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DESIGNING AN INDIVIDUALLY TAILORED MULTILEVEL INTERVENTION TO INCREASE ENGAGEMENT IN HIV AND SUBSTANCE USE TREATMENT AMONG PEOPLE WHO INJECT DRUGS WITH HIV: HPTN 074

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Abstract

People who inject drugs (PWID) face barriers to engagement in antiretroviral treatment (ART) and medication-assisted treatment (MAT). We detail the design, rapid preparation and adaptation, and systematic implementation of a flexible, individually tailored intervention for PWID in multiple settings: Indonesia, Ukraine, and Vietnam. HPTN 074 integrated systems navigation and counseling to facilitate entry and adherence to ART and MAT. Site-level guidance on the intervention involved in-depth interviews (IDIs) among PWID and their supporters and site-specific document review. IDIs emphasized ART misinformation and importance of social support for adherence. The document review revealed differences in health care system barriers, requiring an intervention that was flexible and tailored enough to address key outcomes. Implementation included regular debriefs for iterative adaptations based on participants' needs, including booster counseling sessions and subsidizing pre-ART testing. HPTN 074 provides a unique framework implementing a flexible and scalable intervention to improve ART and MAT outcomes among PWID across multiple settings.

Keywords

HIV; substance use; ART; medication-assisted treatment; injection drug use

2 Injection drug use is a predominant driver of the HIV epidemic in many parts of Southeast Asia, Central Asia, and Eastern Europe. Approximately 50% of new HIV infections in Central Asia and Eastern Europe in 2014 were attributed to injection drug use and associated injection risk behaviors (Booth, Kwiatkowski, Brewster, Sinitsyna, & Dvoryak, 2006; Stimson, 1998; United Nations Program on HIV/AIDS [UNAIDS], 2016a). In Vietnam, nearly 40% of people who inject drugs (PWID) are living with HIV (Mathers et al., 2008; Ministry of Health of Vietnam, 2009). Similarly, the estimated HIV prevalence among PWID in Indonesia and Ukraine is over 20% (UNAIDS, 2016b, 2016c). Countries with concentrated HIV epidemics among PWID will likely benefit from targeted efforts to prevent HIV transmission (Mathers et al., 2010).

1 Timely engagement in HIV and medication-assisted treatment (MAT) is imperative for PWID to improve health outcomes and prevent ongoing transmission. Although treatment as prevention (Cohen et al., 2011, 2016) has not been specifically validated in PWID for the prevention of HIV transmission, the concept holds promise. In addition to the reduction of transmission potential, immediate initiation of ART, regardless of the CD4 count, significantly improves health outcomes (Lifson et al., 2017; Lundgren et al., 2015; World Health Organization, 2015). However, PWID often have delayed entry and suboptimal engagement throughout the HIV care continuum (Hanna et al., 2013; Heimer et al., 2017; Karch, Gray, Shi, & Hall, 2016; Kiriazova, Postnov, Perehinets, & Neduzhko, 2013).

Globally, HIV-positive PWID experience barriers to initiation and retention in HIV care and substance use treatment at multiple levels. Structural barriers that can impede engagement in HIV and MAT include the criminalization of illicit drug use and fractured health care

systems (Joseph et al., 2016; Kiriazova et al., 2017). Social barriers, including lack of social support, can impede engagement (Chu et al., 2015; T. Kiriazova et al., 2017). On an individual level, current injection drug use has been associated with lower awareness of HIV-positive status, a major barrier to HIV care engagement (Mehta et al., 2015). Each HIV-positive PWID may face similar barriers across a range of limited-resource settings.

Novel approaches are needed to design and implement flexible interventions that can be sustainable and tailored to individual PWID needs in multiple settings with limited resources. HIV Prevention Trials Network (HPTN) 074 was designed to determine the feasibility and uptake of an integrated intervention for ART and MAT for HIV-positive PWID in three distinct settings and geographic regions: an academic referral hospital in Indonesia, a specialized infectious disease clinic in Ukraine, and a district level health center in Vietnam (Lancaster et al., 2018). HPTN 074 was found to increase use of ART and MAT, as well as reduce mortality among PWID (Miller et al., 2018). The intervention has the strong potential for substantially reducing morbidity and mortality in PWID globally.

The primary objective for this manuscript is to describe the framework for a flexible, individually tailored multilevel intervention for HIV-positive PWID to improve engagement in HIV care and substance use treatment in multiple settings. We describe our approach for obtaining site-level guidance on an intervention that would be flexible and tailored enough to address key outcomes and scalable across several sites, without being site-specific. We also present the processes for rapid preparation and adaptation, as well as the systematic implementation, including the monitoring and feedback mechanisms for adaptations, utilized for this unique intervention design.

METHODS

DESIGN

Study Setting and Target Population. ¹ This study was conducted in three geographically diverse settings: Jakarta, Indonesia; Kyiv, Ukraine; and Thai Nguyen, Vietnam. These research-experienced settings were selected based on the HIV epidemic among PWID in each location, as well as the potential to recruit and retain this hard-to-reach population. Within Indonesia, the government has recently focused on the scaled up syringe services programs and MAT. MAT was initiated in 2003 and is available at the primary health care level. HIV care and treatment is also decentralized and ART is provided free of charge (Go et al., 2018; Wijayanti et al., 2016). ² Health services in Ukraine are a vertical system with parallel clinics offering specialized care with limited coordination. As a result, HIV and substance use treatment are primarily delivered at separate clinics by separate specialties (Zaller et al., 2015). As of 2016, MAT is available for purchase in pharmacies as well as offered for free at governmental facilities. ¹ Similar to Ukraine's, Vietnam's health system is designed as a vertical, three-tiered system that is overseen by the Ministry of Health (Dao, Hirsch, Giang le, & Parker, 2013). MAT has been rapidly scaled up since 2008 and provided for free by Ministry of Health managed programs (Government of Vietnam, 2008). HIV care and treatment has previously been supported through other funding sources, including PEPFAR, however, PEPFAR funding has significantly decreased since 2016 (Go et al., 2018).

HIV-positive PWID, hereinafter referred to as index participants, who received the intervention were HIV-positive males or females, self-reporting currently injecting drugs, and willing and able to enroll at least one HIV-negative network injection partner. Recruitment procedures are described in more detail elsewhere (Lancaster et al., 2018)—briefly, sites utilized referrals from HIV-testing sites, community out-reach, and injection network referrals to identify potential participants for screening and enrollment. A total of 126 index participants were randomly assigned to the intervention arm between April and June of 2015.

Theoretical Foundation and Conceptual Model.—Our intervention was guided by maintenance theory, social cognitive theory, and diffusion of innovation meta-theories of behavior change, as well as theories of cognitive dissonance, role theory, social norms, and social identity that overlap and expand on those meta-theories (Bandura, 1978; Festinger, 1954; Janis & Mann, 1977; Rogers, 2010; Rothman, 2001; Turner, 1975). According to maintenance theory, decisions regarding behavioral initiation are dependent on favorable expectations regarding future outcomes, whereas decisions regarding behavioral maintenance are predicted to depend on perceived satisfaction with received outcomes (Rothman, 2001). Social identity theory suggests that common experiences and knowledge frameworks are more likely in relationships in which individuals are invested and have a mutual trust which facilitates interpersonal communication, knowledge transfer, and shared understanding (Turner, 1975).

Our multidimensional framework (Figure 1) highlights the role of psychosocial, social networks, and structural processes on behavior change and maintenance. Recent recommendations for improving entry into care, retention, and ART adherence include “multidisciplinary education and counseling intervention approaches”, “one-on-one adherence support to patients through one or more adherence counseling approaches”, and “brief strengths-based case management for individuals with a new HIV diagnosis” (Thompson et al., 2012). The recommendations also include the potential use of paraprofessional patient navigators (Thompson et al., 2012).

Study Objectives.—The primary objectives for the multisite, two-arm, randomized vanguard study were to (1) assess the feasibility of a future randomized controlled trial and (2) assess the feasibility, barriers, and uptake of an integrated intervention for prevention of HIV transmission among HIV-positive index participants.

Intervention Core Elements.—The intervention in HPTN 074 core elements were determined through a series of consultations between study investigators, study site representatives, and key informants, including HPTN community program managers, throughout the study concept and protocol development. The core elements consist of integrated systems navigation (SN) and psychosocial counseling to facilitate entry into HIV care and substance use treatment, facilitate initiation of ART, sustain adherence to ART, and sustain substance use treatment (Table 1). SN is relatively low intensity, short-term case management, designed to be feasible and sustainable. The systems navigator approach was based on the literature of best evidence in case management, including the Antiretroviral Treatment and Access to Services (ARTAS) study and intensive case management study in

Russia (Gardner et al., 2005; Liao et al., 2013; Pearson et al., 2007; Shaboltas et al., 2013; Vargas & Cunningham, 2006). Systems navigators identified barriers to treatment that reside outside the individual or are a function of an interaction between the individual and the health care system. For example, lack of familiarity with a health care organization and how to enroll in HIV medical care may be due to both system and individual factors. A systems navigator helped to identify these barriers, as well as overcome the barriers. Case management services are now common in HIV medical care programs (Vargas & Cunningham, 2006). Approaches were based on findings that system and structural barriers to HIV care and substance use treatment are major impediments for entering and staying in medical care. As barriers to HIV and substance use treatment are diverse and context-specific, a systems navigator approach provided sufficient flexibility to help people address the myriad of system and structural barriers to health care (Kushel et al., 2006; Nachega et al., 2010; Vargas & Cunningham, 2006). SN encounters (either in person or via telephone calls or text messages) were held with the index participants weekly for the first eight weeks and then monthly through the duration of the study.

Index participants received a minimum of two approximately hour-long psychosocial counseling sessions that were individually tailored towards each participant. Participants were offered the opportunity for a minimum of two additional booster sessions for approximately one month and three months after enrollment. The counselor used a standardized needs assessment to determine the index participants' level of need for counseling on risk reduction, drug treatment entry and retention, HIV medical care, and medication adherence. Based on this assessment, additional optional individual sessions were conducted as part of the intervention. Sites were able to offer more booster sessions based on participants' need. For index participants who had low levels of adherence to ART or substance use treatment, additional counseling sessions were available through self-referral or recommendation by members of the intervention team.

The SN approach was integrated with psychosocial counseling focusing on entry into HIV care and substance use treatment and ART adherence. The counseling sessions designed to increase entry into HIV care and drug treatment were based on brief motivational interviewing techniques (Burke, Arkowitz, & Menchola, 2003; Hettema, Steele, & Miller, 2005; Klimas, 2013; Miller, Sorensen, Selzer, & Brigham, 2006; Miller, Yahne, & Tonigan, 2003; Rapp et al., 2008; Sinadinovic, Wennberg, & Berman 2012; Vasilaki, Hosier, & Cox 2006); Screening, Brief Intervention, and Referral to Treatment (SBIRT) approaches; and Cognitive Behavioral Therapy (CBT) exercises for retention into drug treatment developed in HPTN 058 (Metzger et al., 2015). The ART adherence intervention was based, in part, on the Managed Problem Solving (MAPS) intervention (Gross et al., 2013).

To enhance treatment adherence and social support, index participants were asked to identify supporters within their broader social network to provide support for ART and substance use treatment adherence. The psychosocial counselor or systems navigator sometimes facilitated the identification of an appropriate person that was aware of the index's HIV status and were willing to provide assistance with HIV treatment. The positive role of social support on ART adherence and substance use treatment outcomes is well documented (Amico, Harman, & Johnson, 2006; DiMatteo, 2004; Galea, Nandi, & Vlahov, 2004). Receiving emotional social

support promotes entry and retention into substance use treatment and HIV medical care as well as supports ART adherence (Latkin, Sherman, & Knowlton, 2003). In HPTN 074, it was anticipated that supportive individuals could cue the behavior of taking medications, provide verbal reminders, reward timely and consistent taking of ART, as well as buffer stress, which may lead to depression. Depression has been demonstrated to have a potentially negative effects on ART adherence (Gonzalez, Batchelder, Psaros, & Safren, 2011; Starace et al., 2002). In the field of substance use treatment, it is also well established that supportive behaviors by individuals that promote and reward non-drug activities and encourage a reduction in drug use are linked to successful substance use treatment outcomes (Latkin, 1998). Index participants who chose to engage their medical care and adherence supporters in the counseling sessions were offered optional dyad sessions. The index participant and the supporter were offered participation in up to two optional dyad counseling sessions together to practice adherence communication skills, enhance the HIV literacy of their supporters, and develop a medication adherence plan. If the supporter was also a sexual or injection partner, the counseling session also addressed risk reduction.

The content of the dyads sessions was based on the STEP into Action intervention (Tobin, Kuramoto, Davey-Rothwell, & Latkin, 2010).

PREPARATION

Guided by recommendations and processes for adaptation of evidence-based interventions (Barrera, Castro, Strycker, & Toobert, 2013; Escoffery et al., 2018; McKleroy et al., 2006; Wingood & DiClemente, 2008), our rapid preparation and adaptation consisted of two main processes: (1) formative information gathering and (2) development and component testing (Figure 2). These processes are key components of adaptation frameworks, including Castro's cultural adaptation and Replicating Effective Programs frameworks (Barrera & Castro, 2006; Escoffery et al., 2019; Kilbourne, Neumann, Pincus, Bauer, & Stall, 2007).

Formative Information Gathering.

After presenting the flexible intervention design to the local site research staff and key informants, in-depth interviews (IDIs) were conducted among the study population to understand the barriers to ART adherence and identify intervention content to enhance support for HIV and substance use treatment. To ensure rapid preparation, adaptation, and implementation, we conducted a limited number of IDIs in one site with input from all sites on guide development.

In early June 2014, two HIV-positive PWID and their supporters, which included a spouse and family member, were purposively recruited from outpatient clinics in Thai Nguyen, Vietnam. IDIs were conducted within Vietnam given the well-established research infrastructure for HIV-related interventions among PWID. IDIs explored topics such as difficulties obtaining and getting to HIV and substance use treatment appointments, reasons for not taking ART, and role of social support for medical care. Interviews were audio-recorded, transcribed, and translated. Two investigators independently reviewed transcripts to identify themes and patterns in the data. Consensus reached key themes and topics of interest and checked for accuracy against the original transcripts. Local site research staff

and key informants at each site reviewed final themes. Themes that were similar across all sites, drawing on each sites' contextual knowledge, informed psychosocial session topics that were then reviewed and prioritized by members of the protocol team, local site research staff, and key informants from each of the three sites.

Each study site provided a review of site-specific documents on main barriers and facilitators to HIV and substance use treatment. Reviewed documents included published and grey literature, including county-specific Ministry of Health reports. In the end of June 2014, results from the IDIs and document reviews were presented and discussed at a multisite, face-to-face meeting with study investigators, study site representatives, and key informants, including HPTN community program managers. The primary purpose of the face-to-face meeting was to provide a conceptual understanding of flexible intervention design and key outcomes and to identify behavior change skills PWID may need across all sites. Additionally, we reviewed prior HIV and substance use intervention manuals and materials, including Project Accept, SHEILD, and the Brief Alcohol Intervention (Fleming, 2004; Sweat et al., 2011; Tobin, Muessig, Sc Latkin, 2007). During the in-person meeting, we developed and prioritized by importance a list of potential intervention psychosocial counseling session topics.

ADAPTATION: DEVELOPMENT AND COMPONENT TESTING

The formative information gathering provided the foundation for the intervention manual. Initial drafts of the intervention manual began in July 2014. Each session, module, and accompanying materials of the intervention manual were reviewed by all sites and underwent an expert review by members of the HPTN 074 protocol team. In December 2014, component testing was conducted on each of the manual sessions and modules to determine the relevance and areas for clarification or refinement. A total of three HIV-positive PWID who were on ART, including one with good adherence and two with poor adherence, were recruited from Thai Nguyen, Vietnam to participate in the component testing. Three supporters also participated in the component testing of dyad (social support) sessions. After each component testing, the interviewer developed a summary of the responses and provided detailed edits to the intervention manual. The summaries and edits were reviewed by the intervention team from all three sites and protocol team members.

RESULTS

PREPARATION FINDINGS: FORMATIVE INFORMATION GATHERING

The PWID who participated in the IDIs reported that there was a substantial amount of misinformation regarding ART initiation, leading to many PWID being unaware of their eligibility for ART. Participants noted that many of their peers had poor adherence or had stopped taking ART. They indicated that those who were adherent to ART generally had strong social support, including an identified support person to assist with HIV care and treatment management. IDIs with support persons of the PWID indicated the importance of understanding the HIV infection and its effect on mental health among those living with HIV.

The site-specific document reviews revealed several key similarities of barriers and facilitators for HIV and substance use treatment that the HPTN 074 intervention would also need to address. Health system-level barriers were noted across all three sites and included testing costs (e.g., CD4 counts, tuberculosis screening, viral load), administrative requirements, and stigma. Prior to implementation, each site explored local mechanisms, such as donor-driven programs, as options to subsidize costs. This information, along with exact testing costs, were provided to index participants during SN encounters. At an individual level, lack of information and depression were also described as barriers to care. Social and family support, when available, were reported as facilitators for entering HIV and substance use treatment. Given the benefits of social support, an overview of the availability and facilitation of dyad sessions with index participants and their social supporters was provided to index participations during their first psychosocial counseling sessions. While many similarities existed, there were notable differences in the health systems at the sites that would benefit from the flexibility of the intervention design. In Indonesia, HIV treatment is decentralized at the primary health care level; however, poor public transport was a significant barrier to receiving treatment. In Ukraine, HIV testing and treatment are generally provided by separate clinics, resulting in delays for engagement in HIV treatment after diagnosis. While in Vietnam, HIV-positive individuals are required to register in the HIV medical care system with a support person, which offers challenges for those unable to identify or recruit a support person.

ADAPTATION FINDINGS: DEVELOPMENT AND COMPONENT TESTING

In addition to the two mandatory sessions, booster modules were developed to include sexual and injection-risk reduction, substance use treatment, harmful effects of alcohol, reduction strategies, coping with stigma, recognition of depression symptoms, treatment options, and role plays for supporter disclosure. Pilot testing the psychosocial counseling sessions in Vietnam identified the need for intervention scripts that could include socioculturally relevant examples for each site. Accordingly, modifications were made to the counseling materials. The intervention manual materials were provided to the intervention team and key protocol members. Feedback primarily focused on the provision of similar barriers across all sites and solution strategies to assist with index participant goal setting, culturally appropriate guidance on active listening for counselors, and the integration of a counseling diary to aid counselors for note taking and goal setting for index participants. Feedback on the intervention content was integrated prior to implementation.

IMPLEMENTATION

Each site had individuals serving as both the systems navigators and psychosocial counselors rather than separate individuals for each intervention role. This alteration was primarily to ensure continuity of care for the intervention participants as well as enhance future scalability with limited resources. The education level of the intervention staff ranged from high school degrees to medical degrees. Of the two intervention staff in Indonesia, one had a bachelor's degree and the other a high school education, with both certified as addiction counselors. In Ukraine, two of the three intervention staff had masters' degrees and one did not have a college degree; however, all three had completed various coursework

on social work and counseling techniques. In Vietnam, two intervention staff held medical degrees and were practicing physicians.

All three sites participated in a 5-day, face-to-face, in-depth training for HPTN 074, including specific training on the intervention components. The training included the rationale for the study, the philosophy and theory for the intervention components, counseling technique practices, and a series of role play activities, in which real-time feedback was provided by site intervention staff and protocol team members. The sites continued to role play and held debriefs with protocol team members until study initiation.

Of the 126 enrolled index participants randomly assigned to the intervention, 98% ($n = 123$) met with an SN at least once. The median number of SN encounters per index participant during the first 8 weeks ranged from two encounters (IQR: 1,3) in Ukraine, up to four encounters (IQR: 3,5) in Indonesia, and five encounters (IQR: 2,7) in Vietnam. The method of SN contact varied by site, with the majority of encounters in Indonesia and Ukraine occurring in person (56% and 80% respectively), and the majority of encounters occurring by phone in Vietnam (78%). Over-all, 84% completed two or more psychosocial counseling sessions within 60 days of enrollment. Uptake of counseling sessions was high in Vietnam (92%), followed by Ukraine (80%), then Indonesia (76%).

Monitoring/Feedback Mechanisms.—Monitoring and feedback were ongoing throughout the development and implementation of the intervention. The intervention team debriefed weekly at each site. Monthly debriefings were also conducted with the intervention team from each site and protocol team members. The debriefings often focused on clarifications on manual components, need for additional boosters addressing barriers to HIV and substance use treatment, and identification of strategies to prevent counselor fatigue or burn out. Additional ad hoc calls and site visits were conducted for refresher trainings. Intervention adaptations and additional booster modules were reviewed during monthly debriefings prior to integration within the manual.

Adaptations.—Several key adaptations of the original design and materials were systematically integrated based on participant needs (Table 2). Sites elected to have the same individuals serve both as the psychosocial counselors and systems navigators. This reduced staff burden and permitted for continuity of care for each index participant. Based on feedback from the intervention team, additional booster modules were developed to address unique needs of the index participants. Index participants within Indonesia commonly reported the use of benzodiazepines, requiring the development of an additional booster module that specifically addressed education and counseling for benzodiazepine harm reduction strategies. In all the sites, index participants expressed fertility desires; hence, we developed a booster module that counseled participants on strategies for safe and successful pregnancies while preventing HIV transmission. Additionally, a list of health care providers for follow up family planning counseling was provided to index participants. To assist with conducting dyad sessions, conflict resolutions modules were developed to accompany dyad sessions in Vietnam. In Ukraine, brief phone consultations were held with index participants' relatives rather than conducting in-person dyad sessions. Although ART was available for all index participants, pre-requirement testing for ART was subsidized for

participants at all sites. Lastly, some systems navigators delivered ART to index participants who were unable to attend the ART clinic.

DISCUSSION

HPTN 074 was the first study to our knowledge that designed and implemented a systematic intervention that could be uniquely tailored to address barriers to HIV and substance use treatment among HIV-positive PWID across multiple settings. Unlike traditional case management, we used a systematic approach to assist in engagement in care with health systems across a variety of distinct settings. We also manualized and scripted brief sessions for PWID that included booster modules to be administered when relevant. The flexibility of the booster modules allowed the intervention team to address individual participants' diverse needs and barriers.

Our rapid formative work identified a lack of understanding of ART initiation requirements as a barrier for HIV treatment among those living with HIV. Traditional case management has been developed to address barriers to HIV treatment that are often the function of the individual and health system (Vargas & Cunningham, 2006). Projects such as the ARTAS study, an intensive case management study in Russia, have been successful in linking persons living with HIV to medical care (Gardner et al., 2005; Liao et al., 2013; Pearson et al., 2007; Shaboltas et al., 2013; Vargas & Cunningham, 2006). The HPTN 074 intervention deviates from traditional case management by integrating a set of manualized sessions that were provided to participants based on their individual needs for ART initiation. These sessions were developed to address common misinformation regarding ART initiation requirements and were tailored for each distinct setting.

During the implementation of the HPTN 074 intervention, we identified the high costs of HIV services for enrolled PWID participants across all sites. Although the government provides ART, the mandatory pre-ART testing is often not covered. We adapted the intervention to subsidize the pre-ART testing requirements specifically. Future economic evaluations are urgently needed to identify sustainable approaches for alleviating the financial burden of PWID initiating HIV treatment.

The priority for the HPTN 074 intervention was to promote ART initiation and adherence. The intervention included supporting materials on substance use treatment, harm reduction, and MAT initiation. However, these materials were not a primary focus of the intervention. Previous research has shown that MAT, in conjunction with ART, can significantly improve treatment outcomes, including viral suppression (Low et al., 2016). We anticipated that MAT initiation would need to be a major focus for PWID to achieve the numerous clinical and prevention benefits of ART.

Intervention development can be resource and time intensive, particularly for a multi-site intervention in three distinct regions. Indeed, relying on every step within other preparation and adaptation frameworks can take up to several years (Barrera et al., 2013; Castro, Barrera Jr, & Holleran Steiker, 2010; Escoffery et al., 2018). Rather than conducting extensive formative work, we relied on the currently available evidence and integrated information

gained throughout implementation. We supplemented available evidence with a limited number of IDIs among PWID and their social supporters in Vietnam. To ensure rapid preparation and adaptation processes IDIs were not conducted within the Indonesia and Ukraine sites, however, their input was integral during the guide development, analysis, and integration of results within the intervention. Across all three sites, the systems navigators and psychosocial counselors collected detailed notes identifying participant needs. Adaptations to the intervention and supporting manual were made throughout implementation based on participants' needs. This approach allowed for a truly flexible and iterative process for addressing the barriers and needs of the participants.

CONCLUSIONS

The HPTN 074 intervention is implementable and scalable in low-resource settings where PWID are disproportionately infected with HIV. The HPTN 074 intervention provides a framework implementing a flexible multilevel intervention to increase up-take of HIV and substance use treatment across a variety of limited resource settings. Rather than tailoring an intervention for each site, we purposively obtained site-level guidance on a theoretically guided intervention that would be flexible enough while targeting key outcomes at each distinct site. We relied on currently available evidence through our rapid preparation phase and integrated monitoring and feedback mechanisms during implementation to iteratively and systematically adapt core elements of the interventions. Given the success of HPTN 074, large-scale implementation of this intervention should be considered in other PWID populations. Our flexible and scalable intervention provides a flexible and scalable framework for increasing the uptake of ART and MAT among PWID across a variety of limited-resource settings globally.

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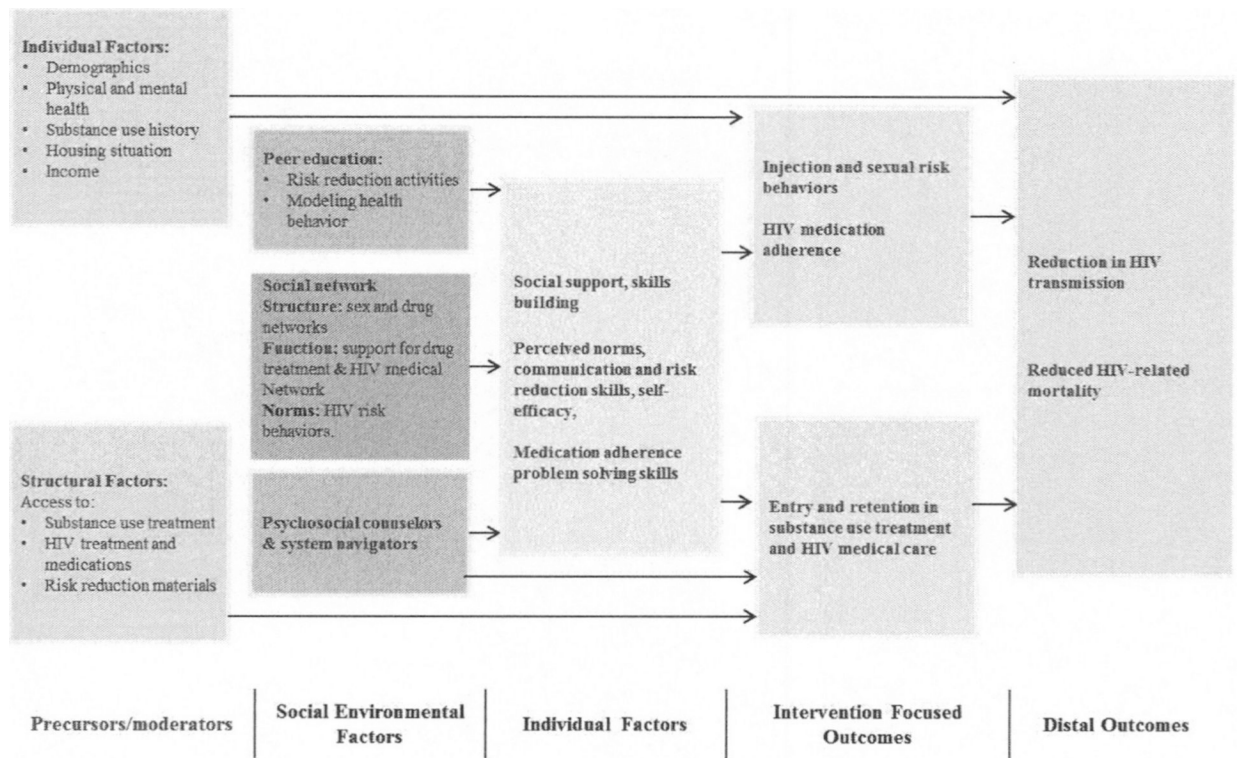


FIGURE 1.
HPTN 074 conceptual framework.

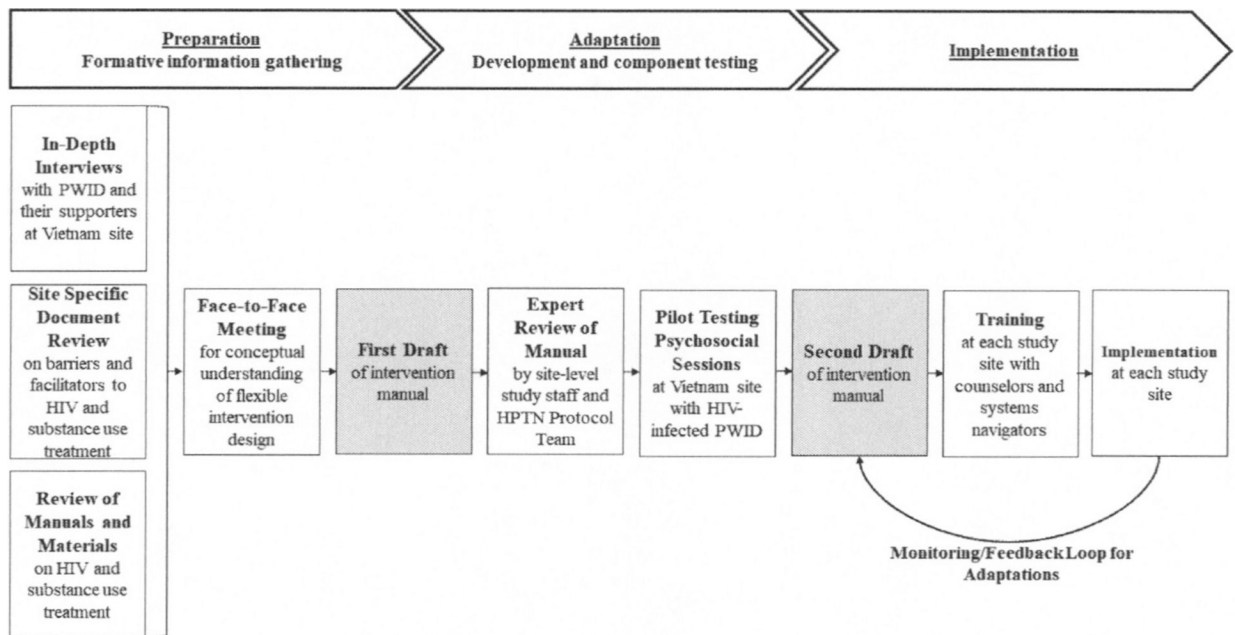


FIGURE 2. Process framework of the preparation, adaptation, and implementation of a flexible, individually tailored intervention for HIV-infected PWID to improve engagement in HIV care and substance use treatment in multiple settings.

TABLE 1.

Components of HPTN 074 Intervention

Intervention core element	Activity/Prepared materials	Description
Psychosocial counseling		Use of motivational interviewing, problem solving, skills building, and goal setting to help with substance use treatment and HIV care and medication adherence
	Mandatory session: Introduction	Explain the purpose of the program Assess participant expectations of the program Assess preliminary treatment needs of the participant
	Mandatory session: HIV treatment	Assess HIV treatment history and status Understand the goal of HIV treatment Assess drug use and treatment history Identify needs (e.g., referral to HIV care, adherence to ART, drug use treatment, and relapse prevention) Discuss and review major barriers to treatment Assess treatment goals and priorities
	Mandatory session; Program goals and adherence	Assess participants' goals, objectives, and expectations of the program Encourage understanding of ART and MAT adherence importance If not currently taking ART—address drug use and options for MAT
	Booster modules	Booster modules to conduct after mandatory sessions are completed. The purpose is to provide a menu of topics that can address common barriers to HIV and substance use treatment. The module chosen depends on the assessment of the index participant's needs and priorities. Topics include; Injecting risk reduction and drug splitting Substance use treatment Alcohol use Depression and stigma
	Dyad sessions	Two booster modules specifically designed to be conducted with an index participant and their supporter. A supporter can be a family member or friend that the participant feels comfortable disclosing their HIV status to. The role of the supporter is to assist the participant in meeting their HIV care and treatment goals as well as substance use treatment goals.
Health systems navigator		Assistance with engagement, retention, and adherence in substance use treatment and HIV care Provide list of HIV clinics and drug treatment centers
ART		Universal provision of ART to all HIV-infected participants, regardless of in-country guidelines

TABLE 2.

Key Adaptations to HPTN 074 Intervention as Identified by Site

Intervention core element	Activity/Prepared materials	Adaptations		
		Indonesia	Ukraine	Vietnam
Psychosocial counseling	Booster modules	Development of benzodiazepine module	Development of family planning and HIV module	Development of family planning and HIV module
	Dyad sessions	Development of family planning and HIV module	Brief phone consultations with index participants' relatives on need and availability of HTV and substance use treatment	Development of conflict resolution and "I" statements modules
Systems navigator	Weekly check-in with participants	Same individuals served as psychosocial counselor and health systems navigator	Same individuals served as psychosocial counselor and health systems navigator	Same individuals served as psychosocial counselor and health systems navigator
ART	Treatment at any CD4 count	Pre-requirement tests of ART (if any) were covered by participants or by donor-driven program, depending on participant's capability	Testing costs covered for the initiation of ART Help in receiving ART; delivery of ART if it is needed because of the circumstances—e.g., a person is ill with a flu at home or is in the closed rehab. The navigators brought ART to several participants while they were treated in a rehab	

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