Official title: A Community-Clinic Collaboration to Improve Outcomes in HIV+ Substance Users Released from Jail

NCT number: NCT03834779

IRB Approved date: 09/11/2020

The University of Texas Southwestern Medical Center at Dallas
Institutional Review Board

Title: A Community-Clinic Collaboration to Improve Outcomes in HIV+ Substance Users Released from Jail
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Version 1

1. Introduction and Purpose:
The long-term goal of this project is to improve HIV and substance use outcomes and reduce recidivism for HIV+ substance users released from jail. The overall objective of the proposed R34 project is to develop and pilot test a multi-sector community-clinic collaborative intervention that can subsequently be implemented on a larger scale (as part of a future R01) to achieve this goal. Our central hypothesis is that HIV+ substance users released from jail can successfully overcome obstacles to re-entry and continuity of HIV care with individualized, culturally competent assistance in navigating both social and medical services.

Aim 1: Develop and refine a collaborative CHW and re-entry program intervention that targets HIV outcomes, substance use and recidivism in HIV+ jail releasees.
Aim 2: Conduct a pilot randomized controlled trial comparing the collaborative intervention (n=40) compared to treatment as usual (n=40) in HIV+ substance users released from jail.

2. Background:
Despite major advances in HIV treatment, which have not only improved individual clinical outcomes but can also prevent HIV transmission to others, only a small proportion of the US HIV+ population is engaged in routine HIV care (41%), receiving antiretroviral therapy (ART) (36%) or has achieved an undetectable HIV viral load (28%).3 Rates of retention in care, HIV treatment and virological suppression are even lower for HIV+ individuals involved in the criminal justice system and substance users in particular,1 which perpetuates health disparities among HIV+ racial and ethnic minorities, youth, and those living in the South.

HIV+ individuals released from incarceration have many competing priorities- such as obtaining housing, food, financial assistance, and employment while simultaneously attending substance use, mental health and probation visits-- which often supersede accessing HIV clinical care.14-16 Previous interventions among HIV+ releasees have included intensified case management or linkage coordinators 5,7,8 but have not directly engaged other sectors in the community– such as the housing system, food banks, employers who hire formerly incarcerated individuals, education centers, religious entities, mental healthcare, substance use treatment, correctional supervision—nor have they utilized formerly incarcerated community health workers (CHWs) who are integrated into the community-based HIV clinic. This project reflects a new national awareness of the need to bridge social and medical sectors to truly impact patient outcomes. Moreover, by focusing on jails, where inmates have short incarcerations and are released locally, rather then prisons, where stays are long and often remote, this project has the potential to create healthier and safer local communities.

3. Concise Summary of Project:
To achieve our overarching goal of improving HIV and substance use outcomes in individuals released from jail, we will develop and pilot a community-clinic collaborative intervention. In the first phase of this project, we will refine the intervention and how best to implement it using the following steps: (a) adapt the Community Health Worker (CHW) intervention to HIV+ substance users and incorporate the CHW into existing processes for Unlocking DOORS (or "DOORs", A non-profit organization we are partnering with) and the HIV clinic, (b) obtain qualitative input from key stakeholders on how best to recruit and enroll participants from the jail and how to implement the integrated intervention at DOORS and the HIV clinic, and (c) pilot test the intervention with 5 subjects. In the second phase of the project, we will recruit (during incarceration) and enroll (within 30 days of release) 80 (40 in each arm) HIV+ individuals who are or were recently incarcerated at the Dallas County Jail, who have uncontrolled HIV and a history of substance use within the past 12 months. Participants will be randomized to the DOORS+CHW intervention versus TAU and all participants will undergo study follow-up visits at 3, 6 and 12 months. The primary outcomes are undetectable HIV viral load and substance use at 6 months; the main secondary outcome is recidivism. Health

behaviors such as adherence to care (attendance of HIV clinic visits, adherence to medications) and other healthcare utilization (substance use treatment, mental health visits, emergency room use, hospitalizations) will also be measured.

4. Study Procedures:
AIM 1: Develop and refine a collaborative CHW and re-entry program intervention that targets HIV outcomes, substance use and recidivism in HIV+ jail releasees.

Introduction. This first aim will be critical to successful implementation of the CHW-DOORS intervention. Employing a formerly incarcerated CHW to assist individuals leaving prison in order to connect to healthcare has been successfully implemented in different settings, but it has not been applied specifically to HIV patients or those leaving jail (v. prison), nor has it been integrated into a community based organization. The objective of this aim is to adapt the evidence-based CHW intervention to the HIV population and to the jail setting and to integrate the CHW into existing processes at DOORS and the outpatient HIV clinic system. Our working hypothesis is that stakeholder input and engagement through semi-structured interviews with patients, medical providers and staff in the different settings where the study will take place (jail, DOORS, HIV clinic) will improve acceptability and successful implementation of the study. In addition, by pilot testing the intervention with 5 subjects, we will be able to optimize recruitment and enrollment processes as well as to assess delivery of the integrated CHW-DOORS intervention in an iterative fashion. These steps will prepare study staff and stakeholders for successful execution of Aim 2.

Research Design. **Aim 1.1:** The first step of Aim 1 will be to train the CHW using the transitions clinic approach, add modules on HIV and substance use and familiarize the CHW with DOORS processes and HIV clinic workflow.

- Transitions clinic training: Dr. Shavit (consultant) developed a post-prison health worker certificate program through the City College of San Francisco. This 20-unit course of study, grounded in public health and social justice, addresses the health impacts of incarceration and chronic disease management. This certificate program has been developed into an online program, including video demonstrations of core CHW competencies and work-based assignments that foster on the job application of concepts and skills.
- HIV training: CHWs will complete additional one-on-one training with Dr. Nijhawan (PI) in basics of HIV epidemiology, diagnosis, clinical presentation, treatment and special populations with HIV (mentally ill, substance users, incarcerated). Dr. Nijhawan will collate existing and develop new reference materials for the CHWs to use throughout the two study phases. Given rapid developments in the HIV field, Dr. Nijhawan will review and update materials every 6 months, providing refresher training for CHWs with each update. Data from stakeholder interviews from Aim 1.2 will also be incorporated into this training module.
- Substance use disorders training: CHWs will also complete one-on-one training on substance use disorders and their diagnosis, presentation and management with Dr. Walker (co-investigator). Dr. Walker will develop reference materials for the CHWs to use throughout the study. Similar to the HIV module, Dr. Walker will update this training module when necessary, systematically review it every 6 months to ensure accuracy, and utilize data from stakeholder interviews from Aim 1.2 to make updates.
- Community resource assessment and process mapping: CHWs will visit community-based resources in Dallas, specifically substance use disorder treatment centers, and will complete process mapping with the outpatient HIV clinic and DOORS as to how a recently released client accesses services.

Aim 1.2: The second step will be to complete qualitative interviews with stakeholders in three different settings- the jail, the HIV clinic and DOORS. All interviews will be semi-structured, one-on-one interviews, with an estimated 4-7 interviews in each setting.

- Jail: interviews will be conducted with administrative staff from jail health as well as from the Sheriff's office (n=2), medical provider or nurse (n=1-2), and patient(s) (n=1-2).
- HIV clinic: interviews will be conducted with a clinic manager and/or medical director (n=1-2), case manager (n=1-2), medical provider (n=1) and patient(s) with a history of incarceration (n=1-2).
- DOORS: interviews with the CEO (n=1), the broker director (n=1), a broker (n=1) and client(s) (n=1-2).

Eligibility criteria for interviewees will be that the participant has worked (or received services) in the target setting for at least 3 months. Recruitment will occur via email (for staff) or referral by provider (for patients/clients). The structured component of the interview guide will prompt interviewee input on study design (e.g., recruitment, intervention, follow-up visits), content of the intervention (e.g., high demand services) and an open-ended component eliciting possible barriers to study implementation. Interviews will incorporate questions on each stakeholders' unique perspective. For example, correctional officers' views about need for security staff presence during recruitment and enrollment, medical providers concerns about clinic workflow, patient/clients' experience with barriers to accessing services after incarceration. All interviews will last approximately 30-45 minutes, will be conducted by the PI or trained research assistant, and will be recorded and transcribed. Participants will receive reimbursement for interviews where permitted (if not currently incarcerated and not employed by Parkland).

Aim 1.3: The final step in Aim 1 will be to complete pilot testing with 5 subjects, which will focus on refining recruitment/enrollment protocols, streamlining study assessments and evaluating the intervention.

Recruitment: In order to protect patient confidentiality, potential subjects will be referred by medical staff who provide clinical care to HIV+ inmates. When an inmate enters the Dallas County Jail, he/she is evaluated by a medical provider within 24 hours (medical assessment program, MAP). At this visit, the inmate can disclose any medical conditions that they have including HIV, in which case he/she will be referred to the jail HIV clinic (scheduled within 1-7 days of jail entry). In addition, HIV testing is offered in an opt-out manner when inmates have blood drawn for any reason (approximately 10% of jail population) and by inmate request, and those with positive test results are referred to jail HIV clinic. Candidates coming through the MAP or HIV clinics who agree to be approached will be contacted by a research assistant (RA). The RA will explain the study to interested individuals, will obtain additional contact information (additional phone numbers, address or location in community where patient could be found) and permission to contact the individual after release. Clinic staff will also routinely request this information from interested individuals in case they are released prior to RA visit in jail. Once released, the research team will contact the individual releasee to schedule an enrollment visit. At this visit, which will occur as soon as possible after jail release (maximum within 30 days of release), the research team will obtain informed consent and enroll the participant into the study. The enrollment may occur at the UT Southwestern HIV research unit (located above the main HIV clinic) or in the community as per participant preference.

Eligibility and Enrollment: In order to be eligible, individuals must: (a) be ≥18 years old, (b) speak English sufficiently to discuss study procedures prior to written informed consent, (c) correctly answer a brief comprehension quiz to confirm understanding of study procedures (d) have a confirmed diagnosis of HIV, (e) have evidence of uncontrolled HIV (viral load >200 copies/mL within 90 days of enrollment, self-reported non-adherence to HIV medications or no community clinic visit in the 6 months preceding incarceration), (f) report or have medical records documenting any opioid (illicit or prescription misuse), stimulant (cocaine, ecstasy, or amphetamines), or heavy alcohol use (as determined by the 3-item Alcohol Use Disorders Identification Test (AUDIT-C) within the past 12 months and (g) provide at least 2 forms of contact information. Individuals will be excluded if they have an acute medical or psychiatric disorder that would, in the judgment of the PI, make participation difficult or unsafe. All participants will be asked to provide a release of information for their medical

records at the jail and community clinics/hospitals. No randomization will occur in Aim 1 as all 5 participants in the pilot testing phase will be assigned to the intervention.

Measures: Baseline assessments will occur after informed consent is obtained and enrollment is complete. These assessments will focus on variables in the conceptual model, beginning with collection of *demographics* (age, race/ethnicity, gender, HIV risk factor). *Social variables* will be measured using similar tools as used in the NIDA National Drug Treatment Clinical Trials Network (CTN) 0049, Project HOPE and "Seek, Test, Treat and Retain" data harmonization measures (marital status, housing instability [with order of stability using published weights][27] education, employment, income (as proportion of federal poverty limit), health insurance, benefits, and social support (using social support scale for HIV patients[28]). Participants will be asked to identify *barriers to HIV care* from a list based on the literature[29] and be given free text options. *Perceived health* will be assessed using a single-item self-reported health measure.[30] *Mental illness* will be assessed using the 18-item Brief Symptom Index (BSI-18), which provides scales for anxiety, depression, somatization and global severity[31] Subjects will also be asked about *health care utilization*, including primary HIV care visits, case management visits, substance use disorder treatment, emergency room visits, and hospitalizations in the preceding 12 months (at baseline) and since the last study visit (at follow-up). As we successfully did in Project HOPE, we will obtain a release of information authorization at the start of the study for each participant for the main facilities that the participant attends and abstract medical records to confirm ED visits and hospitalizations and assess primary reason for the visit and disposition. For assessment of *ART prescription*, pharmacy refill records will be obtained (through Parkland or outside pharmacy), and *adherence* to medications will be assessed using the visual analog scale[32]. *Incarceration* history and interim incarceration (at follow-up) will be collected through self-report and reason for incarceration abstracted from jail records. *Motivation for substance use treatment* will be measured using a readiness and negative attitudes scale.[33,34] *Substance use* will be measured using the World Health Organization's ASSIST (Alcohol, Smoking, Substance Involvement Screening Test) tool,[35] a validated, efficient (5-10 minutes) measure of substance use that has strong psychometric properties and has been utilized in incarcerated populations[36] (see ***Table 1***). The baseline ASSIST assessment will be modified to evaluate substance involvement prior to incarceration and participants will be asked to identify their primary drug of choice. *Substance use* at 6 months will also be assessed via urine drug screen.

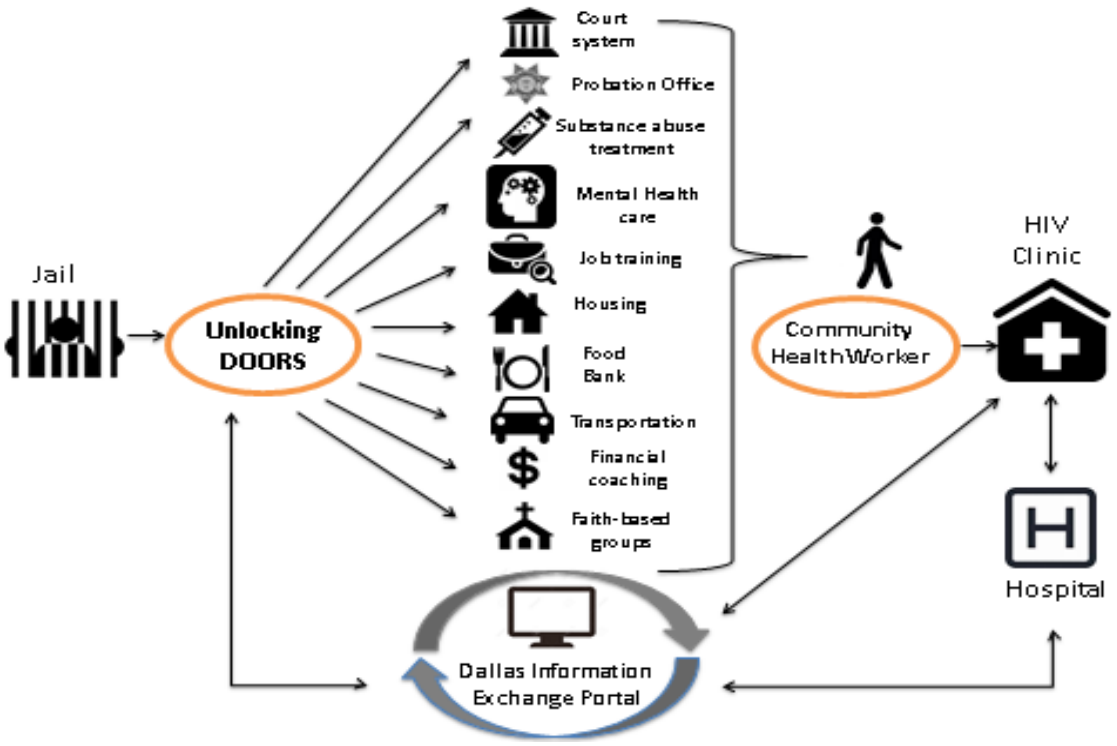

Figure 3 Schematic of CHW-DOORS intervention

Intervention: The first meeting with the CHW will occur at the time of enrollment if possible, depending on availability of the participant and CHW, otherwise it may occur anytime within 14 days of enrollment. After release form jail, the CHW will help the participant navigate to DOORS, where they will meet with a "broker", someone who helps the client/participant arrange and negotiate referrals to services within the extensive partner/provider network ***(Figure 3***). The first broker meeting will typically occur within 2-4 weeks after release, as this is a critical window for re-engagement in care, underscored by the fact that this is also a high-risk period for increased unprotected sex and return to substance use. Per DOORS' standard practice, the broker will complete a comprehensive needs assessment with the participant, including Texas Risk Assessment System score (used throughout Texas criminal justice system and predicts an individual's risk for re-offending as low, medium, high or very high), Career Key (achieved training and work history), benefits calculator, and behaviors and experiences Inventory. Based on these assessments, together with the participant, the broker will develop a personalized re-entry plan with a detailed list of referrals and calendar of scheduled visits with relevant agencies within the DOORS network. In this pilot phase as well as the future pragmatic randomized trial (see Aim 2), both the DOORS and CHW components of the intervention are client-centered and will be adapted to each participant to meet their comprehensive social and medical needs. The central philosophy behind this approach is to "meet participants where they are". This is meant in a literal geographic sense (meeting with participants in their own communities), but also where they are psychologically, in terms of readiness for substance use disorder treatment and HIV care. Much of the CHWs job will be to help the participant navigate the logistics of accessing services, and help with accountability, though the CHW will also employ motivational interviewing techniques to guide participants towards positive substance use and HIV outcomes.

Measuring health behaviors: Two key components of this plan will be to access substance use disorder treatment and HIV care. The CHW will coordinate with the DOORS broker to help the participant schedule and attend visits with referral providers, taking into account the participants medical needs. The CHW will also meet with the participant in the community, and accompany the participant to various visits, specifically HIV clinic visits, mental health care, and substance use treatment. The CHW, as part of the extended clinic medical team, will also participate in dedicated clinic-based team meetings to address the participant's progress.

Measuring intervention "dose": Both the CHWs and DOORS brokers will record referrals made and attended as well as in-person visits with the participant. The CHW will coordinate with the DOORS broker to help the participant schedule and attend visits with referral providers, by meeting with the participant in the community and accompanying the participant to various visits, specifically HIV clinic visits, mental health care, and substance use treatment. CHWs, as part of the extended clinic medical team, will also participate in dedicated clinic-based team meetings to address the participant's progress. CHWs, utilizing an intervention log, will record the number, duration and nature of each visit with the participant, as well as provide a brief progress note. For example, s/he will record "accompanied participant to mental health care visit" and in progress note highlight key issues such as if medications were started. The CHW will also record any scheduled visits with the participant that were missed. This information will be used to monitor and provide feedback to CHWs on intervention fidelity, as well as facilitate 'dose-received' exploratory analysis.

The DOORS broker will follow routine practice at DOORS, inputting referrals into the care coordination software that also feeds into the social-health information exchange. There is no set number of referrals to be made as this depends on the patient's specific needs (not a "one-size fits all" approach). At a minimum, all participants will meet with the broker and CHW at the beginning of the intervention and at least one additional visit. At a maximum, the CHWs will meet with participants once per week, as higher frequency visits will be impractical and will excessively limit the number of participants each CHW can work with. It is estimated that the combined intervention will last 6 months,

and the CHWs will not schedule visits beyond this. However, it is DOORS' policy that there is no set end date for services or 'graduation' from DOORS, therefore participants may continue to receive services from DOORS after the 6 month mark (and recorded during the study period).

Supervision of CHWs: Drs. Nijhawan and Walker will be responsible for supervising the CHWs. Weekly team meetings will be held to discuss and review the intervention logs. (DOORS brokers are supervised by the lead broker at DOORS and overseen by Christina Crain, Esq.) In addition, with participant permission, at least one visit per participant per CHW will be audio-recorded to ensure fidelity to the intervention. Each recording will be reviewed within 2 weeks and feedback provided to the CHW to assure intervention fidelity.

Table 1 Study Assessments

	Baseline	3-month	6-month	12-month
Demographics (race/ethnicity, gender, age, education, marital status)	x			
Social support, transportation, telephone	x			
Barriers to care engagement	x			
Employment, Housing instability	x	x	x	x
Self-reported health status	x	x	x	x
Mental illness	x	x	x	x
Healthcare utilization (clinic, case management SUD, ED, hospitalization)	x	x	x	x
Adherence (visual analog scale)	x	x	x	x
Incarceration history/recidivism	x	x	x	x
Readiness for substance use tx	x	x	x	x
Substance use (ASSIST)	x	x	x	x
Urine drug screen			x	
HIV viral load	(abstract from records)	(abstract form records)	x	(abstract from records)

Follow-up visits and assessments: Research visits will be scheduled at 3 months, 6 months and 12 months. A 4-week window before and 8-week window after the target follow-up dates will be permitted for study assessments. Assessments will be completed at each follow-up visit, including substance use, adherence, healthcare utilization and recidivism, with blood draw for HIV viral load collected at the 6-month visit. In order to maximize efficient utilization of resources, for baseline and other follow-up visits, HIV viral load will be abstracted from medical records (see Table 1). In order to have sufficient time to enroll and complete 12 month study visits for the 80 participants in Aim 2, the 5 pilot participants from Aim 1.3 need to reach at least the 3 month time point but not 6 or 12-month visits before beginning study enrollment for Aim 2. Pilot participants will complete through 12-month visits as this will provide insight as to how best to conduct these later follow-up visits. Where possible, data will be collected in accordance with measures developed by NIDA through the "Seek, Test, Treat and Retain" data harmonization efforts, including any recent updates to these measures. Substance use will be measured using the ASSIST (Alcohol, Smoking, Substance Involvement Screening test) tool,[28] which is a validated measure of substance use developed by the World Health Organization, as an efficient (takes 5-10 minutes) tool with strong psychometric properties, that is easy to administer and score, and has been utilized in incarcerated populations.[29] All participants will receive financial reimbursement for study visits ($25 for each visit, with an additional $25 at 6 months), unless they are incarcerated at the time of the visit. Jail inmates are not permitted to receive any financial incentives during incarceration.

AIM 2: Conduct a pilot randomized controlled trial comparing the collaborative intervention (n=40) compared to treatment as usual (n=40) in HIV+ substance users released from jail.

Introduction. In this aim, we will test the CHW-DOORS intervention that was refined in Aim 1 in a randomized fashion. The goal of this aim is to establish feasibility of a randomized controlled trial in this setting, to determine preliminary efficacy of the intervention and to inform sample size calculations for a fully powered trial. In addition, this aim will provide data regarding key factors involved in HIV+ substance users accessing substance use treatment and HIV care after jail release. Our working hypothesis is that from the stakeholder input and pilot testing completed in Aim 1, we will be able to successfully conduct a pilot randomized controlled trial and gain valuable insight into key predisposing and enabling factors influencing healthcare needs and utilization in this population, and how these may impact HIV viral load, substance use and recidivism.

Research Design. Potential participants will be referred to the research study by Dallas County jail medical providers as described in Aim 1.3. Candidates who agree to be approached will be contacted by a RA who will recruit, and review eligibility criteria (see Aim 1.3). After release, potential participants will be contacted in order to complete informed consent, study enrollment and randomization (to be completed within 30 days of release from jail). All participants will provide 2 specific forms of locator information (telephone number for themselves, friend/family member, address, email, specific location where they may be located to aid in retention efforts). Participants will complete baseline assessments (see Table 1) and will then be randomized to the intervention CHW-DOORS versus treatment as usual (TAU). Randomization will occur by random assignment using a computer program, without block randomization given the small sample size. TAU participants will receive standard of care, which involves passive referral by jail medical staff to the outpatient HIV clinic. Under TAU, once the releasee presents to the outpatient clinic, additional referrals may be made to other services such as housing, transportation, mental healthcare, and substance use disorder treatment. Although DOORS has not been focused on jail releasees, there is the possibility that TAU participants are referred to or seek out services from DOORS (see potential problems and alternative strategies below).

Intervention. Participants randomized to the intervention arm will meet with the CHW and a staff member from DOORS as outlined in Aim 1.3. Any modifications to this protocol after pilot testing in Aim 1.3 will be implemented in Aim 2. The general premise will be the same, where the DOORS broker will complete a needs assessment, generate an individualized re-entry plan and make referrals to providers in the extensive DOORS network. The CHW will assist the participant in navigating these referrals, specifically with regards to HIV care, substance use treatment and mental healthcare. The measurement of the intervention will be as noted in Aim 1.3, with the DOORS broker following routine agency processes for referrals and measurement using the PIECES technology program and the CHW will record specifics (where, when, duration) of each visit and what was addressed during these intervention visits. By this stage, a dedicated protocol will have been developed based on what is learned in Aim 1.3 as to more specifics of the CHW role and how to record intervention dose. The CHW intervention log will continue to be reviewed by Drs. Nijhawan and Walker during regularly scheduled research meetings, with audio-recording and review of at least 10 participant visits.

*Study Assessments***.** All participants will complete baseline assessments prior to randomization and will have follow-up visits at 3, 6 and 12 months as noted in Aim 1.3. A blood draw will be performed for 6-month HIV viral load. Follow-up visits will assess HIV viral load (abstracted from medical record for all visits other than 6 month), substance use (using ASSIST), healthcare utilization including attendance of HIV clinic visits, emergency room visits, hospitalizations and reincarceration. If individuals are reincarcerated at the Dallas County Jail at the time of the follow-up visits, an attempt will be made to complete study visits at the jail.

5. Sub-Study Procedures:

N/A

6. Criteria for Inclusion of Subjects:

By Aim:

Aim 1.2:
Inclusion criteria:

- Involved in care, supervision or administrative processes affecting HIV+ Dallas County Jail inmates before or after release OR
- HIV-infected inmate at Dallas County Jail OR
- Patient at Amelia court clinic with incarceration history OR Unlocking DOORs client

Aim 1.3, Aim 2:

- Incarcerated currently or released from incarceration within the past 60 days AND
- HIV-infected AND
- ≥18 years old AND
- report or have medical records documenting any opioid (illicit or prescription misuse), stimulant (cocaine, ecstasy, or amphetamines), or heavy alcohol use (as determined by the 3-item Alcohol Use Disorders Identification Test (AUDIT-C) within the past 12 months
- Provide two forms of contact information (address, phone number, email, other locator info) AND
- HIV VL >200 copies/mL within past 90 days OR
- No HIV visit in 6 months OR Self-reported non-adherence to medications
- Participants are able to participant if they have not seen an HIV medical provider since their release from Jail.

7. Criteria for Exclusion of Subjects:

Aim 1.2:

- Unwilling to participate
- Unable to consent
- Does not speak English
  Aim 1.3, Aim 2:
- Unwilling to participate
- Unable to consent
- Does not plan to remain in greater Dallas area after release
  Sentenced to prison or other court-mandated program for ≥6 months
- Does not speak English

8. Sources of Research Material:

The main sources of materials will be from participant interviews in Aim 1.2, and from participant study assessments and from blood draw specimens which are collected as part of the study (Aim 1.3 and 2). In addition, Dallas County Jail and Parkland electronic medical records (Jail EMR is Pearl, Parkland is Epic) will be reviewed with the participant's permission (release of information) to obtain certain data elements, such as scheduled/missed clinic visits, or to abstract laboratory data. Also, data on emergency room visits and hospitalizations will be obtained from the Dallas Fort Worth Hospital Council Foundation.

The research team, consisting of the principal investigator (PI), Dr. Ank Nijhawan, co-investigator, Robrina Walker, PhD, and research staff, will have access to individually identifiable private information about human subjects. For the qualitative interviews, all interviews will be transcribed and identifying information (e.g. names of individuals mentioned during interview) in the interviews will be removed. Each interview will be assigned a research ID number and a separate link will be maintained to identifying the subject's role (e.g. clinic patient, security staff, etc.). For Aims 1.3 and 2, all subjects' personal identifying information including contact information will be stored separately from the research database. Each subject will receive a unique study identification number for the purposes of recording study-related data. A link between the study ID and patient name and medical record number will be maintained separately in a locked cabinet in Dr. Nijhawan's research office. An electronic study database will be maintained using Research Electronic Data Capture (REDCAP), a secure, web-based application designed to support data capture for research studies. Data entered into REDCAP will be entered by study ID and will not include personal identifiers.

9. Recruitment Methods and Consenting Process:

Aim 1.2
Recruitment for qualitative interviews will occur in the 3 different settings- the jail, HIV clinic, and Unlocking DOORS. For staff interviews, recruitment will start with email contact. If potential participants agree to an interview, a time will be arranged and the interviews conducted in a quiet setting as per participant preference (e.g. private work office space) and verbal consent will be obtained at that time (provider/staff participants will be given an information sheet about this aim of the study. Jail participants (n=1-2), clinic patients (n=1-2) and DOORS clients (n=1-2) will be referred by medical provider (within the jail and HIV clinic) or DOORS staff member with the patient's/client's permission

Aim 1.3 and Aim 2:
In order to protect patient confidentiality, potential subjects will be referred by medical staff who provide clinical care to HIV+ inmates. When an inmate enters the Dallas County Jail, he/she is evaluated by a medical provider within 24 hours (medical assessment program, MAP). At this visit, the inmate can disclose any medical conditions that they have including HIV, in which case he/she will be referred to the jail HIV clinic (scheduled within 1-7 days of jail entry). In addition, HIV testing is offered in an opt-out manner when inmates have blood drawn for any reason (approximately 10% of jail population) and by inmate request, and those with positive test results are referred to jail HIV clinic. Candidates coming through the MAP or HIV clinics who agree to be approached will be contacted by a research assistant (RA). The RA will explain the study to interested individuals, will obtain additional contact information (additional phone numbers, address or location in community where patient could be found) and permission to contact the individual after release. Clinic staff will also routinely request this information from interested individuals in case they are released prior to RA visit in jail. Once released, the research team will contact the individual releasee to schedule an enrollment visit. At this visit, which will occur as soon as possible after jail release (maximum within 30 days of release), the research team will obtain informed consent and enroll the participant into the study. The enrollment may occur at the UT Southwestern HIV research unit (located above the main HIV clinic) or in the community as per participant preference.

10. Potential Risks:
Confidentiality: Collection of protected health information, including HIV infection, pose a risk to the subject's confidentiality. In addition, answering interview questions related to potential barriers to care may be distressing to subjects, including discussions of substance use and financial stressors.
Blood draw: May result in pain, bleeding, bruising, infection.

11. Subject Safety and Data Monitoring:
As the PI of the study, Dr. Nijhawan will have the primary responsibility for the safe conduct of the study. This will include ensuring appropriate conduct of hiring and training of a community health worker, recruitment and enrollment of participants, implementation and monitoring of the intervention.

Participants' safety will be monitored by maintaining ongoing contact between the research staff (research coordinator, Unlocking DOORS brokers, community health worker) and the PI. Mechanisms for reporting adverse events to the study PI and IRB will include: 1) All study personnel will be trained in recognizing adverse events and how to report them to the PI and IRB if they occur. The main adverse event in this study will be related to the blood draw. Study staff will also record serious adverse events including hospitalizations and deaths as part of the study protocol. 2) The research team (including the PI) will meet weekly during implementation of the multi-sector intervention to review study progress and any safety concerns. All research studies at UTSW require ongoing annual IRB review and reports of adverse events are required as part of these progress reports. The PI will be responsible for contacting the Project Officer in the event that any action occurs.

Given that this is a relatively small, single site pilot trial, which involves minimal risk, a single independent data safety medical monitor will be utilized. This physician expert will not be directly involved in the study and will review all adverse events, adherence to protocol and interim study outcomes at a pre-specified time point during the study (target halfway through study time period).

12. Procedures to Maintain Confidentiality:
The major risk in this study is that of confidentiality, and several measures will be taken to ensure the confidentiality of subjects' personal health information:

a) All investigators and co-investigators will have completed HIPAA training, both for clinical care and research, and Human Subjects protection training.
b) Study data will be compiled in REDCAP to ensure additional information security.
c) A master file with the subject's personal information (name, contact information, birth date, and medical record number) will be stored separately from the research database and all subjects will be assigned a unique study identification number.
d) Any study forms or recordings which contain personal identifying information will be secured in a locked cabinet in Dr. Nijhawan's research office.
e) Participant assessments will be conducted in a private space.

Given the nature of the study, focused on substance users with HIV who are released from jail, a certificate of confidentiality will be obtained. It will be explained to participants that a Certificates of Confidentiality is issued by the National Institutes of Health (NIH) to protect the privacy of research subjects by protecting investigators and institutions from being compelled to release information that could be used to identify subjects with a research project. They allow the investigator and others who have access to research records to refuse to disclose identifying information in any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level.

13. Potential Benefits:

There is the potential for patients to directly or indirectly benefit from this study. Improving access to social services, substance use disorder treatment, and retention in HIV care after release form jail may result in better overall health for participants randomized to the intervention arm. For those who do not receive the intervention, there is an indirect benefit from learning more about the specific needs of released inmates and possible future programs based on what is learned from this project.

14. Biostatistics: (omit this section for peer-reviewed research such as cooperative group, or NIH-sponsored studies, and for industry-sponsored research which has been submitted to FDA)