2011)	Over $500,000	Over $500,000	$200 – 400,000	Under $200,000

Table 2:

Overview HIV Prevention Interventions by Site

	Site 1	Site 2	Site 3	Site 4
Intervention target Group	men & women under 35 years old who inject drugs who use harm reduction services	men & women 18–30 years old who inject stimulants	heterosexually active women 25–40 years old who inject drugs & have children	male & female “poly” drug users 25–35 years old
# of Sessions	10	8	6	8
Session Length (hours)	4, including breaks	1.5	1.5	2
Number of sessions attended, median (IQR)	8 (7–8)	7 (6–7)	6 (6–6)	6 (5–7)
Overall program was very or somewhat helpful, % of participants at follow-up	95.9	98.6	100	97.7
Aim	• increase personal motivation to reduce HIV risk • increase skills and knowledge related to safely purchasing and using drugs	• reduce sexual and injection related risks	• increase HIV-related knowledge • increase personal desire to stay healthy • increase skills related to safe drug use and sex	• establish intention to change drug use behaviors • increase selfefficacy regarding safer drug use and sexual behaviors • improve control over emotional states that may lead to risky behaviors
Approach	• personal risk assessment • identify emotional and situational triggers • communication skills • skill-building related to accessing and consistently using clean needles • peer communication	• personal risk assessment • peer norms about safe injecting • goal setting • condom negotiation skills	• HIV and STI information • personal risk assessment • skill building for safer drug use and sex • identify emotional triggers	• skill-building related to safe drug use and sexual behaviors • identify emotional triggers and coping strategies • communication skills-building

Table 3:

Characteristics of study participants at baseline

	Site 1	Site 2	Site 3	Site 4
	(n=185)	(n=161)	(n=160)	(n=170)
	Mean (SD)	*Mean (SD)*	*Mean (SD)*	*Mean (SD)*
Age (in years)	30.8 (5.7)	30.8 (6.0)	31.0 (5.7)	33.4 (6.4)
	Percent	*Percent*	*Percent*	*Percent*
Sex: female	22.7	22.4	100.0	28.8
Marital status				
Single	39.1	38.8	37.5	41.1
Married	12.8	15.0	20.0	12.5
Cohabiting	36.3	37.5	20.0	32.1
Divorced/widowed	11.7	8.8	22.5	14.3
Education				
Middle school or less	22.2	12.5	10.6	14.7
Some high school	27.0	23.1	15.6	17.1
Vocational training	30.8	46.9	45.6	54.7
Some college	20.0	17.5	28.1	13.5
Employment (any)	48.3	58.8	49.7	44.6
Unstable housing	23.0	2.5	1.3	10.6
Sex work (among women)	26.8	64.7	44.4	41.3
HIV positive (self-reported)	7.1	21.3	0.0	21.9
Drugs injected in the past 30 days				
Stimulant	57.1	98.1	12.5	90.7
Opiate	87.4	91.9	100.0	100.0
Opiate and sedative combined	39.1	42.4	74.4	60.5
Opiate and stimulant combined	50.8	81.3	30.0	89.3
Have ever been on MAT	11.4	27.9	19.4	17.7
Exchanged syringes in the last 3 months	35.7	45.3	44.3	65.9

Table 4:

Missing data rates in pre- and post-intervention risk variables, and resulting variance inflation[a] in estimates of (i) pre-intervention prevalence, (ii) post-intervention prevalence, and (iii) pre-to-post-intervention prevalence change.

	Pre-intervention		Post-intervention		Pre-to-post change
	Missing rate	**Variance inflation**	**Missing rate**	**Variance inflation**	**Variance inflation**
Site 1 (n=185)					
Specific risky behaviors:					
buy drug pre-loaded	21.1%		36.8%		
give syringe to dealer	20.0%		34.1%		
give syringe to partner[b]	58.9%		52.4%		
give syringe to middle person[b]	61.1%		49.7%		
front- or back-loading	14.6%		33.5%		
using common container	23.2%		31.4%		
using used cooker, cotton or water	26.5%		33.5%		
Composite outcome variables of risky behaviors in[c]:					
drug acquisition	52.4%	2.07	50.3%	1.51	2.11
drug injection	23.2%	1.17	37.3%	1.37	1.30
drug acquisition/injection	31.9%	1.33	44.9%	1.48	1.45
Site 1 sensitivity analysis sample leaving out those lost to follow-up (n=141)					
Specific risky behaviors:					
buy drug pre-loaded	21.3%		17.0%		
give syringe to dealer	19.1%		13.5%		
give syringe to partner[b]	57.4%		37.6%		
give syringe to middle person[b]	58.9%		34.0%		
front- or back-loading	14.2%		12.8%		
using common container	23.4%		9.9%		
using used cooker, cotton or water	27.7%		12.8%		
Composite outcome variables of risky behaviors in[c]:					
drug acquisition	52.5%	1.86	34.8%	1.19	1.73
drug injection	21.3%	1.14	17.7%	1.14	1.16
drug acquisition/injection	31.2%	1.29	27.7%	1.18	1.26
Site 2 (n=161)					
Specific risky behaviors:					
buy drug pre-loaded	9.9%		18.6%		
give syringe to dealer	7.5%		18.0%		

	Pre-intervention		Post-intervention		Pre-to-post change
	Missing rate	**Variance inflation**	**Missing rate**	**Variance inflation**	**Variance inflation**
give syringe to partner[b]	25.5%		26.1%		
give syringe to middle person[b]	24.8%		26.1%		
front- or back-loading	5.6%		14.3%		
using common container	10.6%		21.1%		
using used cooker, cotton or water	8.7%		16.1%		
Composite outcome variables risky behavior in[c]:					
drug acquisition	17.4%	1.30	23.0%	1.11	1.21
drug injection	6.8%	1.07	16.1%	1.12	1.11
drug acquisition/injection	6.8%	1.16	17.4%	1.11	1.14
Site 3 (n=160)					
Specific risky behaviors:					
buy drug pre-loaded	8.8%		8.1%		
give syringe to dealer	4.4%		5.0%		
give syringe to partner[b]	13.1%		14.4%		
give syringe to middle person[b]	13.8%		14.4%		
front- or back-loading	11.9%		7.5%		
using common container	6.3%		6.9%		
using used cooker, cotton or water	3.8%		5.0%		
Composite outcome variables of risky behavior in[c]:					
drug acquisition	12.5%	1.72	14.4%	2.03	1.99
drug injection	11.9%	1.08	8.1%	1.04	1.12
drug acquisition/injection	10.6%	1.73	12.5%	2.02	2.18
Site 4 (n=170)					
Specific risky behaviors:					
buy drug pre-loaded	12.9%		18.8%		
give syringe to dealer	10.6%		16.5%		
give syringe to partner[b]	35.3%		41.2%		
give syringe to middle person[b]	38.8%		41.2%		
front- or back-loading	7.1%		15.9%		
using common container	14.1%		20.6%		
using used cooker, cotton or water	11.2%		19.4%		
Composite outcome variables of risky behavior in[c]:					
drug acquisition	25.9%	1.80	32.9%	1.19	1.48
drug injection	10.6%	1.12	17.6%	1.10	1.11

	Pre-intervention		Post-intervention		Pre-to-post change
	Missing rate	**Variance inflation**	**Missing rate**	**Variance inflation**	**Variance inflation**
drug acquisition/injection	15.3%	1.47	23.5%	1.15	1.31

[a]Variance inflation is the factor by which the variance (= squared standard error) of the estimator is inflated as a result of uncertainty due to missing data. This table reports variance inflation in estimating: (i) pre-intervention prevalence, (ii) post-intervention prevalence, and (iii) pre-to-post prevalence change (see estimates in Table 5). Note that this variance inflation factor = 1/(1-FMI) where FMI is the fraction of missing information, defined as the ratio of between variance (variance of the estimate across the imputed datasets) to the sum of between variance and average within variance (variance of the estimate within each dataset). We choose to directly report variance inflation because FMI, a variance partition measure, is often mixed with missing data rate.

[b]At all the four sites, the two items *giving syringe to partner* and *giving syringe to middle person* (to get drug) suffer from higher missing rates than other items due to a flawed skip pattern in the questionnaire.

[c]The composite outcome variables inherit missingness from the specific risky behaviors variables in the original data. The missingness in the two questionnaire items mentioned in note[b] leads to higher missing rates in the first composite variable, *risky behavior in drug acquisition*, which to some extent carries into the last composite variable, *risky behavior in drug acquisition/injection*. Note that a missing value on a composite variable does not imply complete missing information on that value. For example, the composite variable *risky behavior in drug acquisition* variable is based on four specific risky behavior variables. If three of these component variables are 0 and one is missing, then we have partial information on the composite variable even though it is missing; such information is incorporated in the imputed data.

Table 5:

Pre- and post-intervention prevalence and pre-to-post-intervention change in risk behaviors

	Pre-intervention risk behavior	Post-intervention risk behavior	Pre-to-post-intervention change in risk behavior	
	prevalence (SE) (95% CI[a])	*prevalence (SE) (95% CI)*	*prev. change (SE) (95% CI)*	*p-value[d]*
Site 1 (n=185)				
Risky behavior in drug acquisition	50.8% (3.8) (43.4,58.4)[b]	36.5% (2.5) (31.5,41.5)	−**14.3%** (4.3) (5.7,23.0)[c]	<0.0001
Risky behavior in drug injection	61.6% (1.5) (58.7,64.6)	42.3% (2.2) (37.9,46.7)	−**19.3%** (2.5) (14.3,24.4)	<0.0001
Risky behavior in drug acquisition/inj ection	68.0% (2.0) (64.1,71.9)	47.4% (2.5) (42.3,52.4)	−**20.6%** (2.9) (14.9,26.4)	<0.0001
Site 1 sensitivity analysis leaving out those lost to follow-up (n=141)				
Risky behavior in drug acquisition	51.1% (3.9) (43.4,58.8)	37.1% (1.8) (336.,40.6)	−**14.0%** (4.0) (6.0,22.0)	0.0003
Risky behavior in drug injection	62.1% (1.5) (59.0,65.2)	43.8% (1.6) (40.8,46.9)	−**18.3%** (2.2) (14.0,22.6)	0.0002
Risky behavior in drug acquisition/inj ection	67.4% (2.1) (63.2,71.6)	48.7% (1.8) (45.1,52.2)	−**18.7%** (2.6) (13.6,23.8)	0.0001
Site 2 (n=161)				
Risky behavior in drug acquisition	88.2% (1.4) (85.5,91.0)	52.5% (1.3) (49.9,55.0)	−**35.7%** (1.9) (31.9,39.6)	<0.0001
Risky behavior in drug injection	81.0% (0.8) (79.3,82.7)	50.5% (1.4) (47.8,53.2)	−**30.5%** (1.5) (27.5,33.5)	<0.0001
Risky behavior in drug acquisition/inj ection	92.0% (0.9) (90.3,93.7)	57.9% (1.3) (55.3,60.5)	−**34.1%** (1.6) (31.0,37.2)	<0.0001
Site 3 (n=160)				
Risky behavior in drug acquisition	89.4% (2.1) (85.3,93.5)	91.2% (2.3) (86.7,95.7)	+1.8% (2.1) (−2.2,+5.8)	0.2971
Risky behavior in drug injection	53.2% (1.1) (51.0,55.4)	36.1% (0.7) (34.7,37.6)	−**17.1%** (1.1) (14.9,19.2)	<0.0001
Risky behavior in drug acquisition/inj ection	92.0% (1.8) (88.4,95.7)	92.3% (2.1) (88.1,96.5)	+0.2 (2.0) (−3.7,+4.2)	0.8678
Site 4 (n=170)				
Risky behavior in drug acquisition	79.4% (2.8) (73.9,84.9)	63.7% (1.6) (60.4,66.9)	−**15.8%** (3.2) (9.5,22.0)	0.0001
Risky behavior in drug injection	74.7% (1.2) (72.4,77.1)	57.5% (1.2) (55.2,59.8)	−**17.3%** (1.5) (14.2,20.3)	0.0001
Risky behavior in drug acquisition/inj ection	88.4% (1.7) (85.1,91.7)	73.4% (1.4) (70.7,76.0)	−**15.0%** (2.2) (10.7,19.4)	<0.0001

[a] CI = confidence intervals.

[b] Percent symbols are left out of the standard error and confidence intervals to avoid cluttering. For example, at the top-left of the table, 50.8% (3.8) (43.4,58.3) should be interpreted as: the prevalence of risk behavior in drug acquisition at baseline is estimated to be 50.8%, with a standard error of 3.8% and a 95% confidence interval from 43.4% to 58.3%.

[c] The confidence intervals in the pre-to-post change column, if not signed, should be interpreted to be of the same sign as the point estimate. For example, at the top-right of the table, −14.3% (4.4) (5.8,22.9) means that there was an estimated reduction of behavior prevalence of 14.3 percentage points, with standard error of 4.4 percentage points, and the confidence interval indicates the reduction was between 5.8 and 22.9 percentage points.

[d]The p-values here are for permutation tests of the null hypothesis that there was no difference in risk behavior prevalence between baseline and follow-up.