Peer Navigation Manual

A research guide for peer-navigators conducting the navigation for the HIV Prevention Trials Network 094 study

INTEGRA: A Vanguard Study of Health Service Delivery in a Mobile Health Delivery Unit to Link Persons who Inject Drugs to Integrated Care and Prevention for Addiction, HIV, HCV and Primary Care

A Study of the HIV Prevention Trials Network

Final Version 1.1

10 August 2021

Sponsored by:

Division of AIDS (DAIDS), United States (US) National Institute of Allergy and Infectious Diseases (NIAID)

US National Institutes of Health (NIH)

Funded by:

US National Institute on Drug Abuse

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References and materials used to generate this manual include:

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Acknowledgements:

The development of this manual was facilitated by the infrastructure and resources provided by the UCLA Center for HIV Identification, Prevention and Treatment Services (CHIPTS) supported by NIH grant no. P30MH058107. The content is solely the responsibility of the authors and does not necessarily represent the official views of the NIH.

This manual is based on prior evidence based peer-navigation manuals that include LINK LA, LINK2, CHAMPS, and LINKHCV (William Cunningham, et al.), and the HPTN 074 manual (Carl Latkin, et al).

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KEY POINTS FOR CHAPTER 1

Chapter 1 provides an overview of the study, of the navigation manual and of the information needed to deliver peer navigation services for HPTN 094

- Study description and description of the population for the study
- Overview of the models used in this Peer Navigation manual
- Overview of the interventions used in Peer Navigation
- Intervention and Active Control arms: Who gets what and where?

1.1. Aims and Target Population

The overall goal for HPTN 094 is to determine the efficacy of using a mobile health delivery unit ("mobile unit") to deliver "one stop" integrated health services – particularly medication for opioid use disorder (MOUD) and medication for HIV treatment and prevention – to people who inject drugs (PWID) with opioid use disorder (OUD) to improve uptake and use of MOUD, and uptake and use of antiretroviral therapy (ART) or pre-exposure prophylaxis (PrEP). The intervention arm receiving health services in the mobile unit will be supported by peer navigation. An active control arm will receive peer navigation to health services available at community-based agencies. Impact (cost-effectiveness, mathematical modeling) and implementation factors (mixed methods to identify barriers and facilitators of the interventions) will contextualize findings from the efficacy analysis.

For this study, the main aims are:

1. To evaluate whether 26 weeks of "one stop" integrated health services delivered in a mobile unit, supported by peer navigation, improves:
    a. use of MOUD
    b. increases rates of viral suppression among HIV-positive individuals
    c. increases use of PrEP among HIV-negative individuals as measured at 26 weeks, when compared to 26 weeks of peer navigation to similar health services available at community-based agencies.

1.1.1 HPTN 094 Target Population – Who is this study for?

The target population for this study is male and female adults who are HIV-positive and HIV-negative PWID with OUD not receiving MOUD at the time of study enrollment.

Per the protocol, men and women who meet all the following criteria are eligible for inclusion in this study:

- 18 to 60 years of age
- urine test positive for recent opioid use and with evidence of recent injection drug use ("track marks")
- diagnosed with OUD per Diagnostic and Statistical Manual of Mental Disorders (DSM)-5
- able and willing to give informed consent
- willing to start MOUD treatment

- able to successfully complete an Assessment of Understanding
- self-reported sharing injection equipment and/or condomless sex in the last three months with partners of HIV-positive or unknown status
- able to provide adequate locator information
- confirmed HIV status, as defined in the HPTN 094 SSP Manual

*Individuals will not be eligible for enrollment if they received MOUD from a provider in the 30 days prior to enrollment by self-report.

1.1.2 HPTN 094 Setting – Where will this study take place?

The study setting is 5 geographical different U.S. sites where PWID make up a large portion of the at-risk population for HIV and are at high risk for overdose. These sites are research centers in Houston, TX, Los Angeles, CA, New York, NY, Philadelphia, PA, and Washington, D.C.

1.2. Background and Science

Health risks for persons with OUD and living with or at risk for HIV in the US include multiple and overlapping problems that interfere with consistent access to health care, particularly when the substance use disorder is active. The behaviorally disorganizing aspects of substance use disorder can interfere with traveling to existing services (lack of transportation), with willingness to tolerate judgements and attitudes from personnel in health care settings (stigma) and with foregoing pleasure in lieu of healthcare (addiction). Consequently, persons with active addiction spend large amounts of time hanging out together in "hot spots" near jails, criminal justice community supervision programs, syringe service programs (SSPs), parks and tourist areas. The location and size of these hot spots can vary within regions. More, because the needs of individuals who are living near or at these "hot spots" to remain hidden, it often is the case that there are transportation/access barriers for individuals who seek HIV care, PrEP, MOUD or any of a variety of services they may need.

The rationale for this study is based on this premise: HIV outbreaks in the U.S. among PWID occur when simultaneous factors—lack of access to health care (including MOUD), poverty, prevalent poly-substance use, and mental health disorders and others—combine to exacerbate HIV transmission and acquisition. PWID living with or at risk of HIV who are not engaged in MOUD face the nearly impossible task of getting care from bricks-and-mortar clinics that provide separate, siloed care for opioid addiction (methadone, buprenorphine), HIV medications (care and PrEP), STI testing and treatment, primary care, hepatitis testing and treatment, diagnosis and treatment for chronic and other conditions, with limited or no financial resources. Health services to address these diverse problems, when they exist, are often located far away from each other and from the PWID who need them, presenting serious distance/travel barriers to access. The challenge of finding and sustaining HIV care and prevention in the setting of untreated OUD in persons with multiple additional health threats contributed to multiple HIV outbreaks in the US (in Indiana, Massachusetts, Washington, West Virginia). The use of a mobile venue that meets out-of-treatment PWID wherever they might be in their communities and links them to care systems and/or harm reduction is innovative, is likely to save lives and, if efficacious, could be efficiently scaled-up in the US, especially as the US health system responds to dramatic new pressures imposed by the COVID-19 pandemic.

These factors synergistically impair the ability of people who inject drugs who are living with HIV or are at risk to access the services they need to maintain their health. Moreover, these factors differentially impact those individuals who have additional conditions that confer stigma, racism, homophobia and other forms of discrimination. This situation builds upon the existing significance for the scientific community to act to address the intersecting epidemics of addiction and infectious diseases while doing so in ways that call out and put in place interventions that respect the additional conditions of stigma and discrimination for many of these individuals. This manual guiding the peer navigation strategy for HPTN 094 is designed to do exactly that.

The HPTN 094 Peer Navigation Model. The HPTN 094 peer navigation model is guided by a number of overlapping theories: systems theory, self-determination theory, empowerment theory, shared decision- making theory and social support theory. These theories guide how the components of the intervention and the implementation strategies of the navigation are delivered. These strategies, in turn, are used with participants for

engaging and persisting in MOUD, in HIV care and prevention, in testing and treatment for STIs, in primary care and in harm reduction. These theories also emphasize unscripted procedures that mean active listening, empathy, and always positive regard with our participants.

Here is a brief summary of the theories that underlie the HPTN 094 peer navigation intervention:

- **Systems Theory:** Systems theory recognizes the many multi-layered relationships and environments that impact the individual and function as barriers or facilitators to access to the needed elements that sustain health and improve access to care. Factors that can influence health behavior in the system include family, friends, social settings, economic class, and the environment at home. The theory posits that these and other factors influence how individuals think and act, and therefore examining these social structures to find ways to correct ineffective parts or adapt for missing elements of a given system can positively impact behavior. An effective system is defined as one that is organized to support meeting the individual needs, rewards, expectations, and attributes of the people living in the system.

- **Self-Determination Theory:** Self-determination theory is a general theory of human motivation (1). The approach understands motivation for behavior is balanced between autonomous (i.e., the extent to which behaviors originate from the self) versus controlled forces (i.e., the extent to which behaviors are pressured or coerced by intrapsychic or interpersonal forces). From this perspective, people make decisions from their own perspective about what is important to them, given their understanding of the balance between autonomous and controlled forces. The approach fits well with motivational interviewing, in which clients are given free range to examine the pros and cons that support behaviors that in continuing substance misuse, addiction and/or other behavioral problems (2). A key element of self-determination theory is the essence of an individual's intrinsic tendencies being developed and supported to protect and preserve the integrity of that individual. Self-determination theory will be used to guide *case management* for the participants. Areas of behavior change will be identified from the perspective of the participant. While recognizing the organizing impact of ongoing involvement in medication for opioid use disorder (MOUD), peer navigators will have the ability to encourage entry to MOUD while also being able to wait for participants to generate this entry from their own motivations. A similar, respectful strategy will be used to demonstrate the ability for navigators to tolerate their own anxiety in letting participants engage behavior change in their own arc over the 6 months of navigation.

- **Empowerment Theory:** Empowerment theory is defined "…as a value orientation for working in the community and a theoretical model for understanding the process and consequences of efforts to exert control and influence over decisions that affect one's life, organizational functioning, and the quality of community life" (3). The value orientation aspect of this theory emphasizes the principles and framework for organizing knowledge and intervention both within the individual and in the environments in which the individual lives. The theory points to measuring the construct as it occurs in different contexts, to studying empowering processes of the individual and the environment, and to distinguishing this concept from related concepts of self-esteem, self-efficacy, or locus of control. As such, empowerment is an intentional, ongoing process centered in the local community, involving mutual respect, critical reflection, caring, and group participation, through which people lacking an equal share of valued resources gain greater access to and control over those resources. Systems, self-determination and empowerment theory all emphasize the importance of the individual in directing the decisions to be made. As such *motivational interviewing* is a technique that is consistent with these theories and will be used to engage participants in identifying and exploring their definitions and relative value of the positive and negative factors that support their behaviors – in using drugs, in engaging health behaviors, and in constructing all elements of their lives.

- **Shared Decision-Making Theory:** Shared decision-making theory is a behavioral approach in which clinicians and patients share the best available evidence when faced with the task of making decisions, and where patients are supported to consider options, to achieve informed preferences (4). The approach emphasizes use interventions that accomplish these goals: deliberation (i.e., understanding available options and having the time and support to consider what matters most to the individual), option talk (i.e., providing information of available options), choice talk (i.e., statements that evaluate pros and cons of options that are available), decision talk (i.e., exploration of what matters most), initial preferences (i.e., express an initial preference of available options and

what matters most). From this type of model, *cognitive behavior therapy and problem-solving* methods, both of which are interventions, not models or theories of behavior change, can be used to facilitate the "how to" when beginning to intervene on the set of goals that reflect changes that matter most to the participants.

- **Social Support Theory:** Social support theory is centered on the idea that instrumental, informational, and emotional supports improve health. Within the framework of this study, the theory incorporates macro- and micro-level effects, emphasizing how supportive societies and supportive relationships, respectively, can improve health, especially in management of chronic diseases like HIV and addiction (5). This theory will drive interventions that provide emotional support (e.g., provision of empathy and understanding); instrumental support (e.g., provision of resources to attend clinic visits); informational support (e.g., providing information about addiction, HIV care and prevention, and information about resources that enhance health, including housing, food, and transportation); appraisal support (e.g., understanding how systemic racism, stigma, discrimination and other biases interfere with survival goals).

1.3 Core elements of the HPTN 094 peer navigation intervention

In the U.S. there is a lack of access to integrated strategies for people living with HIV or at risk and who inject opioids that leads to HIV outbreaks. The simultaneous factors—lack of access to health care (including MOUD), poverty, prevalent poly-substance use, mental health disorders, racism, COVID-19 and others—combine to enhance risks for HIV transmission and acquisition. PWID living with or at risk of HIV who are not engaged in MOUD face the nearly impossible task of getting care from bricks and mortar clinics that provide separate, siloed care for opioid addiction (methadone, buprenorphine, injectable naltrexone), HIV (ART and PrEP) and primary care (STI testing and treatment, hepatitis testing and treatment, diagnosis and treatment for chronic and other conditions) with limited or no financial resources. Health services to address these diverse problems, when they exist, are often located far away from each other and from the PWID who need them, presenting serious distance/travel barriers to access. The navigation intervention components include theory-driven activities that guide participants to set goals, to ensure linkage to services, to sustain HIV care and prevention in the setting of untreated OUD – all in persons with multiple and overlapping health threats. These health threats and the barriers to access to care that they cause are important contributors to multiple HIV outbreaks in the U.S. The peer navigator will also work with interdisciplinary team in the mobile van and different services in the communities.

The peer navigation intervention requires understanding participants' need for simultaneous access to addiction treatment, HIV treatment, care and prevention, screening and treatment of hepatitis, testing and treatment for STIs, addressing primary care problems and harm reduction including provision of naloxone reversal kits and to clean injection supplies. It is based in the "whatever it takes" philosophy needed to arrange for this comprehensive set of services. Peer navigation interventions also require competencies in Motivation Interviewing engagement skills, and linkage to services. Navigators will be trained, certified by the study, and will demonstrate these competencies prior to being allowed to deliver navigation skills to HPTN 094 participants.

There is no manual that can provide specific interventions that will address the unique needs of each participant. Neither is it reasonable that if such a manual existed, all participants would benefit from moving through sessions in sequence and with all participants benefitting from the same level of engagement with the intervention. Thus, this peer navigation in 094 model understands that interventions are less about technique and more about using theory to guide interventions so that they meet the unique needs of participants who live with a history of opioid use disorder and who are living HIV (PLWH) or are at high-risk, who are not in MOUD. It understands that competent interventions will address the experiences of racism, sexism, homophobia and other factors common to people who face ongoing HIV transmission risks from sharing injection drug equipment and/or from unprotected sex with unknown or sero-discordant partners. This theory-driven approach, which is similar in its foundation to several other HPTN trials (e.g., HPTN 061, HPTN 071, HPTN 073, HPTN 074) guides peer navigators and supports their delivery of competent interventions that address the many elements of stigma, discrimination, micro-aggressions, and hatred that are experienced by people who inject opioids, who have any of a variety of chronic diseases and who are excluded from many of the social determinants of health.

A key component of this model is the provision of ongoing supervision and guidance to support all team members, but especially peer navigators in delivering supportive, sustaining, and respectful interventions independent of where

they are delivered – i.e., on the mobile unit, on text messaging platforms and on mobile telephones. The supervision will be provided by a team member at each research site who will meet weekly with their navigators. The purpose of this supervision will ensure high fidelity to the navigation intervention core components and model and will provide ongoing supervision, professional and social support to navigators to increase retention and to minimize risks for burnout and ensure high quality of adherence to the protocol and deliver of the intervention. The peer-navigation core components of the intervention and supervision will also be guided by additional skills-building treatment approaches that guide the components of the interventions that includes main components:

1. **Skills building conceptual driven interventions.** Extensive training in the five theories of behavior change will aid peer recovery navigators to become competent to meet participants "where they are at" and to help them begin to construct individual change plans for problems identified by participants that address opioid and other substance addiction, infectious diseases, primary care, and sexually transmitted infections. Peer navigators will interact with participants using empathy, unconditional positive regard, and acceptance to assist participants with their engagement in and persistence in MOUD and ART (for HIV care and prevention).

2. **Timing of interventions.** As noted, individuals differ in the types and amounts of interventions needed to reach their goals. Manual-driven interventions, by contrast, usually require navigators to move through intervention sessions sequentially and require fidelity to specific intervention materials. Constructing a manual that dictated this would be impossible as there is no theory to guide timing for addressing HIV care and prevention, hepatitis testing and treatment, STI treatment, primary care problems and need for harm reduction services, including provision of naloxone kits and sterile injection supplies as individuals seek MOUD. This means that efforts to change behaviors and to sustain behavior change will be driven by participants. Interventionists will respect this strategy and will require navigators to wait for participants and to respect decisions that are out of time with the expectations of navigators – and to always provide options for reducing harm and enhancing health when participants do not wish to engage behavior change.

3. **Interventions Used by Navigators.** Training to proficiency in interventions that are consistent with these multiple treatment skills and model will be provided and ongoing supervision. These interventions are integrally linked to the following intervention models and skills described above.

    a. **Motivational Interviewing skills** Particularly important is motivational interviewing. Peer navigators will be hired who can demonstrate capacity to engage motivational constructs such as having accurate empathy, staying client centered, avoiding advisements, and tolerating silence. Advanced training in motivational interviewing will build on existing skills.

    b. **Problem Solving Skills.** Problem solving skills is a formal approach to addressing problems that involves five specific steps: identifiy the problem, propose a set of solutions, implement a preferred solution, determine outcomes from the preferred solution and revise what to do next based on outcomes.Using shared decision making, participants are assisted in ensuring that the problems identified are those that are important to the individual. The process will ensure that participants find value in addressing problem behaviors. The process is in line with S-M-A-R-T goal setting – Specific, Measurable. Achievable. Realistic. Time-bound.

    c. **Cognitive Behavioral Skills.** Cognitive behavioral skills are essential for providing information and exercises that participants can engage to support efforts to reduce problem behaviors, like substance misuse and to improve depressed mood. The essence of cognitive behavioral skills is to emphasize structure as the basis for changing behavior and/or mood. For substance use topics, navigators will use cognitive behavioral concepts for instilling abstinence, preventing relapse, returning to abstinence in the setting of lapse or relapse, stopping cravings from becoming urges and use. Cognitive behavioral concepts for improving mood include identifying depressive biases in thinking, learning skills for challenging biases, monitoring mood levels, supporting sleep hygiene.

d. **Case Management skills** Case management interventions are essential parts of peer navigation and include linking participants to available resources in the community needed to address health problems. Navigators will meet with each participant to develop a care plan that lists the goals and the priorities of participants to address the goals. This begins with ensuring participants have some kind of health insurance that will support their treatments addressed in their plans. Following this foundation, navigators will work with participants to address the goals to be addressed by helping connect participants to available resources in the community. To build consistency in how case management skills are delivered, a navigation plan document is available. Progress notes will track progress toward these goals, and these will be reviewed in supervision on a regular basis.

e. **Social Support skills.** Social support interventions are key to aiding participants to identify the persons in their life who can assist them in being able to engage and persist in the complete range of integrated services offered in HPTN 094, specifically MOUD, HIV care and prevention, STI testing and treatment, care for hepatitis, primary care and harm reduction services. To the extent possible, instrumental support will be provided via vouchers and tokens for travel to and from health visits.

f. **Cultural Competency.** Cultural competency is essential for ensuring peer navigators can intervene with participants along any of the health problems addressed in the integrated strategies. To be culturally competent, peer navigators will receive ongoing training on identifying and responding to internal and systemic racism, homophobia, transphobia, addictophobia, sexism.

4. **Trauma-informed Interventions.** It is likely that this approach that focuses on client-centered, motivational interviewing will likely elicit negative or painful experiences from participants who have experiences with severe and extensive trauma (current and/or historical). In this navigation, peer navigators will not directly try to explore trauma. Instead, peer navigators will link to services by remaining respectful of the preferences of participants for any type of behavior change, no matter how slow. When participants raise issues of trauma during sessions, the mood and tenor of peer navigators will be to project calmness and willingness to accept the participant "where they are at." Peer navigators will point out that there is no rush to resolve trauma experiences. Participants will be advised that peer navigation is not the right place to work on trauma issues; navigators will provide referrals to counselors or therapists who are skilled in managing trauma. This "value-less" perspective reduces power dynamics inherent in the navigation framework. This is important as individuals who have experiences with trauma – from having to engage survival sex, from being homeless or transitionally housed, from violence related to ongoing drug use -- become hyper-vigilant, distrustful and easily feel threatened, when no threat is intended. Therefore, all interactions, both research and clinical, are based in predictability, transmitting calm and engaging participants in ways to reduce stress reactions and increase a sense of trust. As HIV and substance use is often stigmatized, sometimes health care providers treat substance users and those with HIV poorly. It can be difficult to monitor the staff members at agencies in the community that provide services needed by participants. Yet our staff members will monitor services provided by agencies to ensure that participants are treated professionally. Participants who require intensive intervention to address traumatic experiences will be referred to existing trauma-based interventions in the community by the navigator.

5. **Supervision.** Essential to the success of this program and to the health and well-being of peer navigators is the process of supervision. Ongoing supervision will be conducted with peer navigators at each site to ensure fidelity to the models and interventions described. One or more site team members will be identified to provide supervision to navigators. Supervisors will be experienced peer navigators with sufficient training in order to monitor participant safety and navigator adherence to the model and to support retention of navigators. As well, this supervision will be key to ensuring peer navigators maintain mental health and avoid burnout, as many of the participants navigators work with will meet have multiple and severe conditions.

Details of the conceptual model for the peer navigation and the specific counseling techniques that evolve from this are outlined in Chapter 2.

Site-specific Standard of Care Package During Enrollment Procedures. All of the participants interested in being a participant in the study will receive a site-specific standard of care on the medical unit while completing materials needed to determine appropriateness for study participation. This includes provision of comprehensive, integrated harm reduction services to prevent overdose while starting consent and completing measures needed to evaluate appropriateness for participation. In some settings, this will include access to syringe exchange, to condoms and lube, and referrals to MOUD. Next, potential participants will be provided linkage information to agencies for HIV care and prevention services. The potential participants will also receive system navigation to access health insurance (if they need it) and for housing/food. This Standard of Care will be developed in the pre-implementation period at each of the sites. Peer navigators will contribute to editing and tailoring type and quality of care delivered in the community in the Standard of Care Package for each site. The Standard of Care Package documents the list of referrals to the agencies for range of services available, with names of providers at the agencies who are known to be competent and welcoming with our participants. Ideally, the Standard of Care Package can be printed and provided to participants.

In sites that lack access to Medicaid, the Standard of Care package will provide step-by-step instructions how participants can access grants and programs for essential services in the community. The navigator will assist in constructing this Standard of Care package and use it with participants to ensure they have access to the full range of addiction, medical and social services needed, independent of Medicaid expansion status. As these resources change, updates to the package will be ongoing, or at least on a 6-month basis to ensure agencies, services, contact information are current.

Table 1 provides a summary of the conceptual model and the interventions derived from the model used in the peer navigation intervention and the location of these packages of services by each study arm for participants.

Table 1. Model-Derived Navigation Services by Intervention Arm

Navigation Services	Using model-derived interventions, peer navigation services will assist participants to access services for addiction, HIV care and prevention, hepatitis, STIs, primary care and harm reduction. In all settings where it takes place, navigation services are designed to help participants by: a. increasing motivation and social support, and b. learning to identify supportive formal and non-formal network members that can help in the process of linkage and retention in care for participants implementing all services with cultural competency			
	PLWH		HIV-negative	
	Active Control	Intervention	Active Control	Intervention
Navigation services in mobile unit		X		X
Phone/internet and Venue-based navigation services	X	X	X	X
Systems navigation	X	X	X	X
Navigate to health insurance	X	X	X	X
Navigate to Psychosocial Counseling and Social Network support	X	X	X	X*
Navigate to housing, transportation, legal aid resources	X	X	X	X*

Assist in acquiring an ID	X	X	X	X
MOUD				
Navigation to ensure buprenorphine or long-acting naltrexone (whichever available)	Referral	Mobile Unit	Referral	Mobile Unit
Navigation to ensure methadone (if adverse history to above, or patient preference)	Referral	Referral	Referral	Referral
ART				
Navigation to ensure ART for treatment	Referral	Mobile Unit*		
Navigation to ART for PrEP			Referral	Mobile Unit*
Integrated Medical Care				
Navigation to diagnosis and treatment of sexually transmitted infections (STIs)**	Referral	Mobile Unit	Referral	Mobile Unit
Navigation to diagnosis and treatment of hepatitis B and C virus (HBV, HCV)**	Referral	Referral	Referral	Referral
Navigation to basic primary care (site specific)	Referral	Mobile Unit or Referral	Referral	Mobile Unit or Referral
Navigation to mental health	Referral	Referral	Referral	Referral
Navigation to gynecology and obstetrics	Referral	Referral	Referral	Referral
Navigation to specialty care	Referral	Referral	Referral	Referral
Harm Reduction Services				
Navigation to addiction treatment services	Referral	Mobile Unit	Referral	Mobile Unit
Navigation to needle and syringe exchange programs, if legal and available	Referral	Mobile Unit	Referral	Mobile Unit
Injection risk reduction counseling	Mobile Unit	Mobile Unit	Mobile Unit	Mobile Unit
Sexual risk reduction counseling including access to condoms	Mobile Unit	Mobile Unit	Mobile Unit	Mobile Unit
HIV counseling and testing	Mobile Unit/ Referral	Mobile Unit	Mobile Unit/ Referral	Mobile Unit

* For participants who have existing relationships with providers of ART for care or for PrEP at enrollment, navigators will coordinate care with the provider before offering ART on the unit.

** Testing for STIs and HBV/HCV will take place at enrollment and other study visits, as per the protocol Schedule of Visits and Procedures, and so diagnosis of these diseases may occur on the mobile unit at those times in both arms. Treatment based upon these test results will be by referral or in the mobile unit as noted in the table.

*** Risk reduction counseling for the active control arm will be at the mobile unit at study visits, or wherever the navigator and participant meet for encounters. HIV testing will be at the mobile unit at study visits, otherwise by referral.

1.4 Definitions of the scope of services delivered in HPTN 094

It is substance use treatment

The integrated strategy for the range of services addressed in HPTN 094 using the peer recovery navigation intervention covers a lot of different options to increase entry and persistence in MOUD and thereby lower one's risk for acquiring and transmitting HIV. As noted above substance use treatment – and interventions that comprise the individual elements of the integrated strategy will be guided by the models that generate interventions themselves, i.e., motivational interviewing, social support, shared decision making, problem solving, cognitive behavioral skills, case management, systems navigation. Navigators will provide case management to substance use treatment services as needed. The over-arching goal of these interventions is to increase motivation and to identify people in participants' networks who are supportive and promote their engagement in treatment. The intervention is also designed to ensure retention in treatment.

It is basic primary care but NOT comprehensive medical care

Navigation services in HPTN 094 aim to support provision of MOUD, HIV (treatment and prevention), hepatitis testing and referral, STI testing and treatment, primary care and harm reduction services for participants in the study to the end of 26 weeks. For participants in the intervention arm, these services are provided initially in the mobile unit with navigation to the full range of community-based services. In the active control arm, navigators will engage their participants to engage, linked, and retain MOUD services, HIV care and prevention, STI treatment, services for hepatitis, primary care and harm reduction services at available community resources through the end of 26 weeks.

While the care is integrated, it is NOT comprehensive. Navigators and clinicians for 094 will emphasize that for complex medical care issues participants will be assisted to getting that care from local providers. Systems navigation services by navigators will facilitate this process. The navigation services will include providing information about side-effects to the medications for conditions addressed in the integrated strategies and how to deal with them. If side effects require medical attention participants will be encouraged to see their providers.

It is NOT support groups

Although participants are encouraged to share experiences and navigators will offer social support, we will not organize support groups as part of this study's intervention. The navigator will encourage participants to reengage people in their support network – and to build new support networks. Participants who are in need of support groups will be referred to services within their local area.

It is NOT job training or preparation

There is no job training or job preparation activities as part of this intervention.

It is NOT contingency management

Participants should be praised for their continued participation in intervention activities throughout the study and reaching set goals. However, we will not be providing monetary rewards or cash incentives for their behaviors in engaging or retaining in MOUD, ART or any of the range of health services addressed. Incentives may be used to assist with travel costs for participants to attend medical visits, navigation sessions as budgets allow. Participant reimbursements should receive all necessary ethical and regulatory approvals.

It is delivered differently in the two arms

Individual participants in this study will engage with their navigators in different ways and to different degrees, depending on the participants' goals, needs, and individual factors. The navigation intervention is not delivered in a "cookie cutter" fashion, exactly the same for each participant. Nonetheless, the study strives to provide the same "dose" of peer navigation to all participants, no matter the arm in which arm they are enrolled. Navigators will attempt to engage with every participant weekly, for example. Navigators are also required to cover the elements outlined in the first four "Topics" of Chapter 8 in this manual with every participant during the course of their work together, irrespective of arm.

One difference in navigation delivery between arms will be the mobile unit. Once enrollment activities have been completed, sites are expected to not engage with control arm participants at the mobile unit. If it is not possible for the site to avoid engaging with participants at the mobile unit entirely, the engagement should be kept as minimal as practicable. This expectation is rooted in the design of the study, which seeks to distinguish the effects of peer navigation alone, from peer navigation and medical care conducted in the context of a neighborhood-based mobile medical unit. Since it is the mobile unit that distinguishes the intervention arm from the active control arm, the engagement of active control participants in or at the mobile unit must be minimized. It is understood that some of the participants who will enroll in this study will not have a stable home where they can be reached or a cell phone at which they can be contacted. In these cases, it may be necessary for the participant to come to the mobile unit to contact or meet their navigator for an appointment. In this instance, a navigator might need to meet their participant at the unit but should then leave that area to have their discussion or session elsewhere.

KEY POINTS FOR CHAPTER 2

Chapter 2 defines the peer navigation approach, navigation session structure and the process of navigation for both Intervention and Active Control Arms for HPTN 094

- Importance of therapeutic alliance
- Essence of cultural competence
- Supervision
- Number and timing of sessions
- The Navigation Plan Document
- Documentation of goal setting

The integrated navigation skills-building, theory-driven intervention components and implementation strategies emphasize the belief that people are efficient in making decisions, even people who inject opioids. For the most part, when barriers are removed, all people make decisions that enhance their health. Opioid use disorder, however, creates chaotic influences on the decisions PWID make, particularly around drug use, but also regarding other behaviors linked to health status, for example, not taking daily medications for ART for HIV care or prevention, postponing health care appointments and increasing risk behaviors for infectious disease transmission, both sexual and drug-related.

Taking medication that reduces the chaos from opioid addiction is a cornerstone to building health. MOUD improves overall functioning and frees up psychological and cognitive resources that can then become available for engaging health. The navigation thus first points individuals to MOUD then using general case management and skills building, problem solving, and goal setting techniques, engages participants in maintaining MOUD, addresses HIV treatment and prevention and other specific health behaviors.

It is almost a certainty that participants will have ambivalence regarding entering MOUD, and once entered, remaining in MOUD. For most, this will involve induction and maintenance on oral buprenorphine-naloxone. In case participants do better or simply prefer full agonist, participants will be facilitated to enroll in treatment at a narcotic treatment program. Using the theory-based approach, motivational interviewing techniques will be used throughout the program of peer navigation to assist participants in exploring, in identifying, in prioritizing, in engaging and in remaining in MOUD and the full range of health behaviors.

Key factors to the peer navigation approach is motivational interviewing and a range of interventions that underscore listening to the participants and in every interaction treating each one with **empathy, dignity, and respect**. **Empathy** is the ability of navigators to "stay with" the participant and feel as if the participants' problems are their own – without rushing in to problem solve. **Dignity** is the ability to recognize the strength of decision-making participants bring to each meeting. This means that while navigators may believe they have a good sense of how to solve a problem, the solution makes no sense if it is not developed by the participants. **Respect** is the ability to let the final decision about health behavior be that of the participants.

To get to this place, the peer navigator must have the ability to establish good rapport and a therapeutic alliance with participants. **Therapeutic alliance** is that quality of the relationship between navigators and participants that reflects participants' confidence in their navigators' skills and abilities to facilitate unguarded, open, unguarded exploration

of barriers and limits to the factors needed to sustain involvement in MOUD and the integrated health services. One way the navigator does this is to use active listening skills, express empathy, and respect decisions made by the participant. Navigators always meet the participants "where they are at" and only then begin a conversation regarding behavior change. One way they sustain the relationship with participants is to provide social support, including identifying instrumental supports needed by participants (e.g., food, housing, other safety needs). Another aspect of social support is identifying those in their social networks who can aid them in engaging behavior change and sustaining that change over time.

One of the advantages of relying on motivational interviewing techniques and the concepts of engaging participants to drive their treatments is that this stance helps participants build confidence in the therapeutic approach and in the belief that the navigators have their best interests in mind. Staff members can demonstrate this by demonstrating care and respect to participants, no matter how they may appear during navigation sessions or what may have happened since their last navigation session. As well staff members who recognize impacts of systemic racism, discrimination, homophobia, and negative judgements toward participants, particularly on Black and Latino PWID, will build confidence in participants that this opportunity is different than the ones they may have experienced prior. It is not enough for the staff members who interact with participants to treat participants well – the model requires more. Staff members must be able to have empathy for the lives of their participants when navigation services. If done well, this will translate to an organic customer service-oriented approach.

All navigators will complete training on **cultural competencies** to ensure interventions are respectful to the participant (especially participants with health disparities) and to the elements of culture that are important to participants. This will include directed readings, brief assessments (e.g., implicit associations test – IAT), presentations by culture leaders and discussions with supervisors. Cultural competency begins in all interactions with the assumption of positive intention – no all parts. It continues by active support by supervisors and team members who value cultural competency sufficiently to avoid the "bystander effect" that happens when individuals remain silent following a questionable or offensive remark, assuming others will "go out in front" and address verbal behaviors that are not culturally competent.

Ongoing supervision will ensure high quality navigation that adheres to the theories that are the foundation of this navigation model. As well, providing navigation day in and day out to persons with multiple health threats and social and economic deprivation can cause burnout for the persons delivering that navigation. Supervision provided weekly will ensure that navigators feel part of a team and that someone "has their back" as they intervene with participants with serious and immediate needs. One goal of supervision is to keep the goal for this project to accelerate entry into and to persist in substance use treatment, in this case for medications for opioid use disorder (MOUD) as the foundation for improving outcomes for HIV, primary care, and sexual health. The essence of the navigation approach is to help participants to engage and to retain in MOUD and HIV care and prevention, with navigators not providing the drug treatment or HIV services themselves.

Number and Timing of Sessions. The conceptual approach of this navigation approach is intended to remain flexible enough to address the needs of participants with multiple comorbidities while emphasizing the primary goal of entering and retaining in MOUD. The number of sessions, the length of sessions, the topics of sessions are all intended to be flexible to tailor the navigation delivered to the unique needs and problems of the participants. For instance, study participants may have different barriers to obtaining HIV care and remaining adherent to ART. On an individual level these barriers can include depression and other forms of mental illness, stigma, alcohol use, polysubstance use, criminal justice involvement, lack of knowledge about HIV treatment, lack of resources. On a social level, barriers include lack of social support, fear and misunderstanding by family and friends, communication barriers with health care providers. On a structural level, barriers include wait times and availability of medical professionals at clinics, paper work and laboratory results necessary to obtain treatment, and time and resources to travel to HIV clinics. The intervention is designed to be **flexible and meet different needs of participants.** The number of navigation sessions is highly flexible and will depend on the issues encountered and the willingness of the participant to engage the issues. The minimum number of navigation sessions is one. There is no maximum. Ideally, the navigation sessions will provide the minimum number of sessions to effectively address the barriers in accessing MOUD, HIV care and prevention, hepatitis care, STI testing and treatment, primary care problems and harm reduction services.

The Navigation Plan Document. The role of the navigator initially is to meet with participants and develop a navigation plan document with them that outlines the range of services needed: MOUD, ART for care and prevention, hepatitis testing and treatment, STI testing and treatment, primary care and harm reduction. Using case management skills, the peer navigator is expected to engage with participants and discuss the range of action items needed to establish and maintain these integrated services while letting participants explore the value to themselves of each of the goals. The peer navigator will focus on ensuring participants are competent and successful in accessing healthcare and in creating a plan for reaching out to find services and to get to them and ensure they linked and stay in care. The initiation and ongoing changes to the Navigation Plan Document will be documented on the form (Appendix I).

As noted, self-determination theory holds that only problems that are important to the individual are the ones to focus upon. As well, empowerment theory and shared decision-making theory require that the participant be given the latitude to articulate the issues they would like to work on, to rank order their importance to them for addressing them and to determine the timeline for addressing these issues. This process will be supported using a Navigation Plan Document that will capture these elements and make the process transparent to participants, navigators and supervisors. Implementation of the case management plan will be conducted by the navigator, who will help facilitate participants in enrollment in MOUD and into insurance/payment plans for health care (e.g., Medicaid; state programs) and will help address barriers with participants to obtaining HIV medical care, medications, substance use treatment, and necessary laboratory assessments.

The Process of Navigation. The primary study goal is to enter and sustain in MOUD to reduce disruptive behaviors that would interfere with entering and sustaining ARV care or prevention and reduce HIV transmission. Factors that impede MOUD entry and retention in MOUD should be addressed together with participants. Participants may have a range of psychosocial issues, but the focus of the intervention is first to address those that are impeding entering and remaining in MOUD for reducing lapse/relapse to opioid use. The conception here is that the foundation of stable MOUD reduces chaos and facilitates the capacity for participants to then use ART for HIV care and prevention. Navigation sessions will be conducted in person (for those assigned to the intervention arm), and by phone calls and other mobile communication methods for conducting navigation sessions. It is very likely that all navigation sessions will need to be conducted using electronic methods given periodic needs for responding to COVID-19 management, including shelter-in-place orders.

Each session of navigation will allow participants to explore and to plan interventions along the range of integrated services that are intended to enhance health and wellbeing. The sessions will also include skills building, problem solving, goal setting, and social support. At each navigation session it is important to review the goals of the prior session and discuss the participant's efforts in reaching those goals and barriers and facilitators to the goal. **Participants should be encouraged for setting goals but it is not realistic to expect that the participants reach goals at every session. Participant should be praised or verbally rewarded for attempting to reach goals.** Navigators can help participants by suggesting problem solving methods to overcome barriers, if desired. This problem solving should occur when the goals are set and in reviewing them at the next session.

Navigation sessions will include goal setting. Many people have long-term goals such as stopping (or at least reducing) opioid use, improving ability to have stable housing, or better adhering to their HIV medications. With the goal setting exercise major goals such as getting into substance use treatment are broken down into much smaller goals. Then for each smaller goal problem solve with the participant on how they would reach the goal. For substance use treatment, smaller goals could be to first find out the requirements for entering the program. Problem solving would include how they would find out about the requirement. Once they found out the requirements then they would need to problem solve on factors such as how they would get to substance use treatment every day, how they would stay in substance use treatment, e.g., not use substances. This latter requirement would then require goal setting and problem solving regarding how they would avoid high risk situations for substance use.

Based on participants' goals, navigators may work with participants to provide skills building and accurate information about available resources needed to reach the goals. For example, for the goal of starting MOUD and reducing use of illicit substances, providing information regarding controlling substance use may be helpful.

When the goals are set the navigator will ask about potential barriers to the goals and how the participant could address them. Navigators may role play with the participant regarding barriers to the goals or role play skills taught in the session and conversations participants may want to have with supporters and health care

professionals. Navigators should also teach participants how to reframe any failure to achieve the goals, such as self-statements that encourage: “it is great that you set goals, even if you don’t achieve the goals you learn a lot about what things you can do, you can be proud of yourself for working toward the goals.” Navigators – and indeed all study staff members should provide encouragement and acknowledge the success of the participants.

KEY POINTS FOR CHAPTER 3

Chapter 3 provides information defining different interventions to be used with peer navigation. It also provides examples of the interventions that can be used in practice or in review.

- Reflective listening in rapport building
- Principles of motivational interviewing
    1. Express empathy through reflective listening
    2. Develop discrepancy
    3. Avoid argument
    4. Adjust to resistance – exaggerate ambivalence
    5. Support for change talk
- Instructions for role plays to try out intervention skills
- Cognitive behavioral skills
- Problem solving skills
    1. A-B-C
    2. S-M-A-R-T
- Skills building with participants

As previously mentioned, peer navigation using this theory-driven strategy relies heavily on motivational interviewing, case management, skills building and social support interventions to help participants to enter and remain in MOUD. As well, interventions to address other behaviors can include problem solving, cognitive behavioral skills, provision of social support and accurate information regarding identified problems and available resources to address these problems.

Peer navigators are required to be highly trained in the theory-driven navigation interventions and navigation implementation strategies. These tools will be used during encounters with participants. Each technique may or may not be useful for addressing barriers faced by participants, it is up to the navigator to determine which techniques work best in being able to meet participants' needs. It is important to remember that the primary goal for navigation is to assist participants to enter and remain in MOUD while also engaging ART for HIV care and prevention. Navigators should learn all the techniques and ensure that the sessions are interactive and not didactic. Motivational interviewing, role playing, and goal setting are all approaches that can make sessions more interactive.

3.1 Reflective listening

Reflective listening is a main component of building rapport with participants, in addition to building understanding and trust. Reflective listening helps participants feel that they are being heard, that their opinions are being seen, and that their feelings are being understood. This strategy allows for the navigator to establish acceptance and impartial reflection of the participant's experience. It is important that the navigator does not provide their own opinion but tries to understand the participant.

There are 4 main techniques of reflective listening.

1. **Paraphrase**: To restate the information provided by the participant using different words. This technique allows the participant to focus on the content of what they are saying. Paraphrasing must be done without making judgments about the participant's discussion.

Tips for using paraphrasing:

- Use phrases such as "I'm hearing you saying…" or "It sounds like you are saying…"
- Repeat key words but do not repeat the exact statement
- Avoid phrases like "I know what you mean."

Sample dialogue:

Participant: I have been on this buprenorphine, but I am feeling very tired these days. I feel that heroin at least lets me feel something good.

Navigator: It sounds like even though you're taking your medication for opioid use disorder, your drug use lets you feel something that is good.

2. **Summarize**: To concisely reiterate several of the major highlights from the participant's discussion. This technique allows the navigator to review overall progress and recognize any common themes or overtones that are occurring during discussions.

Tips for summarizing:

- Pull together major ideas, facts, or feelings
- Avoid phrases such as, "Do you have any questions?" or "Do you understand?"
- Do not add new ideas

3. **Clarify**: To ask the participant for clarification or to explain an element of the discussion that was vague. This technique provides the opportunity for the participant to expand on their thoughts or feelings and allows for the navigator to check the accuracy of the participant's statements.

Tips for clarifying:

- Do more than just asking "why" as this may sound threatening
- Use open, neutral questions that further draw out the participant's opinion
- Use phrases such as, "Can you tell me a little more about…?" or "Can you help me understand why you feel that way?"

4. **Reflect**: To rephrase the participant's affect or feelings. This technique is "a way of checking rather than assuming that you *know* what is meant".

See Principle 1 in section 3.2 Motivational interviewing

Site specific nonverbal communication can also an important component of active listening. Facial expressions, appropriate eye contact, posture, gestures, and movements are all examples of nonverbal communication. A navigator can keep eye contact, look attentive, lean forward, and nod their head as ways to nonverbally communicate to a participant that they are listening to what is being discussed.

Participants may also express themselves using nonverbal communication. These nonverbal communications can be important cues for a navigator to pay attention to. Below are examples of some nonverbal communications and their *possible* meanings:

Nonverbal cues	Possible meaning
Wavering eye contact	Boredom or fatigue
Intense eye contact	Fear, confrontation, or anger

Rocking	Fear or nervousness; withdrawal
Elevated voice	Discomfort or nervousness
Prolonged and frequent periods of silence	Disinterest, loss of train of thought, or fatigue
Fidgeting	Discomfort, disinterest, or nervousness

3.2 Motivational Interviewing

Motivation is one approach for addressing ambivalence about taking MOUD and ART and the whole range of health problems that require some attention from participants. Motivational interviewing is a therapeutic style intended to help navigators work with participants to highlight their ambivalence about getting into treatment for substance use disorder and once there, to remaining in MOUD. Ambivalence to addiction treatment is a given among PWID. PWID have strong "pros" (ideas, beliefs and experiences that support drug use) and differing levels of "cons" (ideas, beliefs and experiences that are the negative side of continued drug use). PWID may want to stop injecting but do not because of addiction and fear of withdrawal. They may have avoided coming into MOUD in the past as treatment agencies and the personnel in them may have said hurtful or insensitive to them. The one thing that is certain is that few participants will have all "pros" or all "cons" regarding their understanding of their drug use and whether or not to address this issue. Moreover, the level of "pros" and "cons" likely changes day to day – sometimes hour to hour. This ambivalence about treatment is shared not only by PWID who consider either giving up drug use and/or entering in MOUD – but by all persons living with addiction.

As part of the HPTN 094 intervention, we will use **motivational interviewing** tools as a way to highlight PWID's ambivalence regarding the issue of drug use and its treatment. This highlighting of ambivalence is a non-directive method for helping individuals think about and prioritize the importance of addressing the problem at hand (in this case entering MOUD) and the confidence they have in being able to enter and stay in MOUD. Navigators will need to understand and accept PWID's ambivalence because the ambivalence can often remain well into months of treatment using MOUD. Lack of motivation for getting well regarding opioid use, ART medications and the range of other health problems is often due directly to the ambivalence over health behaviors. Remember that ambivalence to starting MOUD and HIV medication may not be stated verbally by participants, but instead be apparent in their actions. If they continuously agree to a plan of action but do not act on it, motivational interviewing may also be useful to identify and highlight the underlying ambivalence to making changes to one's life or behaviors. **Even if participants are not ready to address their substance use, they can still benefit from getting on MOUD.**

Motivational interviewing is practiced with 5 main principles: (1) Express empathy through reflective listening; (2) Develop discrepancy between participants' goals or values and their current behavior; (3) Avoid argument and direct confrontation; (4) Adjust to participant resistance rather than opposing it directly, also known as "rolling with resistance"; and (5) Support "change talk."

Principle 1: Express empathy through reflective listening.

Expressing empathy towards a participant shows acceptance and increases the chance of the navigator and participant developing a rapport.

- Acceptance enhances self-esteem and facilitates change.
- Skillful reflective listening is fundamental.
- Participant ambivalence is normal.

What is reflective listening?

Reflective listening is the foundation of expressing empathy. This approach establishes a safe and open space that is beneficial for exploring issues and stimulating personal reasons and methods for change. Navigators must understand each PWID's unique perspectives, feelings, and values. The success of motivational interviewing relies on the development of a trusting relationship between a navigator and PWID participant.

Reflective listening is <u>NOT:</u>

- *Ordering or directing.* Direction is given with a voice of authority. The speaker may be in a position of power (e.g., parent, employer) or the words may simply be phrased and spoken in an authoritarian manner.
- *Warning or threatening.* These messages are similar to ordering, but they carry an overt or covert threat of impending negative consequences if the advice or direction is not followed. The threat may be one the clinician will carry out or simply a prediction of a negative outcome if the participant doesn't comply—for example, "If you don't stop using drugs, you'll be kicked out of treatment."
- *Giving advice, making suggestion, or providing solutions prematurely or unsolicited.* The message recommends a course of action based on the clinician's knowledge and personal experience. These recommendations often begin with phrases such as, "What I would do is…."
- *Persuading with arguing, logic, or lecturing.* The underlying assumption of these messages is that the participant has not reasoned through the problem adequately and needs help to do so.
- *Moralizing, preaching, or telling PWID their duty.* These statements contain such words as "should" or "ought" to convey moral instructions.
- *Judging, criticizing, disagreeing, or blaming.* These messages imply that something is wrong with the participant or with what the participant has said. Even simple disagreement may be interpreted as critical.
- *Agreeing, approving, or praising.* Surprisingly, praise or approval also can be an obstacle if the message sanctions or implies agreement with whatever the participant has said. Unsolicited approval can interrupt the communication process and can imply an uneven relationship between the speaker and the listener. Reflective listening does not require agreement.
- *Shaming, ridiculing, labeling, or name calling.* These messages express overt disapproval and intent to correct a specific behavior or attitude.
- *Interpreting or analyzing.* Navigators are frequently and easily tempted to impose their own interpretations on a participant's statement and to find some hidden, analytical meaning. Interpretive statements might imply that the clinician knows what the participant's problem is.
- *Reassuring, sympathizing, or consoling.* Peer navigators often want to make the participant feel better by offering consolation. Such reassurance can interrupt the flow of communication and interfere with careful listening.
- *Questioning or probing.* Navigators often mistake questioning for good listening. Although the clinician may ask questions to learn more about the participant, the underlying message is that the clinician might find the right answer to all the participant's problems if enough questions are asked. In fact, intensive questioning can interfere with the spontaneous flow of communication and divert it in directions of interest to the clinician rather than the participant.
- *Withdrawing, distracting, humoring, or changing the subject.* Although humor may represent an attempt to take the participant's mind off emotional subjects or threatening problems, it also can be a distraction that diverts communication and implies that the participant's statements are unimportant.

What does reflective listening look like?

In this strategy, the navigator listens carefully to what the participant is saying, then reflects it back to the participant in an often slightly modified or reframed form. The navigator also acknowledges the participant's expressed or implicit feeling state. This strategy offers a number of advantages:

1. It is unlikely to prompt participant resistance
2. It encourages the participant to keep talking and exploring the topic
3. It communicates respect and caring, while building a working therapeutic alliance
4. It clarifies for the navigator exactly what the participant means
5. It can be used to reinforce ideas expressed by the participant.

Below is a sample dialogue of a navigator and participant, where the navigator uses the reflective listening strategy.

Navigator: What else concerns you about your injecting?

Participant: Well, I'm not sure I'm concerned about it, but I do wonder sometimes if I'm injecting too much.

N: Too much for . . .

P: For my own good, I guess. I mean it's not like it's really serious, but sometimes when I wake up in the morning I feel really awful, and I can't think straight most of the morning.

N: It messes up your thinking, your concentration.

P: Yes, and sometimes I have trouble remembering things.

N: And you wonder if that might be because you're injecting too much.

P: Well, I know it is sometimes.

N: I can see why that would worry you. What else worries you?

Principle 2: Develop discrepancy between participants' goals or values and their current behavior

Developing discrepancy enables the participant to see that her present situation does not necessarily fit into her values and what she would like in the future.

- A participant rather than the navigator should present the arguments for and against change. Navigators can document both the arguments for and against change but should not identify or develop them. That is the job for the participant.
- Change is motivated when participants understand the discrepancy between the advantages of their present behavior and the impact of this behavior on reaching important personal goals and values.

Examples of developing discrepancy
[As a team, brainstorm site specific examples of developing discrepancy.]Note: be careful not to increase feelings of stigma and discrimination. The point is not to shame or humiliate but to get the participants to start thinking about how some behaviors may be preventing them from reaching their goals, and therefore motivate positive change. If people already know why entering MOUD is a problem this will not be needed.
Example 1: "Hmm. Help me figure this out. You've told me that keeping your daughter at your house and being a good parent are the most important things to you now. You've also told me that the pressure of being a good parent makes you want to use heroin. How does starting MOUD fit in with these thoughts?"
Example 2: "You mention that you have a partner, and you don't want your partner or your family members to be disappointed in you or worry about you. How does your MOUD fit in with that?"
Example 3: "You mentioned that you have children, and you want them to be part of your life and to be part of a good future. Yet the stress of your life makes you want some ways to "get away from it all." Tell me your thoughts about where MOUD and/or using injection drugs fits with this.
Example 4: "You mentioned that you would like to live a healthy life and to get your life back. How do you think MOUD will affect this? What are the limits of MOUD in reaching these goals?

Principle 3: Avoid argument and direct confrontation

Arguments with PWID can quickly develop into a power struggle and do not enhance motivation for beneficial change. The goal is to "walk" with PWID participants, like accompanying them through sessions, not "drag" them along or direct their sessions.

- Arguments are counterproductive.
- Defending breeds defensiveness.
- Resistance is a signal to change strategies.
- Labeling or diagnosis is unnecessary. Avoid telling a participant they are an "addict/useless/a criminal". Then avoid diagnoses such as "you suffer from depression".

Principle 4: Adjust to participant resistance rather than opposing it directly, also known as "rolling with resistance"

Rolling with resistance prevents a breakdown in communication between participant and navigator and allows the participant to explore her views.

- Avoid arguing for change. Instead back up and ask for clarification.
- Do not directly oppose resistance. Find out where you are "missing" the participant as when participants respond with "…yes, but…"
- New perspectives are offered but not imposed.
- The participant is a primary resource in finding answers and solutions.
- Resistance is a signal for the navigator to respond differently.

Rolling with resistance strategies	
Strategy	Example
Simple reflection: repeating PWID's statement in a neutral form	***Participant:*** I don't plan to begin MOUD anytime soon. ***Navigator:*** You don't think that MOUD will work for you right now.
Amplified reflection: reflect the participant's statement in a more extreme form	***P:*** I don't know why my partner is worried about me. I only use now every once in a while. I'm much better than I was ***N:*** So you believe that your partner is worrying unnecessarily.
Double-sided reflection: recognizing what the participant has said but then also stating contrary things she has said in the past	***P:*** In spite of my problems, I want you to know I know you want me to go on MOUD, but I'm not going to do that! ***N:*** You can see that your drug use causes you real problems, but you're not willing to start MOUD right now.
Shifting focus: defuse resistance by helping the participant shift focus away from obstacles and barriers	***P:*** I can't take start MOUD because I don't want to lose my friends who use – they're the only people I've got. ***N:*** You're way ahead of me. We're still exploring your concerns about how to MOUD. We're not ready yet to decide how MOUD fits into your and your friends' lives.
Agreement with a twist: agree with the participant, but with a slight twist or change of direction that propels the discussion forward	***P:*** Why are you and my partner so stuck on my injecting? What about all the other problems I have besides drug use? You'd use, too, if all you heard from your partner was nagging about how you're just a screw-up. ***N:*** You've got a good point. There is a bigger picture here, and maybe I haven't understood enough about it. It's not as simple as one person's injecting that has got you to this place. Tell me more about what I'm not understanding from your perspective.
Reframing: offering a new and positive interpretation of negative information provided by the participant	***P:*** My partner is always nagging me about my drug use. She quit awhile back and no longer injects. So she really annoys me with her holier than thou attitude. ***N:*** It sounds like she really cares about you and is concerned, although she expresses it in a way that makes you angry. Maybe we can help her learn how to tell you she loves you and is worried about you in a more positive and accepting way.

Siding with the negative: to take up the negative voice in the discussion	***P:*** Well, I know some people think I need to adhere to my MOUD and HIV medication to have more energy and feel healthier, but I still don't believe it will help. ***N:*** We've spent considerable time now going over your positive feelings and concerns about your MOUD and HIV medications, but you still don't think you are ready or want to change your adherence. Maybe changing would be too difficult for you, especially if you really want to stay the same. Anyway, I'm not sure you believe you could change even if you wanted to.

Principle 5: Support for change talk

The skill in motivational interviewing that is significantly linked with behavior change is "change talk." Change talk is that type of statement individuals make when acknowledging their thinking about, considering, mulling over, or recognizing ways in which their lives would be better with change addressing the problem behavior. Change talk is powerful in predicting change, but also in building self-efficacy in the individual that s/he can be effective in addressing the problem behavior. When a participant believes that she has the ability to change, the likelihood of change occurring is greatly increased. This is known as "self-motivation".

- A person's belief in the possibility of change is an important motivator.
- Verbal statements about the idea and the possibility of change set the stage for change behavior.
- Change talk reflects the perspective of the participant, not the navigator, for choosing when and how to carrying out change – now or in the future.
- Recognizing and reinforcing "change talk" helps participants to know their navigator listens actively to them. It can even help set the stage that the navigator's recognition of change talk becomes a self-fulfilling prophecy.

Sample questions to elicit change talk
Problem recognition • Tell me about what is different now when you consider entering MOUD and/or taking your HIV medications? • Help me understand how you understand your drug use? How will you know when it's too much? • What is different now from what you've done in the past to address your use of heroin or other opiates? • What is your thinking about when is the time to do something about your drug use? • What do you think about other issues, like housing, being depressed or past warrants that might interfere with starting MOUD and taking HIV meds?
Concern • How important is it to you that you do something now about your drug use and your HIV medications? • How confident are you that should you want to do something about your drug use and your HIV medications that you'd be able to be meet your goals? • What would be the "pros" and "cons" of continuing to do what you're doing now about your drug use and your HIV medications?
Intention to change • Good on you that you're thinking that it's time for you to do something about your drug use or HIV medications. • I heard you say that you're not ready now, but you know it's time for change. Good for you. Talking about change is the first step to making change. • It sounds like you're thinking it's time to "get your life back." Do I have this right?

• I don't want you to tell me things to make me happy. So you're truthfulness about not being able to start treatment right now is better than if you lie. Talking about where you are in making change – or not – is a key step.
Optimism • What things come to mind when you reflect on the fact that you've stayed in MOUD for two months now? • You've struggled to not use this month, but you're taking your MOUD and HIV meds. How do you put this together?

3.3 Role-playing

In order to help the participant, become aware of their automatic thoughts about drug, about treatment, about HIV and other illnesses and the resulting emotions that follow from these, the navigator may role play different situations with the participant, pausing at points to identify what automatic thoughts are occurring. This exercise can also be useful to allow participants to practice particular skills they have been building to address identified problems.

For example, role-playing can be a helpful exercise when teaching about refusal skills for substance use. Here are a few tips to help with introducing role playing with a participant:

- Pick a concrete situation that occurred recently for the participant.
- Ask participant to provide some background on the target person.
- Have participants play the target individual, so they can convey a clear picture of the style of the person who offers heroin and the navigator can model effective refusal skills. Then reverse the roles for subsequent role-plays.
- Role-plays can be brief scenarios, such as asking participants if the navigator were the health care provider how would they ask about side-effects. The navigator could play the role of a drug network member who wanted to share injection equipment, a supporter who doesn't understand the important of HIV medication adherence, a drug treatment staff member who is rude to the participant, a family member who nags the participants to take their medication or to stop drug use.
- Role-plays should be thoroughly discussed afterward. Navigators should praise any effective behaviors shown by participants and also offer clear, constructive criticism:
    - "That was good; how did it feel to you? I noticed that you looked me right in the eye and spoke right up; that was great. I also noticed that you left the door open to future offers by saying you had stopped injecting 'for a while.' Let's try it again, but this time, try to do it in a way that makes it clear you don't want your friend to ever offer you drugs again."
- Role playing is also critical for training of navigators for practicing how they would respond to a wide range of situations.

3.4 Cognitive Behavioral Skills

Cognitive behavioral therapy (CBT) is a focused approach to help substance users reach their treatment goals and to help those living with depression to manage their moods by changing depressed thoughts. Cognitive behavioral skills are based on the theory that in the development of maladaptive behaviors patterns like substance misuse, learning processes play a critical role. Using cognitive behavioral skills, individuals learn to identify and correct problematic behaviors by applying a range of different skills that can be used to stop or reduce substance misuse, to reduce depressive moods and to address a range of other problems that often co-occur with these.

A central component of cognitive behavioral skills is anticipating likely problems and enhancing individual's experience of self-control by helping them to develop and to use effective coping strategies. Specific techniques include learning skills for instilling abstinence (or reducing drug use), for preventing lapse/relapse to substance use, for returning to abstinence following lapse/relapse, for self-monitoring to recognize cravings early and to "thought-

stop" these, for identifying and avoiding situations that might put one at risk for use, and for developing strategies for coping with cravings and avoiding those high-risk situations.

3.4.1 Problem solving

Problem-solving involves recognizing and defining a problem that interferes with an individual's means of coping with problems of everyday living. This essentially defines the difference between problem-solving and fantasizing – the problem identified is something that with some commitment and energy allotted – can be changed. An example of a problem that can be changed is to eliminate the need to score heroin to prevent withdrawal symptoms. There are a range of ways to solve this problem and when an individual is able to define the problem and a range of solutions and a commitment to put energy toward the issue, the problem is solved. When problems are too large to solve, for example, the only options are wishing and fantasizing. It's fun to fantasize about what life would be like if it were only the case that you had your wish, but unfortunately change happens only when problems can be identified, a solution proposed and a course of action set about doing.

When meeting with participants, it's helpful to identify problems that have solutions. One of the best ways to help participants define a problem they want to solve that is something that is achievable, believable and that is something to which they are committed.

A. Is the problem **Achievable?** Achievable problems are those that have identifiable solutions. Examples could be engaging MOUD to avoid withdrawal, finding housing for the night, getting current on HIV medications.
B. Is the solution to the identified problem **Believable?** Believable solutions for identifiable problems are those that are reasonable. Examples could be making an appointment and a plan to start MOUD, getting a week of vouchers for a room at a local housing facility, meeting with a clinician to restart HIV medications for care or to begin PrEP.
C. Is the participant **Committed?** Navigation meets participants "where they are at." So problems the participant is not committed to solve are not useful to consider. Navigation is not about magical transformations. Instead, navigation accepts and encourages participants to commit to even short-term change. Building commitment to change over a short arc helps participants (and navigators) to feel accomplished with the process and willing to take increasingly complex steps toward sustained good health.

Problem-solving strategies can be used with a wide range of problems, including addiction and its treatment. But addiction, treatment, HIV-care and prevention are all large goals that don't have single solutions. So participants learn problem-solving skills by repeating the process to identify problems that are **achievable,** solutions that are **believable and** concerns that participants are **committed** to. In this way, navigation respects participants' values and priorities even before engaging the process of solving problems. Navigators can learn what may have worked for participants in the past, what strengths the participant brings to help solve the problem and what problems have meaning enough to deserve attention. Done correctly, this process in problem solving teaches skills that aid participants in feeling increased control over life and the issues that previously felt overwhelming or unmanageable. The process can be extended from practical problem resolution to emotion-focused problems in coping (e.g., increasing control, decreasing stress, and increasing hopefulness).

Strategies for Effective Problem Solving

Once navigators have a sense of the ABCs for participants, some finer grained skills can be useful to building problem-solving skills. In this program, we teach the **S-M-A-R-T** approach to problem-solving.

S: **Specific** goals are those that are concrete, that target a particular area of functioning and focus on it for resolution. When participants start with problems that are "too big" for specific goals/solutions, work with participants to break the problems into parts. An example would be the goal of "getting my life back" in seeking addiction treatment. This is too big for a simple solution. Working with participants to build efforts to address biological/medical, family/social, employment and spiritual problems, progress can be made in each of these domains that contribute toward "getting ones' life back."

M: **Measurable** goals are those that can be measured so that one knows when they area attained (e.g., signing up for MOUD, starting HIV medications for care or prevention, getting housing). Navigators may need to teach participants how to make goals measurable instead of charting goals that are broad, like being happy, living a contented life, finding work/life balance. Instead, participants can learn how to identify the elements of their life that would make them happy, that would define a contented life, that would define the work/life balance. These measurable elements can then be useful to define where participants can work more/SMARTer to reach their goals.

A: **Attainable/Achievable** goals can be reached. They are desired by participants and can be met by participants. Examples of attainable/achievable goals are being able to find MOUD and engage it. Being able to get a drivers license, though it may be a complex goal, is achievable and attainable. Attainable goals are flexible and reinforce the notion that there can be many paths to achieve success in reaching the goal.

R: **Realistic** goals are those whose solutions are reasonable to both navigator and participant. They are practical. They can be implemented and sustained with reason. Examples of realistic goals are to find a way to have safe and affordable housing. Realistic goals can also be complex – like finding safe and affordable housing when one is living close to the streets with no income. But there are programs that can be used to secure housing even for people with little or no income.

T: **Time-bound** goals are those whose solutions are bounded in the now or near future. Finding treatment for now, housing for the week, and medication for the month are time-bound goals.

These **S-M-A-R-T** strategies for problem solving are the essence of this navigation intervention. They respect the participants' values and priorities. They remain focused on the here and now rather than what might be in the future.

3.4.2 Skills building with participant

One of the main components of the Cognitive Behavioral skills taught in this intervention is to help participants engage an individualized set of skills to go about engaging and maintaining MOUD for opioid use disorder and HIV medications for care or prevention. Most of the time, the skills will be new for participants. The common scaffolding of these skills is *structure.* They require a bit of work today, a bit of work over the week and a bit of work for the future. Some of the skills can help participants unlearn old habits associated with ongoing opioid use disorder and replace these with healthier skills and habits. In this example, it is for the most part about *adding* skills – not *stopping* skills.

Participants in this study will present with a wide range of problems – some of them severe. It is impossible to dictate the specific skills that will be needed to address the many and unique sets of problems navigators will discover when talking with participants. Thus, building proficiency in a set of cognitive behavioral skills is the approach taken. In initial sessions, a lot of time and effort will be devoted to complete problem identification using the ABCs and define a small set of SMART goals that can be accomplished.

In initial sessions, there will be time to discuss what is *not* working for participants. Much of the time will be spent building skills needed for participants to address ambivalence regarding their opioid use disorder and treatment for this condition. As well, problem solving regarding engaging HIV care or prevention, committing to daily medication adherence, and identifying barriers to past attempts to sustain HIV medication adherence will be a key part of first discussions.

As these goals are identified, it is possible – though it will depend on the individual participant – to broaden the approach to include evaluation of a range of other problems in which the participant may have a difficult time coping, such as social isolation and unemployment. In this way, learning skills broadly can help participants to improve ability to engage MOUD and HIV medication adherence and generalize those skills to other problems that interfere with meeting personal life and health goals.

3.5 Case management

Case management is a collaborative process that together with a participant assesses, plans, implements, coordinates, monitors, and evaluates the options and services required to meet the participant's health and human service needs. This active process requires navigators to be advocates for their participants, to communicate with gatekeepers of needed services, to know and to use resources in the environment efficiently and to promote high quality and cost-effective services.

When navigators provide case management services, they facilitate participant wellness and autonomy through advocacy, assessment, planning, communication, education, resource management, and service facilitation. Based on the needs and values of the participant, case management is the process of linking participants with appropriate providers and resources throughout the continuum of health and human services and care settings. It ensures that the care provided is safe, effective, client-centered, timely, efficient, and equitable. This approach achieves optimum value and desirable outcomes for all stakeholders.

Case management services are optimized best if offered in a climate that allows direct communication among the case manager, the participant, the insurer, and other service delivery professionals. The case manager is able to enhance these services by maintaining the participant's privacy, confidentiality, health, and safety through advocacy and adherence to ethical, legal, accreditation, certification, and regulatory standards or guidelines.

3.6 Social Support

Peers are encouraged to use interventions that arise from Social Support theory. Interventions based on social support can be categorized into four separate "bins" that include emotional support, instrumental support, informational support and appraisal support.

- Emotional support interventions are those that express empathy, love, trust and caring for the participant. It often comes from significant others within the participant's life. But among PWID, the participant may have burned through their network of people who can provide social support. It's important that navigators provide social support – within boundaries – to participants. This can include statements like: "Good for you. I think you did a great job at that." It can also involve revealing something you like about the participant like: "It means a lot to me that you keep coming back to see me to talk about this journey you're on." It can also be helpful to find others in the participant's social environment to encourage them to provide social support.
- Instrumental Support involves providing real, tangible aid and service. This can be simple things like someone watching over a participant's belongings while s/he attends to a chore. Instrumental support is expressed when people in the participant's lives pay for a meal, pay for a cup of coffee, or offer to provide transportation to work. Navigators provide instrumental social support when they provide transportation vouchers to a doctor's visit or provide snacks when participants visit the mobile unit.
- Informational Support involves providing facts about different aspects of living with opioid use disorder and HIV (or living at risk). While it's not helpful to go on a "search for truth" when participants hold beliefs that are not fact-based, it can be helpful simply to provide facts about addiction and HIV/HIV risks. Sometimes participants can be upset when learning about different aspects of addiction and HIV, so remaining calm and remaining focused only on delivering the facts, not interpreting the meaning of the facts, can provide support.
- Appraisal Support involves providing an outside perspective to participants about how well you think they are doing. It's important when offering appraisal support that the navigator does not positively exaggerate the facts of how the participant is doing. (Think of when you've told someone they look terrible, when they in fact look terrible.) When participants are doing poorly in their addiction or HIV care or prevention, it can be hard to avoid trying to minimize the negative part of what you see and/or to exaggerate the positive of some part of the participant's presentation or life. That is a human reaction. We don't want people to feel bad or even feel worse, due to something we say. So there is a pull to minimize the negatives or to give a "sunny" evaluation of how well a person is really doing in real time – especially when the participant is

struggling. On type of comment that gives appraisal support would be to point out that the participant continues to stay on a recovery journey – even if right now things are not so good.

3.6 Cultural Competence

Cultural competence is a way of being when doing the work of a navigator – not so much about a set of skills to learn. Addiction and HIV (or being at risk) means that participants will have already two conditions that cause others to be afraid of them or to express stigma toward them when seeking services. "Addictophobia" is a real condition that happens when people who are not addicted overlook, minimize and sometimes blatantly discriminate against participants with OUD when they seek medical services or seek treatment services – it even happens when participants go to grocery stores. This gets internalized quickly and participants become expert at scanning the environment for people who are likely to discriminate against them and get out before something happens that results in shaming or discrimination. In most cases, life teaches participants that their wariness in expecting addictophobia is often justified. When participants have other conditions that carry stigma, like living with HIV, like being a man who has sex with men (MSM), like being from minority race/ethnicities, like having mental health disorders or stimulant use disorder, participants may be unable to even dream of a life that involves recovery – the distance between that and where they live is just too far. When a navigator interacts with participants, including when providing social support and referrals during navigation, it is key to remember that the participant is sensitive to being told what to do. That's part of what happens when living with being discriminated often. Here are some skills that can help you provide cultural competence.

- Acknowledge differences between you and your participant. In this case, talk with participants openly about their addiction, their condition with HIV (or being at risk for HIV). Just not being afraid to talk about these issues directly helps keep the conversations direct and clear.
- Learn about different cultures and different genders – but don't do this by interviewing your participant. If there are questions about your participant's experiences with some kind of difference, do your homework: read a book, see a movie, talk with your supervisor or a peer navigator.
- Assume positive intention. Even when people are saying something uninformed or something that can be hurtful to others, assume positive intention (as opposed to: "Can you believe that s/he said that?).
- Provide opportunities for people to correct themselves. By assuming positive intention, you can help point out that the particular remark might have been understood differently than the speaker intended. You can do that by saying to someone, "I know you don't mean to hurt her, but what you said didn't sound like how you intended it. Can you try to restate your point?"
- Don't be a bystander. When someone makes a statement that hurts someone's feelings by being insensitive or discriminative, people feel uncomfortable and generally what follows next is big silence. Counter that by stepping in. Talk directly to the person and state that you assume positive intention, but what you said was hurtful. What was the point you were trying to make? This lets the person have an opportunity to retract hurtful comments and helps keep the space safe that is around you.

KEY POINTS FOR CHAPTER 4

Chapter 4 provides information, scenarios and examples that can be useful for role-plays. This is helpful for training and for refreshing communication skills for peer navigators in HPTN 094.

- Suggested role play scenarios
- Supervision and navigation forms
- Conflict resolution skills materials

All navigators are expected to receive training in motivational interviewing, problem solving, cognitive behavioral, case management, social support and cultural competency skills (see chapter 3) prior to implementing the intervention. As well, navigators will be experienced in being able to respond to participants' experiences of trauma – especially skills and strategies that avoid causing additional pain to participants or causing participants to re-experience trauma in session. All members of the staff will be continuously reminded of the aspects of stigma, discrimination, homophobia, racism, trauma and sexism that PWID often face, *especially* when they seek care for addiction, HIV or other health threats and barriers to social determinants of health. All navigators should thoroughly read the manual and practice a wide range of role plays based on different scenarios. This will be managed by the main study training and by the navigator supervisors at each site.

Suggested role play scenarios:

- Participant is on MOUD and ART and hasn't used injection equipment for years (s/he succeeded in getting around inclusion criteria)
- Participant is not on MOUD, ART or PrEP, and does not want any of these interventions – except there is the desire for research compensation
- Participant is willing to start MOUD but has no money and no busses run to where MOUD or HIV care/prevention is; uses opioids and stimulants to pass the time
- Participant was on MOUD and ART last month, but was "rolled" on the street and the medications stolen
- Participant is "yessing" or telling navigator what they think the navigator wants to hear
- Participant was hospitalized for HIV disease last week, has never been on MOUD, does day labor (male)/sex work (female) when not sick and while living with HIV, frequent use of methamphetamine
- Participant is not from U.S., is not housed and is doing well on both MOUD and ART
- Participant is not doing well on MOUD due to problems with mental health (severe depression) and housing issues
- Participant overdoses and doesn't want MOUD as s/he wants to be "drug-free."
- Participant wants you to connect him/her to detox to be done with this once and for all.
- Participant wants MOUD, but the partner wants to continue using and will leave if participant engages MOUD.

During role playing activities, navigators should practice documenting the session using appropriate forms and progress notes. In addition to role playing, mock participant folders can be developed to have navigators discuss recommended next sessions for the participant.

With role playing, supervisors should role play delivery of sessions, strengths and weaknesses in making contact, in engaging motivational interviewing and in working to increase fidelity in using the communication skills in the manual – i.e., not doing "what comes naturally."

Once navigators have an excellent grasp of the skills and are able to conduct sessions without looking at the manual, they may start to develop additional site-specific materials based on unique site-specific barriers and facilitators as well as different patterns of substance misuse and social behaviors. During this process, site-specific issues that affect cultural competency (e.g., navigators who can conduct sessions in Spanish, navigators knowledgeable of available resources, competent in understanding race/ethnic differences in navigation and in the culture). It is likely that some of the navigators have had prior experience in advising others for ART and for substance use treatment. Navigators may bring approaches they've honed that reflect their style to the intervention, including personal experience. It is vital, though, to learn new techniques and approaches as presented in the manual to implement this theory-driven approach to interventions that address barriers on individual, social, and structural level. Twelve-step approaches to recovery are offered as an option but are not a requirement and are not part of the navigation process. These approaches may be vital to continued health of navigators themselves and that experience can be shared with participants. But the focus of the intervention is toward MOUD and HIV care/prevention – not to pointing participants to 12-step groups. Navigators cannot be sponsors of participants in the study.

The number of sessions and contents of the sessions engaged will be decided by the navigators and the participants. It may be helpful to have sessions more often in the initial phases of the 6 months for participants. It is expected that navigators will meet with participants at least once to complete the initial evaluation using the ABCs and start setting SMART goals.

It's also important to remember: Everybody gets to be somebody's favorite! Participants who have negative reactions to their navigator can request to be reassigned to a different navigator once with no problem at the beginning of navigation. But once a relationship starts between a participant and navigator, it's important to work through problems that often develop over time. This natural process is "grist" for the navigation mill. Participants are encouraged to discuss reactions with their navigators to arrive at a solution to resolve negative experiences, well before they might grow into problems that would interfere with participants retaining in MOUD and ART for care or prevention. In all interactions, it is important that navigators and participants respect each other.

In order to stay on top of emerging reactions during the process of navigation and to ensure fidelity to the theory-driven model, weekly supervision sessions will be held at each site by a named supervisor. Weekly supervision in these sessions will discuss:

- Specific cases
- Materials used by navigators
- Successful skills or techniques
- Challenges encountered in implementing the intervention
- New barriers identified
- Novel and successful approaches attempted to address barriers
- Trauma and how to manage trauma in participants, both when in and out of sessions
- Cultural issues, especially when navigators have different addiction, HIV status, race/ethnicity, sex, sexual orientation and/or socioeconomic backgrounds from participants.

These discussions should be summarized on the **Supervision Debrief Forms for supervisors** (Appendix II) **and navigators** (Appendix III).

Conflict Resolution

Conflict occurs when people (or other parties) perceive that, as a consequence of a disagreement, there is a threat to their needs, interests or concerns. There is a tendency to view conflict as a negative experience caused by abnormally difficult circumstances. The people in the dispute (also known as disputants) tend to perceive limited options and finite resources available in seeking solutions, rather than multiple possibilities that may exist 'outside the box' (Healey, 1995).

Therefore, conflict can be defined as a disagreement through which the parties involved perceive a threat to their needs, interests or concerns (Mayer, 1990). Conflicts, to a large degree, are situations that naturally arise as we go about managing complex and stressful life situations in which clients are personally invested (Ury, 1988).

Recognizing when a client may benefit from conflict resolution skills training

Conflict comes about from differences between individuals; their needs, values and motivations. Sometimes through these differences individuals can complement each other, but at other times there will be conflict. Conflict is not a problem in isolation, it's how it is dealt with that determines whether it resolves or escalates (Helpguide, 2006).

Conflict can endanger relationships, but if handled effectively, it can provide opportunities for growth, ultimately strengthening the bond between two people. Since relationship conflicts are inevitable, learning to deal with them (rather than avoiding them) is crucial (Bercovitch, 1984).

As a navigator, recognizing and managing conflict is also an essential part of building emotional intelligence. By being able to teach clients the skills needed for resolving conflict you are assisting them to keep their relationships strong and growing. An unresolved or ignored conflict can engage large amounts of our attention and energy. It is not always easy to fix the problem that ignites a conflict, but it can be of great benefit to provide clients with the skills to manage conflict effectively.

For many, attempts to deal with conflict result in:

1. Avoidance or withdrawal – e.g. let's not talk about it
2. Anger and verbal or physical aggression
3. Emotional blackmail – e.g. you never, you always
4. Inappropriate use of power – e.g. while you are living in my home you will…
5. Passive aggression – e.g. not talking to one another
6. Compromise and giving in – usually leaving at least one person aggrieved

Not one of the above results is an ideal way to end conflict. When considering working with clients who might benefit from conflict resolution skills training it is important that the navigator demonstrates the skills through practical application, such as role-play. This ensures the client can translate understanding into action and facilitates learning.

Additionally, conflict resolution training will not be effective if a client learns the skills but is afraid to apply them (e.g. because their communication style is passive). A navigator will need to recognize these factors and modify their training accordingly (e.g. include assertiveness training in the process) (Healey, 1995).

The basic values a navigator needs to be aware of

Every client has distinctive viewpoints that are equally valid (from where they stand) as the other party involved in the conflict. Each person's viewpoint makes a contribution to the whole and requires consideration and respect in order to form a complete solution. This wider view can open up the communication transaction possibilities. It may require one party to change their mind chatter that says: "For me to be right, others must be wrong" (Alexelrod, 1984).

Encourage your client to consider how the problem or the relationship will look over a substantial period of time. Looking at the conflict or problem in question in terms of a longer timeframe can help clients become more realistic about the consequences of the conflict as well as exploring options to resolve the conflict (Alexelrod, 1984). Clients experiencing conflict tend to respond on the basis of their perceptions of the situation, rather than an objective review of it. This is where having a counseling intervention can benefit the client in overcoming their subjective frame of reference.

Subsequently, clients filter their perceptions (and reactions) through their values, culture, beliefs, information, experience, gender, and other variables. Conflict responses are both filled with ideas and feelings that can be very strong and powerful guides to our sense of possible solutions (Healey, 1995). As in any problem, conflicts contain substantive, procedural, and psychological dimensions to be negotiated. In order to best understand the threat perceived by those engaged in a conflict, all of these dimensions need to be considered.

As navigators we can assist clients to develop healthy, functional and positive coping mechanisms for identifying conflicts likely to arise, the consequences, as well as the strategies in which clients can constructively manage their conflicts. New opportunities and possibilities may be discovered which in turn will transform the personal conflict into a productive learning experience (Healey, 1995).

Creative problem-solving strategies are essential to the application of positive approaches to conflict resolution. The client needs to be able to learn how to transform the situation from one in which it is 'my way or the highway' into one in which they entertain new possibilities that have been otherwise elusive (Ury, 1988).

Source: http://www.mentalhealthacademy.net/

"I" Statements

Use an "I" statement when you need to let the other person know you are feeling strongly about the issue. Others often underestimate how hurt or angry or put out you are, so it's useful to say exactly what's going on for you - making the situation appear neither better nor worse.

What Your "I" Statement Isn't

Your "I" statement is not about being polite. It's not to do with 'soft' or 'nice', nor should it be rude. **It's about being clear.**

It's a conversation opener, not the resolution. It's the opener to improving rather than deteriorating relationships.

If you expect it to be the answer and to fix what's not working straight away - you may have an unrealistic expectation.

If you expect the other person to respond as you want them to immediately, you may have an unrealistic expectation.

What you can realistically expect is that an appropriate "I" statement made with good intent will transmit to the other about what you want, what you experience, what you expect.

When to Use:

When you need to confront others about their behavior

When we feel others are not treating you right

When you feel defensive or angry

When others are angry with you

STEP 1. LISTEN

How to listen

- Firstly - Do not interrupt
- Make sure your body language shows that you are listening
- Do not give advice (unless asked for)

Example leader sentences:

What I'm hearing is....

Did you say....

So you reckon....

I understand that....

So you say that....

STEP 2. USE "I" AND NOT "YOU'

Example leader sentences:

When I'm....

When I....

I think that I....

I feel that I....

My concern is....

STEP 3. REFER TO THE BEHAVIOUR NOT TO THE PERSON

Example leader sentences:

When I'm shouted at I....

When I'm sworn at I....

When I'm pushed around I....

When the towels are left on the floor I....

When I think I'm not being heard I....

When the toys are left on the floor I....

STEP 4. STATE HOW THE BEHAVIOR AFFECTS YOU

Ask yourself ... how does this behavior affect me or make me feel?

Example leader sentences:

I feel unappreciated when....

I'm worried that something will go wrong if....

My concern is that....

I get really anxious when....

I get really scared when....

I feel hurt when....

I feel tired when....

STEP 5 STATE WHAT YOU NEED TO HAPPEN

Example leader sentences:

I need to....

I would like....

What I'd like to see happen is....

It would be nice if....

For children there is a sixth step which includes a consequence. However, it is recommended not to use the sixth step until the second time around. It is also at this time that the type of consequences can be discussed with the child

if they are old enough. Other ways of getting children to be responsible for their own behavior is to use the "When .... then .... " statement or a behavioral reward chart.

For example

"**When** you've taken your suboxone **then** you can go out for the day."

STEP 6. STATE THAT THERE IS A CONSEQUENCE TO THEIR ACTIONS

If..... then.....

For example:

If the towels continue to be thrown on the floor there will be no watching Simpsons later.

OVERALL EXAMPLE 1

STEP 1 LISTEN & REPEAT	So you reckon I interrupt all the time?
STEP 2 USE "I" NOT "YOU"	OK ... but when I'm ...
STEP 3 BEHAVIOR	shouted at ...
STEP 4 EFFECT OF THE BEHAVIOR	I feel threatened and disrespected right now.
STEP 5 WHAT YOU NEED TO HAPPEN	I need you to understand me. Please please don't shout at me and I will try not to interrupt you.

OVERALL EXAMPLE 2

STEP 1 LISTEN & REPEAT	So you're saying I never see the good things that you do and you feel unappreciated?
STEP 2 USE "I" NOT "YOU"	OK ... but when I'm ...
STEP 3 BEHAVIOR	sworn at ...
STEP 4 EFFECT OF THE BEHAVIOR	I feel put down and hurt ...
STEP 5 NEEDS	I'd like not to be spoken to in that way ...

Source: http://www.compassioncoach.com/how_and_when_to_use_i_statements

KEY POINTS FOR CHAPTER 5

Chapter 5 provides an overview of the barriers to MOUD and to HIV care and prevention. When working with participants, be familiar with systems/structural barriers, social barriers and individual barriers to these treatments

- A table is provided that outlines the systems/structural barriers, the social barriers and the individual barriers to MOUD and to HIV care and prevention

Only a minority of people living with opioid use disorder enter MOUD – and even fewer of these folks stay in MOUD for six months or more, which is what we're asking participants to do in this study. We know that there can be strong motivations to start MOUD and to stay on ART, but there are real problems that come up, usually throughout being in these treatments, that need to be dealt with. That's why we're using navigation with the goal of helping participants to remain in MOUD and ART for HIV care or prevention.

For most participants living with opioid use disorder, the common reason to join the study and to consider getting into MOUD is to "get their life back." But most also agree that the barriers to consistent access to MOUD are real and cause problems. For some, these barriers exist because MOUD is not available; MOUD is offered at places that are far away or at places that are not near public transportation. Other times, MOUD may available, but participants have no resources to pay for the treatment. These problems are the key reasons for this project: people who need MOUD often cannot find the care they need. And if they do find that care, it is difficult to remain in that care for a range of reasons. Using navigation, we're here to use theory-driven skills to help participants to find MOUD, to engage MOUD and to stay in MOUD.

For people living with HIV or at risk and who also inject opioids, getting into MOUD is reaching only half of the vital health services needed. In the setting of untreated opioid use disorder, consistent ability to stay in ART care or prevention can feel impossible. The impact of untreated opioid use disorder often means periods of incarceration (due to warrants, unpaid tickets, public intoxication, vagrancy), of engaging survival sex, or living on the streets or in shelters are HUGE barriers that interfere with people being able to have their HIV medications with them. In the setting of untreated opioid use disorder getting onto HIV treatment and adhering to the treatment is difficult, especially when there are other competing life challenges. In the table below we will provide an overview of known barriers to initiating and adhering to MOUD and to HIV medications for care and prevention.

The known barriers fall into three main categories: Structural, Social, and Individual (see table below).

- **Systems/Structural Barriers** are lack of resources (clinic or personnel) or systems (e.g., paperwork requirements), which interfere with persons wanting to start or to adhere to MOUD and ART for HIV care or prevention.

- **Social Barriers** are aspects of participants' lives – their family dynamics and their relationships with their friends and sexual partner that may make them feel less support should they decide to start and adhere to MOUD and ART for HIV care or prevention.

- **Individual Barriers** are related to the individuals own mental and physical health, perceptions and knowledge, competing life priorities, personal histories and level of opioid and poly-substance use that make it challenging to start and adhere to MOUD and ART for HIV care or prevention.

Systems/Structural Barriers	Social Barriers	Individual Barriers

Health systems
• Provider not available for MOUD
• Costs for MOUD not covered
• Need more tests and results to start ART*
• Costs of testing and medications to start ART*
• ART not available
• Physician would not provide MOUD and/or ART due to drug use*
• Getting onto MOUD and ART is too complicated (paperwork and requirements)*
 	
Infrastructure/Systems
• Transport/travel to clinic is difficult
• Travelling for work or holidays
• Don't have an ID card*
• No time to go to clinic
• Cycled in and out of jail/prison
• Fear of future arrest
	Family network
	• No support from family
	• Spouse/partner not in support of MOUD and/or ART
	• Responsibility to take care of family members
	Friends/Sexual partner network
	• Friends or partner continue to use
	• Friends/partner not interested in my access to ART
	Social stigma
	• Don't want others to know I have addiction/ HIV
	• Fear disclosure of addiction/HIV will lead to rejection, homelessness, violence,
	Housing/Social stability
	• Homeless
	• Moving frequently
	Stigma & Discrimination
	• Experiences being disrespected in addiction and HIV care settings
		Mental health
		• Depression/Panic/Trauma
		  ○ Felt too depressed to go to clinic
		  ○ Suicidal ideation and past suicide attempts
		Scheduling
		• Forgot, away from home, change in routine
		• Missed appointments and embarrassed/ashamed to go back
		Physical Health
		• Too sick to go to clinic.
		• Other illness
		Avoidance/Motivation
		• Not ready to think about my addiction or HIV status
		• Too many other things to do in a day
		• I do not feel sick (esp for HIV disease)
		Medication related
		• I don't want to switch a drug for a drug (MOUD)
		• I prefer traditional/non-western medicines (ART)
		• I do not think medicine will help me get my life back
		• I don't feel anything (MOUD, ART)
		Side effects/drug complications
		• My medications get stolen all the time
		• I don't always have food or water to take medicine
		• Side effects such as nausea, headaches, disruptive sleep, GI problems
		Substance use and risk behaviors
		• Want to get off all drugs before starting ART
		• Drug use/drinking stopped me from getting to clinic
		Information
		• I don't know how to get onto MOUD or ART*

* Barriers relevant to initiating MOUD and ART for HIV care/prevention

KEY POINTS FOR CHAPTER 6

Chapter 6 reviews the responsibilities of the navigator and the knowledge needed to help participants with the integrated strategies for HPTN 094.

- Key role of relationship-building with participants
- Communication managed between clinic and health care staff
    1. Knowing workers at all of the places your participants need services
- Weekly check-ins with participants
- Ability to work with participants to meet their needs

The primary responsibility of the navigator is to build a strong and open relationship with participants to set the foundation to address systems/structural barriers to entering and retaining in MOUD and in ART for HIV care or prevention. These barriers are as varied as are participants, but as noted earlier, may include difficulties in getting signed up for Medicaid or other insurance programs to pay for MOUD, ART and primary care, in keeping appointments for MOUD or ART for HIV care or prevention, in adhering to medications for MOUD or HIV care or prevention, and in brokering between health care professionals to ensure access to care for the entire spectrum of integrated health services.

Navigators need to have detailed knowledge of MOUD and HIV medical care and prevention resources within their site. This includes compiling and refreshing names of workers at each of the clinics that provide services spanning MOUD, HIV medical care, other drug treatment, mental health services, social/housing services, employment services, legal aid/legal services and food. An electronic registry of these services, agency locations, contact persons, and contact information will be maintained at the site and updated regularly. The navigator will have access to the list of services exist in the community that will guide referrals for their participants to needed services. This registry will be adapted on ongoing basis by the research site. Navigators must be always checking and always be sensitive to the systems barriers that interfere with enrollment into all aspects of these services – sometimes you really can't get there. As well, navigators should have a solid working familiarity with the types of services, agencies and contact persons at services frequently needed (e.g., healthcare insurance, primary care, etc). In working with participants around services, navigators will use intervention skills described above, such as goal setting, cognitive behavioral skills, motivational interviewing, social support, case management and cultural competency to assist the dialog with participants to secure these services. These tools should also be used in each encounter with participants.

6.1 The Roles

a) Navigators are to address **communication issues** between clinic and health care staff members and participants. If necessary, navigators can accompany participants to health care visits or join telehealth services remotely.
b) The navigators may **meet with the clinic and health care staff** to explain the study and their role, answer questions about the study, and **serve as a contact for the drug treatment and HIV medical care and prevention services.**

Required knowledge: Navigators should know enough about the drug treatment system and HIV and primary care sites so that they can call or visit health care providers who can help them address certain issues (with signed release of information). They should also have sufficient information to help participants avoid typical problems and barriers. Navigators should be familiar with the clinics and the providers of MOUD and ART for HIV care and prevention to be familiar with typical issues that the providers address. The more navigators know about the health care system the more they can be proactive and assist participants as well as enhance relationships with providers.

c) Navigators can also help by knowing the type and personnel at other organizations that provide services for medical care, drug treatment, sexually transmitted infections, hepatitis, and harm reduction. The navigator can assist the participant in locating site specific services such as housing services or substance use support groups for those who seek peer support. The activities of the navigator will be determined in part by the services available and by the needs of the participants.

Required knowledge: Navigators should learn about the non-health care services available, and who is eligible to use these services. For example: If Narcotics Anonymous is not available in your site, find out if there are equivalent peer run support groups for cessation of substance use.

Weekly check-in by the navigator: Navigators will have an initial encounter with the participant on day of randomization. Following this, the navigator will check-in with the participant weekly, or more frequently if necessary. The check-ins may be done verbally by phone or in person.

The goal of check-ins is to assess the participants' experience with and identify any barriers to MOUD, HIV medical care (or prevention) and adherence to treatment medications. If the conversation is by phone, the navigator will first assess whether it is an appropriate time for the participant to discuss his/her health care needs. The call should be when participants can talk privately and can concentrate on the conversation. The navigator should ask the participants if it is a good time to talk or whether it would better to talk another time. If the participant indicates that it is not a good time to talk then arrange for another call. If the navigator is unsure then ask about the participant's setting and potential for interference by others.

Prior to the check-in the navigator should review the participant's information to determine a scope of the needs for the participant and if there has been progress toward setting goals. If the participant expressed a goal of going to the methadone clinic and getting onto methadone, then the navigator will ask if he/she made to the clinic and is currently on methadone. If the participant had a goal of going to the HIV medical clinic and getting on ART, then the navigator will ask if they were able to get to the clinic. If they were unable to get to the clinic then the navigator will ask about barriers. Some of the barriers may require the navigator to talk to health care providers or other clinic staff (systems/structural barriers, see chapter 5). Some of the barriers may be due to individual factors such as concomitant substance use (methamphetamine/cocaine/alcohol use), mental health problems or social factors such as relationships with family (see chapter 5). If the navigator identifies systems/structural barriers to address, such as talking to a health care provider about an issue, the navigator should check with the participant about a course of action, get releases of information and then contact the participants later to inform them about the outcome of the intervention. If the navigator identifies individual or social barriers, he/she may ask about getting help at local agencies for the participant, getting releases of information, and the contacting the participant later to provide information about the outcomes. The navigator may also suggest the participant schedule an in-person meeting as some issues may be too complicated or sensitive to address over the phone.

6.2 Other contacts

Navigators are encouraged to use text messaging and to encourage participants also to use text messaging as a way to stay in touch or to make brief check-ins. If needed, the navigator may make home visits (with another staff member accompanying). This approach may be used if the participants is ill, impaired, or does not respond to other methods of contact. Also, if there is a crisis or event such as drug relapse, messaging may be helpful to stay in contact with participants until barriers are addressed and resolved for in-person visits.

The navigators may be requested by the participant to interact with the participant's network injection or sexual partners. Any contact between the navigator and the network partner will only focus on needs/wants of the participant. Navigators remain advocates for participants, so it is okay for navigators to speak (with appropriate releases) with drug or sexual partners. But these interactions can only be to provide support for the participant. Partners who might be appropriate for study participation can begin the screening procedures for themselves.

Navigators are not expected to provide navigation or referrals to any the study participants' sexual or drug-use partners.

KEY POINTS FOR CHAPTER 7

Chapter 7 provides a step-by-step structure for the initial navigation session.

- Review limits of navigation
- Provide naloxone reversal kit – and instructions on how to use it
- Provide harm reduction supplies
- Collect release of information forms to talk with providers/clinicians
- Collect follow-up/contact information
- Start needs assessment: client-centered, goal setting process to start MOUD, ART or PrEP
- Assess participant safety and work with participant to ensure safety and health

7.1 Initial Navigation Session

Navigation starts for all participants during the enrollment visit. As part of this visit, navigators will meet with clients to begin the process of relationship building, of assessment, of treatment planning and of case management. Starting with the enrollment visit, navigators introduce themselves to participants. They do all they can to help participants to feel valued and appreciated. This is an essential skill that we expect all navigators to have – being able to be a good human being when working with participants. During this initial session navigators will use their skills as a "good human being" to also complete the tasks common to all first help-intended sessions:

1. Review what navigation is and what it isn't and remind the participant of the limits of confidentiality that are listed in the informed consent form that they signed to enter the study. It can be helpful to remind participants of these limits from time to time as topics of self-harm, threats to others or concerns regarding safety of children and elders arise in discussions.

2. Provide a naloxone reversal kit along with a discussion on whom among the participant's social and/or drug using network can help with limiting risks for overdose and for conducting overdose reversal using naloxone. Participants may believe that starting MOUD eliminates or reduces risks for overdose. This is true when buprenorphine is on board (either oral or injectable). But when the medication wears off, risks for overdose actually *increase* because participants lose their tolerance to opioids and attempt to use a dose of illicit opioids equal to what they had used prior to entering therapy. Risks for overdose for patients on methadone maintenance therapy also rise during periods of lapse/relapse. Navigators should have discussions early on regarding management of opioid overdose risks *regardless* of treatment type, how well participants are doing currently, or how consistently participants engage treatment.

3. Provide harm reduction supplies. Although the goal for treatment with MOUD is for the individual to not use drugs, the reality is that relapse during therapy is common. Providing clean needles and syringes, and other drug use paraphernalia is not enabling drug use, but it is ensuring drug use is done in the safest way possible, if relapse is to occur. Some, but not all, participants may feel awkward asking for sterile injection supplies – especially when they know their navigator is invested in getting them to start and remain in MOUD. A

"matter of fact" response is often appreciated – we're not giving you permission to have a lapse or relapse, but in case you do, we're definitely interested in limiting harms to your health. Harm reduction supplies also includes providing condoms and lube.

4. Collect signed release of information forms to talk with providers and clinicians who provide any of the range of health services for participants. Upload these onto your server to facilitate access while in the field.

5. Collect names and contact information from at least three people who navigators have permission to reach out to if there is a need to re-establish contact. Best practice would be to ask participants to reach out to persons named to provide contact information to ensure working phone numbers.

6. Using a client-centered process, begin a needs assessment and goal-setting process with participants using the ABCs and SMART goal setting. If there's time, use the form to begin collecting information about prior experiences with MOUD, with ART for HIV care or prevention, for physical and mental health, for housing, for family/social functioning, for employment and for spiritual functioning. As you see below, the goal here is not to DO all of the work in one session. It will be best to start with one or two goals that participants identify as their top priorities. If it is not part of your participants' top priorities, be sure to raise the goal of entry to MOUD. This will ensure a discussion on this important goal.

The first and subsequent navigation sessions follow a similar structure. They begin with an introduction of a topic (or topics) to be covered in the navigation session. In this initial session, the navigator introduces him/herself and talks a bit about the overview of navigation and how it fits with MOUD, with ART for HIV care or prevention and with the entire range of integrated services. This introduction will help the participant to begin to feel confidence in the navigation process and to feel safe with the study. Navigators will acknowledge that this first session at the enrollment visit will be different from ones that follow as there is the need to collect much information, to get signed permissions to talk to providers and to begin the process of needs assessment and goal-setting. So there will be more questions to be asked, more answers to be recorded and more direction from the navigator on the structure of the session.

Navigation sessions are required of all participants at the enrollment visit. The table that starts Chapter 8 below provides the list of sessions and suggested order of topics to engage in the initial navigation sessions, independent of condition arm. In the initial session, it's good to go over these with the participant to provide an overview of what are the integrated services delivered in HPTN 094. That way you can understand what is important to the participant in ordering optional topics for navigation. Remember – you don't have to DO each of these topics in the initial session. But it is helpful to review the range of topics you're going to want to discuss with participants while they are in the research program.

Once the required topics have been completed with the participant, there are optional topics that can be conducted with participants over the six months. The purpose of these elective topics is to provide a "menu" of topics or issues that can address common barriers to people living with opioid use disorder and who have HIV or are at risk. The list of elective topics is provided in the table in Chapter 8. The module chosen depends on the assessment of the participant's needs and priorities. In addition, all of the topics can and should be revisited to address ambivalent feelings that emerge regarding continued MOUD or ART for HIV care or prevention.

7.2 Overview of navigation documents

The navigator is responsible for completing each of the following documents during/or after each encounter:

1. Navigation Plan in REDCap…see example in Appendix I . Required at Enrollment Visit or soon after, then update as needed when goals are revised.
2. Navigator Client Contact/Encounter Form in REDCap. Required at each encounter, and any contact attempted or completed with the participant. This document includes drop down menus for principal areas of need and a free-text area for progress notes

3. Navigation Session CRF in Medidata Rave. Required at each encounter…sites may assign another team member to complete this CRF such as the data manager.
4. Other documents per locally-determined procedures, such as progress notes if not kept in the Contact/Encounter form.

7.3 Materials

In Chapter 8, the materials needed in-person visits are provided. As this study starts, though, it is impossible to predict whether there will be changes needed when conducting navigation sessions to respect local restrictions on in-person health visits due to the COVID-19 pandemic.

Due to this, materials should be made available to participants at their randomization session. Participants may elect not to take any/all of the materials. Even if there are no COVID-19 restrictions, participants may not find the materials useful as some will not have reliable access to storing pill boxes, to make notes or to take tear-sheets with session materials that have information that can be consulted later. In such instances, discussions about how best to get information to participants are vital. As well, there may be naturally occurring opportunities to provide resources to participants. For example, navigators may accompany participants to their appointments for specific services, which presents opportunities to provide informational and referral materials to participants.

With COVID-19, it is possible, even likely, that navigation sessions will have to be conducted online (zoom) or on cell phones. It may be worth considering whether a booth or tent can be set up outside the mobile unit where navigators could conduct sessions remotely or in person. As COVID-19 restrictions may limit in-person contacts, additional materials that can help facilitate medication adherence (e.g., pill sorters, blank paper or cards to write schedules or take notes) can be given to participants in a "navigation swag kit." These materials should be provided during first session. Swag can be given at any time during the study.

Session materials, including pamphlets that include referral agencies, names and phone numbers should be prepared into electronic formats that can be texted and emailed to participants who elect not to use paper. Materials and supplies can be prepared and replenished regularly to participants over the course of the stud

KEY POINTS FOR CHAPTER 8

Chapter 8 contains a list of different topics, required and optional. The chapter begins with tasks for the introductory session, ending with preliminary goal setting.

- Introduction session; Required topics – Topic 1 to 4; Optional Topics – Topic 3 to 11
- Relationship building
- Review confidentiality
- Explanation of the study
- Brief needs assessment

Overview of Navigation Topics in Chapter 8

Session Title	Description
Introduction to program and preliminary needs assessment • Relationship building • Defining limits of confidentiality • The goal of the navigation for this study • Overview of the navigation sessions • Provide harm reduction supplies • Brief needs assessment	Conduct during enrollment visit
Topic 1: Harm reduction. • Review Initial Session and What has Happened Since then • Conduct harm reduction • Setting goals for starting or restarting MOUD (using ABCs) • SMART goals to help problem solving	Required topic
Topic 2: Session 2a/2b: Setting goals for starting or re-starting ART for HIV care or prevention (using ABCs) Session 2a • Review Session 1 and What has Happened Since then • Assess HIV treatment history and status • Understand the goal of HIV treatment • Identifying needs (referral to HIV care, adherence to ART, drug use treatment, and relapse prevention,) • Discuss and review major barriers to treatment (e.g., side effect)	Required topic

Session 2b • Review Session 1 and What has Happened Since then • Assess HIV prevention history • Understand the goal of PrEP • Identifying needs (referral to PrEP care, adherence to PrEP, drug use treatment, and relapse prevention,) • Discuss and review major barriers to treatment (e.g., side effect)	
Topic 3: Program Goals and Adherence • Review Previous Session and What has Happened Since then • Check-in on MOUD, ART, PrEP • Review barriers to getting medical care and set goals • Use "My Health Map" to identify side effects to MOUD, ART, PrEP to discuss with clinician • Adherence barriers and facilitators for MOUD, ART, PrEP medications • Provide harm reduction supplies • Start needs assessment: client-centered, goal setting process to start MOUD, ART or PrEP • Assess access participant safety and make recommendationsReview Previous Session and What has Happened Since Then • Assess participants goals, objectives and expectations of the program	Required topic
Topic 4: Setting goals for safety – housing, harm reduction, food security (using ABCs) □ Review Previous Session and What has Happened Since then □ Check-in on MOUD, ART, PrEP □ Review housing status and plans □ Do case management and system navigation to arrange stable housing □ Introduce topic of food security □ Introduce topic of personal hygiene	Required topic

Elective Topic Titles	Description
Topic 5: Sexual risk reduction (HIV and STI-relevant) □ Review Previous Session and What has Happened Since then □ Check-in on MOUD, ART, PrEP □ Present information about sex risks (U=U) □ Additional risks from drug use, intimate partner violence, and other factors □ Conduct activity with the risk ladder and see where participants place behaviors by risk □ Discuss personal sexual risk reduction plan	Optional topic
Topic 6: Injecting risk reduction and drug splitting □ Review Previous Session and What has Happened Since then □ Check-in on MOUD, ART, PrEP □ Begin discussion in injection risks □ Conduct risk ladder exercise about injection behaviors □ Develop personalized risk reduction plan for injection behaviors □ Discuss drug splitting □ Conduct risk ladder exercise about drug splitting □ Develop personalized risk reduction plan for drug splitting	Optional topic
Topic 7: Use of stimulants - methamphetamine, cocaine, crack and tobacco use □ Review Previous Session and What has Happened Since then □ Check-in on MOUD, ART, PrEP □ Begin discussion about stimulants and how they are used by participant □ Do a motivational interview about stimulant use □ Consider links between trauma and stimulant use □ Harm reduction of Narcan, fentanyl test strips □ Considerations of change regarding stimulant use	Optional topic
Topic 8: Use of benzos, barbs, alcohol and other downers □ Review Previous Session and What has Happened Since then □ Check-in on MOUD, ART, PrEP □ Recognize how many people use alcohol in the U.S. □ Identify amount of alcohol that is risky and consequences to alcohol use for those living with HCV. □ Discuss use of benzodiazepines, barbiturates and other drugs that are used to manage anxiety □ Discuss ways these drugs interact with opioids to increase risks for overdose □ Discuss whether or not to change use of these drugs, including drink/drug refusal skills. □ Developing alternatives to drinking □ Setting goals regarding drinking and use of downer drugs	Optional topic

Topic 9: Depression and Stigma ☐ Review Previous Session and What has Happened Since then ☐ Check-in on MOUD, ART, PrEP ☐ Provide information about depression and how to identify it ☐ Learn techniques (and practice them, if possible) that help stop depression feelings ☐ Discuss stigma experiences that occur from using drugs, from HIV, or aspects of living with these conditions	Optional topic

8.1 Initial Session: Introduction to Program and Preliminary Needs Assessment

KEY POINTS FOR CHAPTER 8, Initial Session

In this Session the navigator introduces navigation, builds rapport and learns about the participant's needs.

- Build Relationship
- Define limits of confidentiality
- Explain the goal of navigation in this study
- Provide overview of the navigation sessions
- Provide harm reduction supplies
- Conduct a brief needs assessment

The initial session will be conducted during the **Enrollment Visit**

Session activity	Suggested script/Probes	Notes
Introductions and explain the purpose of the session	Hi and welcome to the study. My name is [navigator] and my role in this study in the beginning is to work with you towards the goal of getting healthier in terms of your drug use, HIV, hepatitis, primary care, and your sexual health. We will be spending some time, at first, in getting to know each other and for me to understand your health goals. I will be teaching you some skills that may be helpful for you in dealing with drug use, HIV, and other things that are important for you in your life. I appreciate that people have different priorities and goals in their lives, and I want to ensure that this study is useful to you. I look forward to learning more about you and what is important to you through the study.	Assess the amount of time the participant has already spent that day for the enrollment activities. If it was a long time, and the participant appears tired, keep this section short, and help them with referral needs including assisted disclosure throughout the following sessions.
Review confidentiality	Our team consists of navigators, supervisors, physicians, nurses and research associates; I am one of the navigators and will help you interact with our staff and with the people at the clinics where you'll get care.	Navigators should keep progress notes, including log of meeting days and times, record of discussion topics and any

	Everything you tell us will be kept confidential within our team. There are limits to this, however. If you tell me you intend to harm yourself or someone else, or if you tell me you have harmed or will harm children or elders, I am required to break confidentiality and to make a report to authorities. Here are the specifics [give them]. People who are study team members and some others from NIH may monitor some of the study documents. But for everything else and for everyone else, unless you specifically give us permission to talk to someone – even if that person is a medical provider for you, we cannot talk to anyone. As your navigator, I will keep notes of what we talk about today, so that I (or another navigator) can refer back to our notes in future sessions.	homework assignments to ensure continuity of care.
The goal of navigation for this study	The main goal of the study is to help you to get you into MOUD and care or prevention for HIV to help you live a healthy life. Throughout this study, the goal is progress, not perfection. This means sometimes you'll reach your goals and sometimes you won't. That's to be expected. I understand there are pros and cons for whatever you want to do about your drug use – and those pros and cons can change at any time. If you are interested in drug use treatment, we will help you get into a program. Where you get this treatment will depend if you are randomly assigned to get treatment on the mobile unit or get treatment somewhere else. Either way, I will help you get into and stay in treatment. Also, we will talk about ways to control your drug use. Regardless of what you want to do about your drug use we want to ensure you get good medical care that includes treatment for HIV infection (if PLWH) or prevention for HIV (if not living with HIV).	The philosophy of navigation in this study is harm reduction. People actively using drugs can be successful in getting and staying in MOUD and in getting and staying in HIV care or HIV prevention. There are a variety of ways people can address injection drug use. For most, it is helpful to get guidance from others when starting MOUD. The best kind of help can be from peers when receiving navigation The goal of the navigation is to find the kind of treatment you like that will work over the long term. As long as you're doing the work, your harm is being reduced – so whatever happens, keep working at it!
Overview of the navigation sessions	The navigation provided is meant to be flexible, but we do want you to complete four topics on problems many people often face when making decisions about getting drug abuse treatment. There is another set of elective topics for further navigation sessions as you wish. Topics offered for discussion include [show the list of required and elective sessions]. In general, each navigation session will be a week apart. Each session will be 30-45 minutes. We will also provide help navigating drug treatment, HIV, STI and primary care clinics, and places to go for hepatitis testing and treatment and for harm reduction supplies and services. We'll also work with you with local agencies should you need help getting into housing, employment.	The required topics are: • Setting goals for harm reduction/MOUD • Setting goals for ART/PrEP/HIV • Program goals and adherence • Setting goals for safety: housing, harm reduction, food security The optional topics are: • Sexual risk reduction (HIV and STI-relevant) • Injecting risk reduction and drug splitting

	If you are having difficulties accessing medical services or there are issues with your MOUD, HIV care/prevention or other services, I or another member of our team may be able to assist you. For example, we can provide assistance with getting appointments. These sessions will last 6 months. The goal of navigation is to find a place that is good and acceptable for you to receive MOUD near where you live. Most of the work in finding and enrolling in MOUD will be done over the first four months. If more navigation is needed after 6 months we will assist you in finding other services in local clinic locations.	• HCV care and treatment (if living with HCV) • Use of stimulants • Use of benzos, barbs, alcohol and other downers • Depression and Stigma •
Provide Materials and Results	*Provide naloxone kit with instructions of how to instruct those around the participant (friend, partner, running buddy) in how to use the kit to reverse an overdose.* *Distribute condoms and lube packets.* *Record on the navigation form the number and type of harm reduction supplies delivered to the participant.*	
Questions	Do you have any questions about the study?	
Brief Needs Assessment	We appreciate that you just completed a survey telling us about your health and drug use history and other relevant aspects of your life. Now I'd like to go over in a list of issues that many people have when living with opioid use disorder and HIV – or are at high-risk for HIV infection. I know a lot has happened today, so I don't want to keep you long. But I do want to make sure to discuss these following areas to make sure we address anything that is urgent and requires action today. There will be time to explore the full list on a different day. Let's see. As we go over the list, let me know which of these you are feeling an urgent need to address right now. How are you doing in these areas? 1. MOUD status 2. PrEP or ART adherence status 3. Mental health status 4. Harm reduction status 5. STD test and treat 6. HCV treatment 7. Primary medical care status 8. Housing status	Use the responses to develop the Navigation Plan

	9. Food status 10. Hygiene needs Use the responses to the following to develop the Navigation Plan.	

8.2 Topic 1: Harm Reduction Setting goals for starting or re-starting MOUD

KEY POINTS FOR CHAPTER 8, Topic 1

This session reviews material for required Topic 1.

- Review events from preliminary session during check-in with participant
- Introduce harm reduction concepts and provide supplies
- Begin setting goals for starting MOUD (using ABCs)
- SMART goals to help with problem solving

Topics and Objectives

Harm reduction. Conduct harm reduction

- Provide naloxone kit with instructions on using it
- Provide harm reduction services, if available

Setting goals for starting MOUD (using ABCs)

- Get baseline information (to assess the preliminary needs of the participant)
- Start discussion on pros and cons of MOUD using motivational interviewing
- Explain ABCs and start setting priorities for MOUD

SMART goals to help problem solving

- Assess participant expectations of the program
- Explain SMART goal setting and brief problem solving
- Set homework for next session
- Identifying areas for navigation using SMART goals for problem solving (referral to MOUD care, adherence to MOUD, treatment support services, including relapse prevention)
- Discuss and review major barriers to treatment (e.g., side effects, distance, lack of health insurance)

Module activity	**Suggested script/Probes**	**Notes**
Introduction	It is good to see you again. In the last session I was able to learn a little bit about you and some of the things that you would like to accomplish in this program. Can you tell me how things have been going for you since the last session? Let's review your risks. Can you talk a bit about your opioid use? What has happened since our last session? Can you talk a bit about your risk for HIV infection from injection behaviors? What about sexual behaviors?	Spend time building rapport with participant. We want the participant to enjoy sessions so they are motivated to engage with their navigator. Reviewing **the Navigation Plan Document** and keeping details of how motivation for MOUD shifts will help with continuity and give

	What kinds of harm reduction supplies do you need today? *(naloxone, condoms, lube, injection supplies)* Let's start the session by reviewing the Navigation Plan Document for you. We can always make changes to the document. It's supposed to grow and to change with you as you move through this program.	participant confidence that you are listening and that you care. Review the Navigation Plan Document Review aspects of opioid use and HIV risks
Harm Reduction	Today's session starts with discussion about harm reduction. Harm reduction is a set of behaviors people with opioid use disorder can do that improve their health. Sometimes harm reduction means MOUD. Sometimes harm reduction means using sterile injection supplies. Sometimes it means having Narcan on hand by your friends and loved ones during periods of relapse should overdose happen. Regarding HIV, harm reduction means taking medications regularly for HIV care or prevention. It can also mean knowing your viral load levels (if you're positive), or getting tested for HIV regularly (if you're negative). It also means using condoms with sexual partners who are new and either are serodiscordant or unknown HIV serostatus. We're going to take a few minutes now to talk about what you're willing to do to limit your harm due to use of opioids and to HIV.	Provide naloxone kit with instructions of how to instruct those around the participant (friend, partner, running buddy) in how to use the kit to reverse an overdose. Distribute condoms. Record on the Navigator-Client Contact/Encounter form the number and type of harm reduction supplies delivered to the participant.
MOUD	We begin today talking about MOUD. It's always possible for you to have started MOUD before starting this study. Let's talk about the pros and cons of your thinking about MOUD. What are the pros? What are the cons? What are your thoughts about being able to keep using MOUD? In this session we are going to spend more time discussing your experiences with MOUD and how they impact your thoughts about starting MOUD, staying on MOUD or restarting MOUD. 1. When you first came in you indicated that you were interested in which kind of MOUD [choose relevant option]: ☐ Methadone ☐ Buprenorphine ☐ Naltrexone 2. You had experience with the following MOUD types (check appropriate boxes): ☐ Methadone	Record pro and con responses regarding MOUD on Navigator-Client Contact/Encounter form. Record current status on Navigation Plan Document Record whether they have medications and the outcomes of this discussion in text box of the Navigator-Client Contact/Encounter

	□ Buprenorphine □ Naltrexone 3. Which of these medications are you currently on? □ Methadone □ Buprenorphine □ Naltrexone 3. How has this changed since you the last time I saw you? **Probe:** Since I last saw you, have you seen a provider for MOUD? Started MOUD? **If taking MOUD:** Do you have your medication with you today? If yes – What are you doing to make sure your medications are not lost or stolen? If no – Where do you keep your medications when you are out and about?	
Trauma	While the vast majority of people living with OUD also have experienced and have witnessed traumatic events, this navigation intervention is client-centered and we won't try to force you to talk about or do something you don't want to do. You are always in control. This is an important issue to us – making you feel confident that you are in control of whatever you discuss. Maintaining a sense of control is a major issue in living with trauma. We will work to make sure you are not presented treatment materials or treatment discussions that might lead you to re-experience traumatic events or memories. We want to help participants to learn ways to avoid talking about trauma (except with therapists or counselors who are working with participants on trauma) and learn how to set limits for when (if ever) they want to discuss trauma and with whom.	
Setting goals (using ABCs)	Using the information from this and prior discussions, today we're going to start by setting goals for getting into, staying into or restarting MOUD. We see MOUD as a part of harm reduction. In what ways does MOUD reduce harm? *[Prompt for a few answers. If unable to come up with any, propose reducing numbers of injections, not needing to score drugs to prevent withdrawal]* Now getting started with MOUD means one thing, but as a goal it only makes sense for any person if it starts with the ABCs.	Record responses of participant of **A-B-C** in progress notes in the Navigator-Client Contact/Encounter form in REDCap.

	The **A** is for Achievable. Talk about the extent to which starting MOUD is or is not Achievable for you. The **B** is for Believable. Talk about your thoughts about whether starting MOUD is or is not believable for you. The **C** is for Committed. Talk about your thoughts on whether starting MOUD is or is not something you can be committed to. Over time we're going to use the ABCs to review other goals you may want to have in addition to your goals regarding MOUD, like taking HIV meds, finding stable housing, getting tested and treated for hepatitis C, having food security. But for today, let's start with MOUD. We start with MOUD because by using medications to reduce the chaos of opioid use, you'll have possibilities for change in other areas of your life.	
Review of Barriers to MOUD	Tell me your experiences in getting onto MOUD and staying on MOUD. What are the barriers that interfere with your getting onto or staying onto MOUD? Where have you received services for MOUD in the past that were acceptable to you?	
SMART goals	As you think about behaviors you might want to change while you're in this study, any number of goals might come up. Let's start by trying to define one or more MOUD goals using a process called setting SMART goals. S is for ***specific.*** A specific goal is one that has a specific solution. For example, getting housing is a specific goal and one that we can work on. M is for ***measurable.*** A measurable goal is one that has a measurable outcome. For housing, the measurement can be answered by the answer to the simple question: Where did you sleep last night? A is for ***achievable/attainable.*** Getting housing is achievable. There are measurable ways to get it. R is for ***realistic.*** Realistic goals are those that can are more than wishes – they are possibilities. Housing may be possible as an achievable goal. Getting housing in a fancy house is likely unrealistic. T is for ***time-bound.*** Time-bound goals are those that relate to the here and now. Getting housing for the next day or week or month, depending on vouchers or other housing supports that are available, is time-bound. Now let's think about one or two goals you might want to work on. Let's start with ABCs and use the SMART process to set goals to work on.	Note outcomes of discussion in navigation progress note form.

Case Management	Now we're going to take some time to get referrals in place for one or more of the goals you identified for working on. Take out the goals and pick at least one to work on with the participant. Review the pros and cons of working on each specific goal. Talk with participant and see if there is one or more goals that s/he will allow a case management procedure. Key goals that should be case managed early on in the process involves getting participants signed onto Medicaid or other resources to pay for health care, mental health, substance use, pharmacy, and primary care services.	Record goals onto navigator client contact/encounter form and navigation plan documents in REDCap. Note relevant referrals.
Summary	Do you have any questions about MOUD? Do you have any questions about ABCs or SMART goal setting? Is there any information in this topic that was not clear? Do you have any additional questions? Using the discussion we had today, including the Navigation Plan Document, let's agree on actionable steps to start, to continue or to restart MOUD before we talk next time.	

8.3 Topic 2a: Setting goals for starting ART for HIV care

KEY POINTS FOR CHAPTER 8, Topic 2a

Chapter 8, Topic 2s reviews required material for People Living with HIV/AIDS. The tasks involved are to engage or re-engage participants in HIV care

- Review responses from last session, especially harm reduction and MOUD status/needs
- Discuss HIV treatment history and status of HIV care
- Discuss the goals of HIV treatment, including barriers/facilitators of taking ART
- Identify needs and provide navigation
- Engage goal setting to maintain HIV outcomes, especially during lapse/relapse

Topics and Objectives for Session

- Assess HIV treatment history and status
- Understand the goal of HIV treatment
- Identifying needs (referral to HIV care, adherence to ART, drug use treatment, and relapse prevention,)
- Discuss and review major barriers to treatment (e.g., side effect)

Session activity	Suggested script/Probes	Notes
Review	Welcome back. The last time we met, we talked about harm reduction and about MOUD. We discussed a lot about your thoughts about medications. I'm interested in hearing your thoughts about medications today. What harm reduction supplies do you need today? What are your thoughts about your Navigation Plan Document, given your experiences since when we first drafted it? Before we get started today, let's quickly review the areas to make sure that any urgent issue gets addressed in addition to today's topic. 1. MOUD status 2. ART adherence status 3. Mental health status	Spend time building rapport with participant. We want the participant to enjoy sessions, so they are motivated to come back. Taking notes of what participant tells you **in the Navigator-Client Contact/Encounter form and/or Navigation Plan Document in REDCap** and reviewing details will help with continuity and give participant confidence that you are listening and that you care.

	4. Harm reduction status 5. STD test and treat 6. HCV testing and treat 7. Primary medical care status 8. Housing status 9. Food status 10. Hygiene needs	
Explore HIV treatment status	In this session we are going to focus on your HIV medical care. When you first came in you indicated that [choose relevant option]: 1. You hadn't seen a doctor for HIV, 2. You had been to an HIV clinic but are not on antiretrovirals (ARVs), 3. You are in care and taking ART How has this changed since you the last time I saw you? **Probe:** Since I last saw you, have you seen an HIV doctor? Started ARVs? Do you know what your viral load is? **If taking ARVs:** Do you have your pills with you today? If yes - I would like to make a note of what you are taking? If no - do you know the name of the drugs? If yes or no – please bring your pills in next time also so we can discuss your specific medications.	Record current status on the Navigation Plan Document Record whether they have pills and what medication they are taking in progress notes
HOW HIV MEDICATIONS WORK:	We will discuss the barriers and challenges to your getting HIV medications to improve your health and staying on them, but before we do this, I would like to briefly go over how HIV medications work. You may know most or all of this information but this information may help you plan your HIV medical care. - Most people who have HIV can live long and productive lives due to medications. - These medications, which are called antiretrovirals, stop the virus from reproducing in your body. They don't get rid of the virus, but they work in different ways to stop HIV from reproducing itself in your body. Somehow, though, when you stop taking the medications, the virus comes back and attacks your body and again starts to reproduce itself. If you start and stop taking your medications, they may stop working. - These medications are very powerful and can have side effects. Many of these side effects go away after a while but sometimes your health care provider may recommend a different medication.	**Reminder:** There is strong evidence that people who are currently using drugs can be successful and adherent to ARVs.

	- Once you are on HIV medications you tend to get healthier, stronger, and are less likely to get sick. The reason for this is the medications stop the virus from destroying your immune system. The immune system is what defends your body against disease. - The sooner you can get on HIV medications and take them every day, the better for your health. - This is really important: If you are on MOUD and you use drugs or relapse, you should continue taking your HIV medications. The HIV medications protect your health when you are on MOUD and even if you relapse to using drugs and alcohol. - There are two key measures of how well your HIV medications are working. o The first is your CD4 count. CD4 is a type of cell in your body and is a measure of the health of your immune system. A high CD4 count means that your immune system is functioning well. o The other measure is viral load. Viral load is a measure of how much HIV you have in your body. A lower viral load usually means that HIV medications are stopping the virus from reproducing. Sometimes there is so little virus in your body that the tests cannot find them. This is called 'undetectable', but this doesn't mean that there are no viruses. If you stop taking medications the viruses will quickly start to reproduce in your body. o The goal is to get to 'undetectable' and to stay 'undetectable.' When you are undetectable, you cannot transmit HIV to others. You also are less likely to get sick from other illnesses – as HIV is not interfering with your immune system in protecting your health.	
REVIEW OF BARRIERS TO HIV CARE	Tell me your experiences in getting onto HIV meds and staying on them. What are the barriers that interfere with your getting onto HIV medications? What are the barriers that interfere with you being able to stay on HIV medications?	
REVIEW OF INFORMATION SESSION:	I know we have covered a lot of material. Let's go over the most important points with a quiz: 1) What do you want to be high, your CD4 or Viral Load? Answer (regardless of what they respond): CD4 you want to be high as it is a measure of how well your immune system is working. Viral load you want to be low as it is measuring the amount of virus in your blood.	You can make cards with the quiz questions.

	2) When is it better to start ARVs? Answer: As soon as you are eligible. 3) Can you start ARVs if you are currently taking drugs? Answer: Yes, there is no reason to postpone ARVs while you are still taking drugs. 4) What happens if you stop taking HIV medications (ARVs)? Answer: The virus will start replicating again and come back. Also, the drugs may stop working.	
If currently taking ARVs. Assess adherence	Now let's discuss HIV treatment again. • When was the last time you missed any of your anti-HIV medications? • In the last month, on about how many days did you miss at least one tablet? You mentioned you are **currently taking ARVs.** Tell me about times when it was difficult to take your medications. When was the last time you didn't take your medications? What was the reason you did not take medication? How often do you not take your medications? There are a lot of strategies to help with medication adherence. What methods do use to help remember to take your medications? It is great that you have some strategies. Next time we meet we will discuss other strategies. [If they cite side effects as a reason for not taking medications] Remember, many of these side effects go away after a while but sometimes your health care provider may recommend a different medication. Discuss these side effects with your doctor. [Assess whether participant needs help communicating with doctor] Next time we talk we will discuss in more detail some strategies to help with medication adherence.	**For participants who know they have high viral loads [>1000]** and report high levels of adherence it is possible that either they were not highly adherent until recently or that that they have drug resistance; that is, their HIV is resistant to their current ARV treatment. For the latter situation a change in ARVs is indicated. However, it is often difficult to distinguish between suboptimal adherence and resistance without resistance testing. If participants report high ART adherence, but viral load levels remain high, the navigator should assist participant with seeing their providers and asking about resistance testing.
If not on ARVs: Assess READINESS to start ART	Now let's discuss HIV treatment again. When thinking about the next few weeks **how important is getting on HIV treatment to you on a scale from 1 to 10?** 1 being the most important, and 10 being the least important. When thinking about the next few weeks **how confident are you that you can get onto HIV treatment on a scale from 1 to 10?** 1 being the most confident, and 10 being the least confident. **If ARVs are a low priority:** Go to next activity on motivational interview	

	If ARVs are a priority: Go to next activity on barriers	
Motivational Interview if ARVs not a priority.	The medical treatments for HIV have helped many people. What are your thoughts about the benefits of being on ARVs? What are your thoughts about the costs/consequences to being on ARVs? How do you balance the benefits and costs/consequences about taking ARVs when thinking about your own health? [if participant's health is not a concern at this time, point out that people often can't tell that HIV is weakening their body. A doctor can tell you about how HIV is affecting your body and about when it is important to receive ARVs.] Mention each of the specific benefits to taking ARVs that are listed by the participant. Ask the participant to help you understand the importance of each of these. In similar way, mention each of the specific costs/consequences listed by the participant to taking ARVs. Ask the participant to help you understand the importance of each of these. If any/all of these costs/consequences are based in incorrect information, ask if you can talk more about these. For example, "how would your thinking change if your doctor told you that ARVs don't eat your bones?" Let's revisit the issues of importance and confidence about your getting onto ARVs and being able to keep taking these meds. How has your pros and cons of ARVs changed? Can I help you get a medical appointment for HIV medical care? (if no, would you like to talk to a doctor to find out more about the benefits of HIV medical care? If the participant says yes, make a connection with a doctor/NP to talk with the participant as soon as possible)	Use active and reflective listening with the participant. Note whether concerns are structural in nature, or more due to personal circumstances or beliefs. Revisit HIV knowledge activity, if participant does not see benefit of ART. These notes will help you to determine which sessions are a priority for participant, and whether they need navigation to one or more problems linked to HIV or OUD. Remember the 5 principles of MI: (1) Express empathy through reflective listening; (2) Develop discrepancy between clients' goals or values and their current behavior; (3) Avoid argument and direct confrontation; (4) Adjust to client resistance rather than opposing it directly, also known as "rolling with resistance"; and (5) Support self-efficacy and optimism.
Plan - if not on ARVs Use A-B-Cs to set S-M-A-R-T goals.	Let's go over what you need to bring to the clinic…… *Review Referral Instructions* Let's make a plan for your getting a medical appointment and going to the HIV clinic. When starting or re-starting ART is a goal, it only makes sense for any person if it starts with the ABCs. The **A** is for Achievable. Talk about the extent to which getting onto ART and all that entails is or is not Achievable for you. The **B** is for Believable. Talk about your thoughts about whether getting onto ART and all that entails is or is not believable for you.	Record the outcomes of the ABCs and SMART goal regarding ART in the Navigation Plan.

	The **C** is for Committed. Talk about your thoughts on whether getting onto ART is or is not something you can be committed to. We start with getting onto or staying on ART today because by using medications to reduce your viral load and to control your HIV disease, you'll have possibilities for change your health toward the better. It is great that you are making a plan. What positive things can you say to yourself to encourage you to go to the clinic?	
Barriers to initiating ART **– If not on ARVS**	For all participants who are not currently on ARVs. Probes: What types of things get in your way of getting onto ARVs? What barriers do you have to going to the clinic? What are your thoughts about going to the clinic while continuing to use drugs and or alcohol? What worries do you have about telling (or not telling) your doctor about your drug use? Once you make an appointment are there ways you can remind yourself to go or have some else remind you? [PROBLEM SOLVE: Give the participant the cards listing possible barriers to getting on treatment. Ask participant if there are any other barriers that are not listed In survey. If there are create a card (from blank paper) and put into pile of cards] EXERCISE: Sort the cards (Section 8.12.1) listing reasons for not being on ARVs. Put them into piles of: not a problem; somewhat of a problem; a big problem. The cards can have symbols to help in the case of reading difficulties.	Review barriers listed on the baseline survey to see if they match or if you have any additions from this session. Cards for pile sorting will be colored separately into a) Structural barriers that a navigator can address and b) Barriers related to personal beliefs and circumstances which a navigator can address.
SMART goals	As you think about behaviors you might want to change while you're in this study, any number of goals might come up. Let's start by trying to define one or more ARV goals using a process called setting SMART goals. S is for ***specific.*** A specific goal is one that has a specific solution. For example, getting onto ART is a specific goal and one that we can work on. M is for ***measurable.*** A measurable goal is one that has a measurable outcome. For getting onto ART, the measurement can be answered by setting the date you want to have your medication and take the medications. A is for ***achievable/attainable.*** Getting ART by the date is achievable. There are measurable ways to show this happens. R is for ***realistic.*** Realistic goals are those that are more than wishes – they are possibilities. ART by a certain date may be possible as an achievable goal, but may require seeing a doctor who is nearby. Seeing your doctor who is far from you is likely unrealistic.	Note outcomes of discussion in navigation progress note form.

	T is for ***time-bound.*** Time-bound goals are those that relate to the here and now. Getting and taking ARVs every day for the next three months is time-bound. Now let's think about one or two goals you might want to work on. Let's start with ABCs and use the SMART process to set goals to work on.	
For the next session	Before the next session, I would like you to think of what are some of your priorities and or goals are for your life at the moment? When thinking about this, we would like you to focus on your health, especially HIV and your drug use. Your goal or priority might be directly to improve your health through addressing your drug use or getting onto treatment for your HIV. Or your goal might be to get healthier to improve your relationships with family or friends or your work opportunities. Please think about these goals and priorities for next time.	Important questions for navigators: Is participant sexually active? Does sexual transmission need to be addressed? (Sexual risk reduction module) Does participant lend or give any injection equipment? (Injecting risk reduction & drug splitting, 9d) Does the participant receive pre-filled needles and/or used needles? (Injecting risk reduction & drug splitting, 9d) Remember the tips for goal setting: A) Use A-B-C to identify goals worth working on right now. B) Use S-M-A-R-T to develop the way to reach your goals. provide rationale for setting goals

8.4 Topic 2b: Setting goals for starting PrEP for HIV prevention

KEY POINTS FOR CHAPTER 8, Topic 2b

This Topic provides guidance for participants who are HIV-negative, but at risk for HIV and other infectious diseases

- Start session by reviewing last session about harm reduction and MOUD
- Assess current and past history of HIV prevention
- Discuss the goal of PrEP
- Troubleshoot how to get PrEP (finding a referral to PrEP, adhering to PrEP, consider whether drug use affects PrEP)
- Discuss and review barriers to PrEP and set SMART goals

Topics and Objectives for session

- Assess HIV prevention history
- Understand the goal of PrEP
- Identifying needs (referral to PrEP care, adherence to PrEP, drug use treatment, and relapse prevention,)
- Discuss and review major barriers to treatment (e.g., side effects)
- Make a plan for achieving PrEP goals

Session activity	Suggested script/Probes	Notes
Review	Welcome back. The last time we met, we talked about harm reduction and about MOUD. We discussed a lot about your thoughts about medications. I'm interested in hearing your thoughts about medications today. What harm reduction supplies do you need today? Before we get started today, let's quickly review the areas to make sure that any urgent issue gets addressed in addition to today's topic. 1. MOUD status 2. PrEP status 3. Mental health status 4. Harm reduction status 5. STD test and treat 6. HCV testing and treat	Spend time building rapport with participant. We want the participant to enjoy sessions so they are motivated to come back. Taking notes of what participant tells you **in the Navigator-Client Contact/Encounter form and/or Navigation Plan Document in REDCap** and reviewing details will help with continuity and give participant confidence that you are listening and that you care.

	7. Primary medical care status 8. Housing status 9. Food status 10. Hygiene needs	
Explore HIV prevention	In this session we are going to focus on HIV prevention. When you first came in you indicated that *[choose relevant option*]: • You hadn't seen a doctor for a long time. • You had been to a clinic or seen a doctor but you are not on PrEP, • You are in care with a clinic and a doctor and taking PrEP Has this changed since you the last time I saw you? **Probe:** Since I last saw you, have you seen a doctor? Started PrEP? **If taking PrEP:** Do you have your pills with you today? If yes - I would like to make a note of how many of the pills you've been taking. What days have you forgotten to take your PrEP?	Record current status in **Navigator-Client Contact/Encounter form in REDCap.**
HOW PrEP WORKS:	We will discuss the barriers and challenges to your getting HIV medications to improve your health and staying on them, but before we do this, I would like to briefly go over how HIV works and who PrEP prevents getting HIV. You may know most or all of this information but this information may help you plan your HIV medical care. - HIV is a virus that we can get either through sexual contact or through sharing drug use equipment with others - The best way to prevent HIV is abstaining from sex or always having safe sex with condoms and not sharing drug use equipment - However, this is very hard for many people for many different reasons. - For several years now, we know that certain medications can prevent somebody from getting HIV even if they are exposed to HIV through sex or through sharing drug use equipment. - These medications are called PrEP. There are two approved medications for PrEP. One is called Truvada, and the other one is called Descovy. - The reason for the difference is that all data on safety and effectiveness of Descovy in preventing HIV are from men. - The sooner you can get on PrEP medications and take them as directed the better for your health. Even if you are using drugs or relapse you can	**Reminder:** There is evidence that people who are currently using drugs can be successful and adherent to PrEP.

	take PrEP. Don't stop taking PrEP even if you use drugs. Your risk for HIV is the highest when you are using drugs, so PrEP is especially important during this time.	
REVIEW OF INFORMATION SESSION:	I know we have covered a lot of material. Therefore, let's go over the most important points. Let's do a quiz: 1) Is HIV preventable? Answer (regardless of what they respond): Yes. 2) What ways can someone prevent getting HIV? Answer: Having safe sex or abstaining from sex, not sharing drug use equipment, and by using PrEP. 5) Can you take PrEP if you are currently taking drugs? Answer: Yes there is no reason to postpone PrEP while you are still taking drugs. This is probably when you need it the most. 6) What happens if you stop taking PrEP? Answer: You will be at risk for getting HIV if you have unprotected sex or share drug use equipment.	You can make cards with the quiz questions.
If currently taking PrEP. Assess adherence	Now let's discuss PrEP again. • When was the last time you missed any of your PrEP medications? • In the last month, on about how many days did you miss at least one tablet? You mentioned you are **currently taking PrEP medications.** Can you tell me about times when it was difficult to take your medications? When was the last time you didn't take your medications? What was the reason you did not take medication? How often are they unable or forget to take their medications. There are a lot of strategies to help with medication adherence. What methods do use to help remember to take your medications? It is great that you have some strategies. Next time we meet we will discuss other strategies. [If they cite side effects as a reason for not taking medications] Remember, many of these side effects go away after a while but sometimes your health care provider may recommend a different medication. Discuss these side effects with your doctor. [Assess whether participant needs help communicating with doctor] Next time we talk we will discuss in more detail some strategies to help with medication adherence.	Studies in men who have sex with men suggest that taking PrEP at least 4 times a week is highly protective of HIV. In women, daily adherence (7 days a week) is necessary for protection. It is unknown the dosing requirements to prevent HIV through sharing drug use equipment. Because of that, we recommend dosing every day.
If not on PrEP. Assess	Now let's discuss PrEP again. When thinking about the next few weeks **how important is getting on PrEP to**	

READINESS to start PrEP	**you on a scale from 1 to 10?** 1 being the most important, and 10 being the least important. When thinking about the next few weeks **how confident are you about getting on PrEP on a scale from 1 to 10?** 1 being the most confident, and 10 being the least confident. **If PrEP is a low priority:** Go to next activity on motivational interview **If PrEP is a priority:** Go to next activity on barriers	
Motivational Interview if PrEP is not a priority.	Tell me your thoughts about PrEP. Let's write down the pros and the cons of starting PrEP. What are you concerns about receiving PrEP? Do you think that PrEP would be useful to you? If no, are you concerned that PrEP medications don't work? Are you concerned about your risk of getting HIV at this time? Sometimes risk happens out of the blue. For example, an unexpected sexual event or needing to share injection equipment due to life happening. What experiences do you have that are similar to this? What would be the benefits of your getting on PrEP medications? Thinking about the pros and cons, do you think that you want to get a medical appointment so that you can get PrEP? (if no, would you like to talk to a doctor to find out more about the benefits of PrEP? If the participant says yes, sign appropriate releases and set up visit with PrEP provider.	Use active and reflective listening with the participant. Note whether concerns are structural in nature, or more due to personal circumstances or beliefs. Revisit HIV knowledge activity, if participant does not see benefit of PrEP. These notes will help you to determine which sessions are a priority for participant. Remember the 5 principles of MI: (1) Express empathy through reflective listening; (2) Develop discrepancy between clients' goals or values and their current behavior; (3) Avoid argument and direct confrontation; (4) Adjust to client resistance rather than opposing it directly, also known as "rolling with resistance"; and (5) Support self-efficacy and optimism.
Plan - if willing to consider PrEP Use A-B-Cs to set S-M-A-R-T goals.	Let's go over what you need to bring to the clinic…… *Review Referral Instructions* Let's make a plan for your getting a medical appointment and going to get onto PrEP. When starting or re-starting PrEP is a goal, it only makes sense for any person if it starts with the ABCs. The **A** is for Achievable. Talk about the extent to which getting onto PrEP and all that entails is or is not Achievable for you. The **B** is for Believable. Talk about your thoughts about whether getting onto PrEP and all that entails is or is not believable for you. The **C** is for Committed. Talk about your thoughts on whether getting onto PrEP is or is not something you can be committed to.	Record the outcomes of the ABCs and SMART goal regarding PrEP in the Navigation Plan.

	We start with getting onto or staying on PrEP because by using medications to protect against HIV transmission, you'll have possibilities to change your health toward the better. It is great that you are making a plan. What positive things can you say to yourself to encourage you to go to the clinic?	
Barriers to initiating PrEP – **If not on PrEP**	For all participants who are not currently on PrEP. Probes: What types of things might get in your way of going to the clinic? What kinds of concerns do you have about going to see a PrEP provider? Once you make an appointment are there ways you can stay motivated to go? What about someone reminding you of your appointment? *[PROBLEM SOLVE: Give the participant the cards listing possible barriers to getting on treatment. Ask participant if there are any other barriers that are not listed In survey. If there are create a card (from blank paper) and put into pile of cards*] *EXERCISE: Sort the cards (Section 8.12.1) listing reasons that you are not yet on PrEP. Put them into piles of: not a problem; somewhat of a problem; a big problem. The cards can have symbols to help in the case of reading difficulties.*	Cards for pile sorting will be colored separately into a) Structural barriers that a system navigator can address and b) Barriers related to personal beliefs and circumstances which a navigator can address.
SMART goals	As you think about behaviors you might want to change while you're in this study, any number of goals might come up. Let's start by trying to define one or more PrEP goals using a process called setting SMART goals. S is for ***specific.*** A specific goal is one that has a specific solution. For example, getting onto PrEP is a specific goal and one that we can work on. M is for ***measurable.*** A measurable goal is one that has a measurable outcome. For getting onto PrEP, the measurement can be answered by setting the date you want to have your medication and take the medications. A is for ***achievable/attainable.*** Getting PrEP by the date is achievable. There are measurable ways to show this happens. R is for ***realistic.*** Realistic goals are those that are more than wishes – they are possibilities. PrEP may be unrealistic if you do not have medical insurance or do not have free PrEP medications available to you. T is for ***time-bound.*** Time-bound goals are those that relate to the here and now. Getting and taking PrEP every day for the next three months is time-bound. Now let's think about one or two goals you might want to work on. Let's start with ABCs and use the SMART process to set goals to work on.	Note outcomes of discussion in navigation progress note form.

Plan - if not on PrEP	Let's go over what you need to bring to the clinic… [*Review Referral Instructions*] Let's make a plan for your getting a medical appointment and going to the clinic. Arrange for ways to cover the costs of provider and labs. Make arrangements for transportation. Make arrangements to receive medications. Make arrangements for first dose and ongoing adherence. Anticipate need for refills/lost medications. It is great that you are making a plan. What positive things can you say to yourself to encourage you to go to the clinic?	
Summary	Before the next session, I would like you to think of what are some of your priorities and or goals are for your life at the moment? When thinking about this, we would like you to focus on your health, especially PrEP and your drug use. Your goal or priority might be directly to improve your health through addressing your drug use or getting onto PrEP. Or your goal might be to get healthier to improve your relationships with family or friends or your work opportunities. Please think about your goals and priorities for next time.	Important questions for navigators: Is participant sexually active? Does sexual transmission need to be addressed? (Sexual risk reduction module) Does participant lend or give any injection equipment? (Injecting risk reduction & drug splitting, 9d) Does the participant receive pre-filled needles and/or used needles? (Injecting risk reduction & drug splitting, 9d) Remember the tips for goal setting: C) Use A-B-C to identify goals worth working on right now. D) Use S-M-A-R-T to develop the way to reach your goals. provide rationale for setting goals

8.5 Topic 3: Program Goals and Adherence for Integrated Health Care

KEY POINTS FOR CHAPTER 8, Topic 3

Topic 3 guides discussion about setting program goals and increasing adherence with each of the types of treatment – MOUD, ART/PrEP, harm reduction, STIs, primary care.

- Begin the session by reviewing what has occurred since last session (ART for people living with HIV/AIDS; PrEP for people at risk for HIV/AIDS)
- Check-in on MOUD, ART, PrEP
- Review barriers to getting medical care and set goals
- Use "My Health Map" to identify side effects to MOUD, ART, PrEP to discuss with clinician
- Adherence barriers and facilitators for MOUD, ART, PrEP medications
- naloxone reversal kit – and instructions on how to use it
- Provide harm reduction supplies
- Collect release of information forms to talk with providers/clinicians
- Collect follow-up/contact information
- Start needs assessment: client-centered, goal setting process to start MOUD, ART or PrEP
- Assess access participant safety and make recommendations

Topics and Objectives

- Assess participants' goals, objectives and expectations of the program
- Understand the importance of MOUD, ART or PrEP adherence
  If not currently taking MOUD, HIV medications or PrEP – address drug use and options for drug treatment

Session activity	Suggested Script/Probes	Notes
General Check-in	Do you have any other updates from last week? How are you feeling? How have things been with your relationships with other people? Before we get started today, let's quickly review the areas to make sure that any urgent issue gets addressed in addition to today's topic. 1. MOUD status	Navigators should keep people on task but allow for general check-in each time they meet. Record relevant updates and changes in the Navigator-Client Contact/Encounter form in REDCap to assist consistent follow-up. Update the Navigation Plan Document in REDCap as needed.

	2. PrEP or ART adherence status 3. Mental health status 4. Harm reduction status 5. STD test and treat 6. HCV testing and treat 7. Primary medical care status 8. Housing status 9. Food status 10. Hygiene needs	
Check-In on MOUD	Welcome back. It's good to see you again. The last times we met, we talked about how [HIV medications/PrEP] work, and I got to know you a little better. Let's do a bit of review: **#1 GOALS AND PRIORITIES:** I asked you to think of what are some of your priorities and or goals are for your life at the moment, and what are some things that you would like to accomplish. I asked you to focus on your health, especially HIV and your drug use. **What are your thoughts about these?** **Remind me,** what are some of your goals and priorities? *[if goals/priorities are new/emergent, please add these to the navigation plan document.]* **Let's see.** Is there anything in particular you would like to accomplish in the next weeks? **Probe:** Your goal or priority might be directly to improve your health through addressing some aspect of your drug use or getting onto treatment for HIV or for PrEP. Other goals might be to make steps toward stable housing. Still others could include taking care of your physical or mental health or to improve your relationships with family or friends or to improve your work opportunities. [*Important: Note the participant's main goals in navigator progress note and on the Navigation Plan document in REDCap, then use that information during next session to determine the most appropriate session/module to cover*] MOUD	Provide positive feedback even if homework was not accomplished. During each session discuss the participant's goals regarding MOUD and ARVs for care/PrEP. Discuss the concept of **goal setting** and **breaking larger goals into smaller steps.** For example, to get onto MOUD, individuals may first have to get onto Medicaid or make other arrangements for payment. Then they would talk to friends and acquaintances about what they are doing about MOUD. They could have a goal of talking to three friends/people about their thoughts about getting onto MOUD. Starting MOUD is a major goal, it is best to break this goal down into steps. Some of these steps may involve finding the best place to receive MOUD – or it may involve getting housing situated to support staying on MOUD. As well support programs are available that they may want to have a goal of attending such programs. Other aspects of the goal setting would include **avoiding situations that increase the risk of relapse.** Finding activities that are a substitute for drug use is an important goal. Developing methods of dealing with stress is important, as is finding people with whom to talk if there's a desire to use drugs.

	Let's review what's going on 7with your MOUD care. From our previous meetings, I believe you said that *[identify the correct option from below]:* **(#1)** You had not seen a provider about getting onto MOUD **(#2)** You had seen a provider but were not yet on MOUD **(#3)** You were prescribed MOUD medications but hadn't started taking them **(#4)** You are on MOUD currently Is this still correct? **<u>If category #1 #2 or #3, not on MOUD since last visit:</u>** Now when looking back at the plan we made last time. You were planning to…… *[For example: schedule an appointment; get onto Medicaid; collect the necessary paperwork; go to an intake appointment; fill your prescription for MOUD]* Did you manage to make any progress on that? **If yes,** wonderful. *[Check the Navigation Plan Document and tailor the discussion appropriately]* • Have you seen a doctor about your MOUD? • If no, have you made an appointment? • Are you currently on MOUD? [*Additional Probes*] What progress did you make?....Can you tell me about your experiences?....Where you prescribed MOUD*?* ***If yes,****.. [Move to activity "if on MOUD - Adherence"]* ***If no,*** *lets discuss the next steps to get you into MOUD…[Go over the cards about barriers to get to MOUD]….* **If no,** don't worry, we are pleased that you decided to return to the study and recognize that getting MOUD is a complicated process. Ok, let's talk about the challenges you faced in trying to meet your goals. It can be helpful to list barriers and then plans to overcome them. For category #1 – *[Go over the cards about barriers to get onto MOUD]… [Make a plan for next steps]…Move to activity "if NOT on [MOUD] – Addressing Drug Use"]*	Overall, the sessions aim to break down the <u>goal setting</u> process into manageable steps, acknowledge and reward them for accomplishing these steps, and provide skills training and social support to achieve these steps. An important aspect of <u>goal setting</u> is encouragement and verbal praise for all the small steps in achieving the goal. For example, if the participant has the goal of reducing drug use, one step would be to think about how they could avoid drug using friends. The navigator should encourage them for such a step, but these steps should be based on the participants' own goals and the steps that they decide to take to achieve these goals. NOTE CURRENT MOUD STATUS IN THE NAVIGATION PLAN Document in REDCap]

For category #2 - When is your next appointment? *[Make a plan with participant to get to it – involving systems navigationr when necessary]… Move to activity "if NOT on [MOUD] – Addressing Drug Use"]*

For category #3 & #4 - *[Move to activity "if on [PrEP/ARVs] - Adherence"]*

If option 4, on [PrEP/ARVs] **during last visit.** Did you remember to take your pills today?

[*Move to activity "if on [PrEP/ARVs] - Adherence*"]

If no, can you remember what pills you are taking? *[Show participant card of regimes and ask them to identify what they are on] [Move to activity "if on [PrEP/ARVs] - Adherence"]*

PrEP/ARVs

Let's review what's going on with your PrEP/ARV care. From our previous meetings, I believe you said that *[identify the correct option from below]:*

(#1) You had not seen a medical provider about your [HIV/PrEP]

(#2) You had seen a provider but were not put on [HIV medications/PrEP]

(#3) You were prescribed medications but hadn't started taking them

(#4) You were on [HIV medications/PrEP]

Is this still correct?

If category #1 to #3, not on ARVs/PrEP during last visit: Now when looking back at the plan we made last time. You were planning to…… *[For example: schedule an appointment; collect the necessary paperwork; go to a [HIV/PrEP] medical appointment; fill your prescription for ARVs/PrEP]* Did you manage to make any progress on that?

If yes, *wonderful.*

[*Check the Navigation Plan Document and tailor the discussion appropriately]*

- Have you seen a doctor about your [PrEP/HIV treatment]?
- If no, have you made an appointment?

	• Are you currently on ART/PrEP? [*Additional Probes]* What progress did you make?....Can you tell me about your experiences?....Where you prescribed [*PrEP/ARVs*]? **If yes,**.. [*Move to activity "if on [PrEP/ARVs - Adherence"]* **If no,** lets discuss the next steps to get you into treatment…[*Go over the cards about barriers to get to the clinic*]….[*assess need for systems navigation*]…[*Move to activity "if NOT on [PrEP/ARVs] – Addressing Drug Use*"] **If no,** don't worry, we are pleased that you decided to return to the project and that getting medical care is a complicated process. Ok, let's talk about the challenges you faced in trying to meet your goals. It can be helpful to list barriers and then plans to overcome them. For category #1 – [*Go over the cards about barriers to get to the clinic*]… [*Make a plan for next steps*]…*Move to activity "if NOT on [PrEP/ARVs] – Addressing Drug Use"]* For category #2 - When is your next appointment? [*Make a plan with participant to get to it – involving systems navigation when necessary*]… *Move to activity "if NOT on [PrEP/ARVs] – Addressing Drug Use"]* *For category #3 & #4 - [Move to activity "if on [PrEP/ARVs] - Adherence"]* ***If option 4, on** [PrEP/ARVs] **during last visit.** Did you remember to take your pills today? *[Move to activity "if on [PrEP/ARVs] - Adherence"]* **If no,** can you remember what pills you are taking? *[show participant card of regimes and ask them to identify what they are on] [Move to activity "if on [PrEP/ARVs] - Adherence"]*	
If On MOUD		

ACTIVITY #1 Adherence	*Discuss the medications for MOUD, ART and PrEP:* There are three MOUDs. Oral Naltrexone and Injection Vivitrol. This is a medication that blocks all opioids once on board. That means you won't feel high if you take opioids while these medications are on board. To take this MOUD, one has to be clear of opioids for at least 7 days (10-14 days is preferable). There are some "rapid induction" strategies that are available, but still it is not unusual for most of these to take about 4-5 days. Once onto oral naltrexone, most providers would prefer to then place a Vivitrol injection. This allows for 3-4 weeks of complete blockade of opioids. What this means is that if you use heroin or other opioids, you won't feel anything. The problem with this medication is that people often stop taking it – and usually not telling their provider. This can be dangerous, as people overdose and some number will die if they inject themselves with their usual dose of opioids after they have been drug free for a while and the naltrexone or Vivitrol has worn off. That's because people lose their tolerance to opioids after a period of non-use. Methadone is a different medication that completely substitutes for heroin and other opioids. Some people prefer methadone as it can hold people well – as people find the dose that works for them (i.e., the dose that stops supplemental use of opioids), most do not supplement their doses. Methadone is available only in narcotic treatment programs and we will help you with referrals to one near where you live if you prefer methadone. Buprenorphine is the third option for MOUD. It can be prescribed by outpatient doctors and nurse practitioners. It is a partial agonist, which means it works both as an agonist like methadone to block opioid withdrawal – while also providing a ceiling effect, which blocks the ability to get high (and also blocks respiratory depression thereby preventing overdose) when people use supplemental opioids when on buprenorphine - like naltrexone does. Buprenorphine is available using oral methods and we will help you to get access to buprenorphine while you're in this program. While all three medications work, we would recommend strongly seeking buprenorphine or methadone medications. Both require daily medication taking, but the agonist effects of both medications really help people	For the adherence sessions for those who are reporting high levels of medication adherence we may want to ask them to anticipate events that may impede adherence. Some common events are change in routine, such as staying out late, traveling, and not feeling well. Sometimes participants may forget to take medications on time. If they are taking it twice a day (morning and night, the first dose can be taken until mid-day). For once a day if they forget in the morning they can take up until night. If they take at night then they can take the following morning The main message for side-effects is that most of them go away after a week or two for serious side effects see health care provider immediately. Also consult with health care provider about any side effects. For participants on methadone or buprenorphine their dose may need to be adjusted if they are on ARV. They should tell their methadone or buprenorphine health care provider that they are on ART. There are no interactions with PrEP.

	over the long term to avoid lapse or full relapse to opioids. If you are not on MOUD, ART or PrEP, what has made it difficult for you to get onto these medications? ***If client missed medications*** When was the last time you missed any of your MOUD doses? • Within the past week • 1-2 weeks ago • 3-4 weeks ago • 1-3 months ago • Never In the last month, on about how many days did you miss at least one dose of medication? __ __ days [*Record on progress notes and make a notation of good/not so good adherence on the Navigation Plan Document*] Now let's discuss whether you missed medications for ART or PrEP [*if client missed medications*] When was the last time you missed any of your doses for ART or PrEP? • Within the past week • 1-2 weeks ago • 3-4 weeks ago • 1-3 months ago • Never In the last month, on about how many days did you miss at least one dose of medication for ART or PrEP? __ __ days [Record on progress notes and make a notation of good/not so good adherence on the Navigation Plan Document] ADHERENCE PLAN: [*Work with client on developing an adherence plan to MOUD, ART or PrEP. Develop a plan of when the client will take the medication.* *Discuss factors that can help remind the client when to take the medication. This often is correlating medications with daily ablutions. Brush your teeth and take your MOUD, ART, PrEP.* *Work out a detailed plan for when MOUD, ART or PrEP will be taken. Discuss impediments to the plan. What happens if they travel (especially important for methadone)? Emphasize that if the client forgets to take the medication the client should resume their medication as quickly as possible. Acknowledge that it may be difficult to take medications as directed. Discuss barriers*	[Go through **My Health Map** together (see further down this section)]

	and challenges, and problem solve the solution. Discuss the importance of medical appointments even if the client is feeling good. Emphasize that even if the client is using drugs they should stay on their medication. Their medications will be helpful even if they are using. They should also go to their medical appointments when they are using drugs. Drug use is difficult to stop and to stay stopped. You must be in touch with your body so you're clear on what you are experiencing and can describe it to your doctor. This leads us to the two most important rules: Rule #1: Tell your clinician your responses to MOUD and ART or PrEP. If you're having any symptom appear, change, disappear or reappear, tell your clinician what's up. Write it down so you do not forget. Rule #2: Always apply Rule #1. It can be helpful to write down what happens to you in this program so you can share your experiences with your clinicians. Keeping a daily record as you experience symptoms is better than trying to remember later. Here we have a My Health Map which is a simple way to track what you're feeling by drawing on a silhouette of a body and answering a few questions. You can use copies of the map to keep track of your symptoms over time. Or use a personal health record, which you can use to record many aspects of your MOUD, ART or PrEP. The key things to report to your doctor about any given symptom are these: Frequency: How often do you experience it? Is it something you only notice a couple of times a month? Multiple times every day? All day, every day? Intensity: Is this a minor problem or something severe? If you rank it on a scale from one to five, where does it fall? If the intensity varies, noting this in detail with each occurrence can be part of the daily record you keep. Duration: Is this a problem that lasts only a few minutes or does it continue over many hours or days? When it happens, does it come and go, or does it continue without a break? Pattern: Can you identify any pattern related to when and why the symptom occurs? Does it only happen at a certain time of day? Does it occur shortly after you take your MOUD, ART or PrEP? If it's a stomach or gastrointestinal symptom, is there any pattern related to	[Sites can come up with common questions that can be put in as probes.]

	eating particular foods or beverages? Does your level of physical activity affect it? Does it only occur at night? What about CRAVINGS? Cravings are urges to want to use drugs (opioids, stimulants or both together). Cravings are body states that are much like hunger and emotional feelings – in that cravings are signals from the brain to motivate behaviors (find food, get and use drugs). Cravings are signals that MOUD dose or type of medication is not right for managing the opioid use disorder. Talk with your provider about cravings as soon as you feel them to be able to make changes to your MOUD. Cravings can be for more than opioids. Severe cravings for cocaine and/or methamphetamine happen when people use these drugs frequently and at high doses. As with cravings for opioids, cravings for cocaine or methamphetamine are brain symptoms that are like feelings – they just happen. It is possible, though, to block cravings by thought-stopping, doing exercise or "urge surfing" – just waiting for cravings to pass. But without doing something to stop cravings, they frequently grow and proceed until use happens. Understanding the sequence of: **trigger → thought → craving → use** is helpful. You can ignore triggers, block/stop thoughts and "surf" cravings or urges. Failure to do anything to stop the process, though, often ends with use. Treatment: Is there anything you have found that helps? Perhaps most importantly, tell your doctor if a side effect is adversely affecting your life in important ways. If you have constipation or diarrhea so often it keeps you from leaving the house, that's important. This is true for the whole list of symptoms that can cause undesirable changes in your life.	
Adherence Barrier – Forgetting and Refills	FORGETTING Many people report that they sometimes forget to take their medication. Others don't like to take HIV drugs when using opioids, cocaine and methamphetamine. Remember to take your meds – *especially* when drug use is active. Let's talk about some strategies that can help you remember. - *Discuss what might be helpful for addressing medication adherence. It might help to provide a*	

	pill box. If so, show how the pill box works for medications OTHER THAN buprenorphine. - *Discuss where the participant will store their medications and how they prevent medications from getting lost or stolen. In particular discuss where buprenorphine tablets or film will be stored to prevent loss/theft.* - *If participant has unstable housing, discuss possibilities for storing MOUD, ART or PrEP (if they are taking oral daily product)* • *Develop a plan of when and where the client will take the medication. Developing a routine. Is there a time that participant could take medication at the same time every day? Discuss how to make medication an activity when teeth brushing, when having meals, when drinking morning coffee and other types of daily, predictable behaviors.* • *Ask if they have a cell phone with an alarm clock or another alarm clock that they could use. Teach participant how to set up reminders. [Site should explore the best reminders e.g., texts, automated emails, google calendar reminders, cell phone alarms…]* • *Discuss impediments to the plan. What happens if they go away for a few days?* *Emphasize that if the participant forgets to take the medication the participant should resume their medication as quickly as possible. If participant remembers on the day that they forgot their dose, tell them to take missed dose before bedtime. If participant remembers on a following day, tell them to just start taking doses as normal (do not double up on doses).* REFILLS: *Another factor that may impact adherence is not obtaining medication refills on time. Help the participant plan and problem solve for obtaining refills at the pharmacy.* • *Discuss the importance of medical appointments even if the participant is feeling well. Emphasize that even if the participant is using drugs it is best to stay on their medications. Their medications will be helpful even if they are using. Participants should also go to their medical appointments when they are using drugs. Have a discussion with participants regarding whether or not they want to tell their doctor about drug use. This is about the level of trust with the doctor not to*	

	"fire" the patient when finding out about drug use. • *Medical appointments: Suggest to the participant that it can be useful to think about questions to ask during the medical visit and write these questions down. It is important to tell your medical provider about any side effects or other medical problems. Also discuss potential barriers to attending a medical appointment. There are opportunities for telehealth that were not available prior to COVID-19.*	
Adherence Barrier- Common Side Effects	***Share with participants the common side effects to MOUD are related to the gastrointestinal system***. *When people are in withdrawal from opioids, upset tummy (including vomiting) is common. This is usually accompanied by diarrhea. These common symptoms can also signal impending relapse – especially when on MOUD. Over-the-counter medications, like Pepto (stomach upset) and Immodium (anti diarrheal) are commonly used to manage gastrointestinal symptoms during withdrawal.* *Side effects for MOUD also involve largely gastrointestinal effects. The most common of these is constipation (all opioids are constipating).* *Headache is also a frequent side effect to opioid withdrawal and to antagonist MOUD (Vivitrol, naltrexone, narcan). This is an example of hyperalgesia (sensitivity to pain linked to withdrawal from opioids). These headaches (and other general pains) respond to over-the-counter ibuprofen and acetaminophen for many, but some report relief only from opioids.*	
INFORMATION REVIEW AND CLOSE OUT	INFORMATION OBTAINED TODAY: I would like to review your information and some of things we have talked about. *[With Participant, review the following topics that you have already covered]:* 1. MOUD and [PrEP/HIV] medical care 2. MOUD and [PrEP/HIV] adherence status 3. Drug treatment status 4. Current Drug Use? 5. Currently sexually active? 6. Current levels of alcohol use? 7. Housing 8. STDs and treatment 9. Need for harm reduction 10. Primary care 11. Mental health/depression	
Adherence Barrier- Common	*[Review site common side effects with participant. Detailed information on different medications and their*	**PrEP** Truvada

Side Effects of ART and PrEP	*side effects are in below in this section: "**Common ART Side Effects**" and "**Side Effects of PrEP**".]*	-Gastrointestinal (first month) -Kidney (long term) -Bone (long-term) -Headache -Fatigue <u>Descovy</u> -Gastrointestinal (first month) -Headache -Fatigue -Weight Gain -Changes in cholesterol **ARVs** - *See below "**Common ART Side Effects**"* **MOUD** - *See below "**Side Effects of MOUD**"*
INFORMATION REVIEW AND CLOSE OUT	INFORMATION OBTAINED TODAY: I would like to review your information and some of things we have talked about today. *With Participant, review the following topics on the Navigation Plan Document:* 1. [PrEP/HIV] medical care 2. [PrEP/HIV] adherence status 3. Drug treatment status 4. Current Drug Use? 5. Currently sexually active? 6. Current levels of alcohol use?	
SUMMARY	*Verbally reward the participant for coming in, and tell them they are doing a great job as adherence is very difficult* Example: You are taking important steps to improve your health. *Summarize the barriers identified, the participant's goals for HIV treatment and treatment adherence. The summary should be sufficiently detailed that another navigator can review prior to the next session and be able to continue the intervention without repeating prior materials.*	

My Health Map

1. Name

2. Date

3. How am I feeling?

- Choose a number from 1 to 10 to describe how you feel: 1 = feeling bad 10 = feeling great
- Think about your body. What feels better or worse physically? Do you have any specific symptoms or pain? Draw this on the body: Mark these spots and add words or symbols to describe what you feel and where.
- Think about your mood. Are you feeling more happy or sad these days? Draw this on the body: Mark these spots and add words or symbols to describe how you have been feeling.

4. Encouraged by/Discouraged by

- Write down what have you done this week that made you feel encouraged about your health and wellness. For example, you may have eaten a healthy meal, taken your medication on time, attended a support group or exercised.
- Write down what happened this week that made you feel discouraged about your health and wellness. For example, you may have missed a dose of your medication, had unpleasant side effects or did not exercise.

5. Life happenings

- Think about any important happenings in your life this week. Write down what you feel hopeful about and what you are worried about.

6. Medications and other substances (herbal therapies, vitamins, marijuana, alcohol, etc.)

- List any medications or other substances you are currently taking or want to take.
- Write down whether you missed any doses this week.
- Write down any challenges with taking your medications. For example, you may have had difficulty remembering to take them or were unsure whether to take them with food or on an empty stomach.
- List fatigue, nausea, depression or other side effects you had.

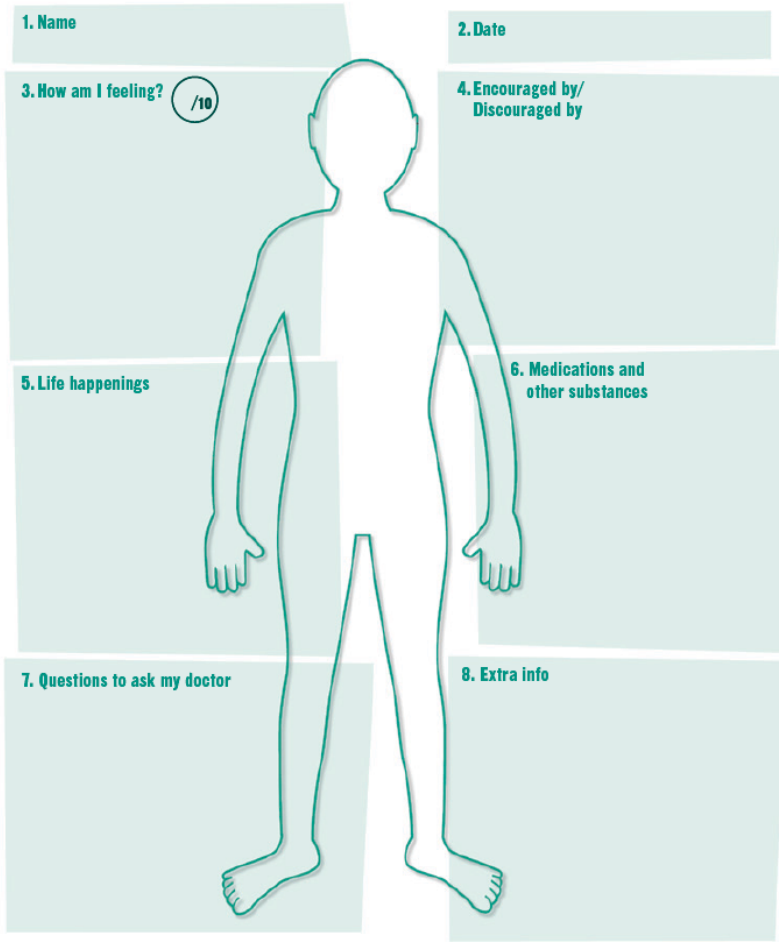
7. Questions to ask my doctor

- Write down any question you would like to ask your doctor. For example, you might want to know how to deal with side effects, get test results, or find out about your reproductive health.

8. Extra info

- Write down any extra information. This information could include, for example, your CD4 count or viral load.

My Health Map



Common ART Side Effects

Medications for HIV, also called antiretroviral therapy (ART), has evolved dramatically since the original regimens in the 1990s. Now, most patients can be typically managed with a one-pill, once-a-day regimen. Newer regimens also have the advantage of having little to no side effects or toxicities than older regimens have. At the beginning of starting HIV therapy, especially if HIV has been untreated for many years and T cell counts are very low, many perceived side effects may actually be related to unmasking opportunistic infections or the immune response recovering – a syndrome called immune reconstitution syndrome (IRIS). The key is to have contact with the treatment team and never discontinue the medication. There are over 20 medications for HIV and it is impossible to concisely go over every possible side effect for each specific regimen. Different HIV medicines can cause different side effects. Side effects from newer HIV medicines typicall last only a few days or weeks. For example, nausea, fatigue, and trouble sleeping are some short-term side effects of HIV medicines. Please the following resource for specific side effects of each medication: https://clinicalinfo.hiv.gov/en/guidelines/adult-and-adolescent-arv/adverse-effects-antiretroviral-agents

Nausea

All medications can cause nausea, though some (for example, protease inhibitors) are more likely to cause this problem than others. If the nausea or appetite loss you are experienced just after beginning the new medication, the drug is a possible cause of the symptoms. If the problem doesn't improve over the next few weeks, counsel to visit the medical provider to talk about it. In many cases, these side effects diminish or disappear after a short time on the medication, so it may be worthwhile to stick it out rather than immediately stopping or switching drugs.

Another factor to consider is the timing of the medication. The medical practitioner or pharmacist may determine whether taking the medication at a different time of day could help. Some drugs cause less nausea when taken with a full meal; others should be taken on an empty stomach.

Diarrhea

Diarrhea is another common side effect of ART. In patients with OUD this is complicated as it can also be cause due to withdrawal. HIV itself damages the gut by attacking immune cells there. If diarrhea is frequent, watery, lasts for more than a couple of days or contains blood is important to consult the medical provider. Many HIV medications are a common cause of diarrhea, gas and bloating. Other causes include functional bowel disease (irritable bowel syndrome and inflammatory bowel disease), lactose intolerance or gluten sensitivity. Infections, including bacterial and parasitic infections, can also cause diarrhea. These causes can be dangerous and lead to severe health problems, such as wasting.

It is crucial to prevent dehydration when a patient is suffering from diarrhea. As long as diarrhea continues, recommend that the patient consumes plenty of calories and drink plenty of healthy fluids, such as water, herbal teas, and broths. Sugary fruit juices or soda should be avoided. Minimum fluid consumption should be at least 1.5 litres of fluids every day, and more if the diarrhea is ongoing and causing substantial fluid loss.

Headache

Headaches can sometimes be a side effect of ART. In some cases, headaches will only occur during the beginning of therapy and will gradually disappear over the next few weeks. In other cases, they may remain long-term, and the only solution may be to switch drugs. Medications should be particularly suspected as a cause of headaches when a new medication was recently been started. Note, however, that such reactions can occur even after months of using a particular drug. If the headache is severe, persistent, and associated with changes in the patient's mental status or behavior, the patient should be referred to the emergency room as the patient may be experiencing an infection of the central nervous system.

Vivid dreams

Sleep problems are possible side effects of certain antiretroviral drugs. Of all the antiretroviral drugs now the most likely to cause severe sleep problems was the non-nucleoside analogue efavirenz (Sustiva, and in Atripla). This medication can cause insomnia, vivid dreams and nightmares. For some people, the nightmares can be intense and terrifying and can cause repeated wakening in the night. Luckily, this medication is rarely used, but if it is, this may be a good reason to switch to a newer regimen.

Comments on Integrase Inhibitor containing regimens

In the U.S., as of 2020, all first line regimens contain an integrase inhibitor (bictegravir, dolutegravir, or raltegravir). Integrase inhibitor containing regimens are generally well tolerated. In clinical trials, the most commonly reported adverse reactions of any grade with an incidence above 5% included diarrhea, nausea, and headache. Some studies have shown greater weight gain among people initiating INSTI-based regimens.

Side Effects of PrEP

Two FDA approved medications exist for pre-exposure prophylaxis (PrEP) of HIV: tenofovir disoproxil fumurate (TDF)/emtricitabine (FTC) [Truvada], and tenofovir alafenamide (TAF)/emtricitabine (FTC) [Descovy]. Their differences are mainly in their side effect profile. During the course of the trial, a third medication may be approved for PrEP: Cabotegravir. If and when this occurs, this chapter will be updated to include information regarding cabotegravir.

Tenofovir disoproxil fumarate (TDF)/emtricitabine [Truvada]

Gastrointestinal

During the first month after starting TDF/FTC, gastrointestinal symptoms are common. The most typical are nausea and diarrhea. These usually last only a few weeks, and the best recommendation is to continue the medications. Some PrEP users report, taking the tablet during or soon after a meal can reduce the nausea and vomiting.

Kidney health

While uncommon, TDF/FTC can also affect kidney health progressively decreasing kidney function. There are typically no symptoms of this until late stages of disease. During treatment with TDF/FTC, doctors monitor for evidence in changes of kidney function in the blood and urine. There is no specific treatment other than discontinuing the drug, and exploring other options for HIV prophylaxis.

Loss of bone density

Also rare, but important to note, is that TDF/FTC may cause some loss of bone density, which can lead to a higher chance of bone fractures. Again, there is no specific symptoms of loss of bone density until late stages of the disease. It is unclear when it is best to start monitoring bone mineral density or how often to do it, or if supplementation with vitamin D or calcium decrease the risk of decreased bone mineral density. If there is sufficient concern from the medical practitioner, a FRAX score can be calculated or a DEXA scan obtained.

Tenofovir alafenamide (TAF)/emtricitabine (FTC) [Descovy]

TAF/FTC is a newer formulation that does not have the side effects related to kidney health or loss of bone density as those caused by TDF/FTC. TAF/FTC may cause similar gastrointestinal side effects to TDF/FTC at after starting the medication. But again, these symptoms typically subside during the first month after starting the medication.

Metabolic

Minor issues related to TAF/FTC include a small degree of weight gain and small increases in LDL cholesterol and triglycerides.

Side Effects of MOUD

Methadone

Dose related effects: Too low

Especially at the beginning of treatment with methadone withdrawal signs may be an issue. These signs and symptoms may occur when the methadone dose starts wearing off. Everybody has different tolerances to opioids and patients metabolize methadone differently. There is no way to know the exact dose a patient should start on. The rule in methadone is to *start low, and go slow,* as too high a dose or increasing the dose to fast could lead to overdose. Signs of methadone withdrawal (or that of any other opioid) include runny nose, yawning, high temperature but feeling cold and sweating with goosebumps, irritability and aggression, loss of appetite, nausea and vomiting, abdominal cramps and diarrhea, tremors, muscle spasms and jerking, back and joint aches, and cravings. If these are occurring, a physician may increase the methadone dose every 5 to 7 days until the withdrawal symptoms and cravings go away.

Dose related effects: Too high

On the other end, if the dose is too high, severe side effects and even death may occur. If the dose is too high symptoms like sleepiness may occur. This is especially prominent at the peak of the methadone dose, which around 4 hours after taking the dose. Patient may call this *nodding off*. A more severe side effect is an overdose. The signs of overdose (specific to any opioid) are depressed breathing, stupor or coma. Immediately call an ambulance, and get your naloxone kit. If oxygen is available, this should be provided, and naloxone administered without delay.

Gastrointestinal

The most common side effect is constipation and sometimes bloating. This is common with the use of any opioid including illicit opioids like heroin and fentanyl. Recommendations include increasing water intake, eating a balanced diet which includes high amounts of fiber, exercise. Patients should generally avoid laxatives, but can use over the counter medications like stool softners (ducosate, Dulcolax) or magnesium. If despite these recommendations, constipation is still an issue and impacts the patient's quality of life, doctors can prescribe specific medications that may also help.

Cardiac

Methadone can lead to an alteration in the heart's rhythm that can be potentially fatal. Specifically, methadone prolongs a segment of an electrocardiogram called the QT. A prolonged QT can then lead to a specific type of arrhythmia called *torsades de pointes.* Although there is no specific methadone dose at which this can happen, many doctors may start monitoring electrocardiograms at methadone doses above 100 mg. The risk of this arrhythmia is increased when abnormalities in patient's electrolytes (potassium or magnesium) are present. Signs of electrolyte abnormalities are not specific, but some of the following may help to identify electrolyte abnormalities. Signs of low potassium levels like muscle pain or weakness, muscle cramps, or a heartbeat that does not feel normal. Signs of low magnesium levels like mood changes, muscle pain or weakness, muscle cramps or spasms, seizures, shakiness, not hungry, very bad upset stomach or throwing up, or a heartbeat that does not feel normal. Symptoms of an actual arrhythmia require a patient to go to the emergency room and include loss of consciousness, dizziness, chest pain, palpitations, shortness of breath, among others.

Pain

Methadone is an opioid, and as such is expected to treat pain. Methadone has long acting effects on withdrawal and cravings (expected around 24 hours), however, methadone only treats pain for 8 to up to 12 hours. After this period pain returns until the next methadone dose. This is a problem for patients with chronic pain syndromes. Ideally in this situation, the methadone dose could be split in half providing adequate pain relief and treatment of OUD over 24 hours. Sadly, the State and Federal regulations make this difficult, and government exceptions and approvals are needed for this to happen. Alternative approaches include using over the counter non-opioid pain relievers (acetaminophen or naproxen) or referring to the patient's doctor for better management of pain. Prescription options include medications to treat neuropathic pain (duloxetine, gabapentin, pregabalin) or even short-acting opioids.

Metabolic

Methadone (like other opioids) can alter sex hormones. This may lead to decreased decreased libido. This can be a big problem for a patients' quality of life due to issues in their sexual relationships, and in turn, lead to patients leaving MOUD. The most important thing to do is, let the patient know that this is a side effect, and that if it is a problem affecting his/her/they quality of life, he/she/they may ask their doctor to be screened for alterations in their sexual hormones, and treatment may improve their symptoms. The other side effect from changes in a patients' sexual hormones is that over time these sexual hormones are important for bone density. Patients who have used illicit opioids for many years, but also MOUD, may develop premature osteoporosis. Screening for osteoporosis is likely of benefit to people with OUD, although, to our knowledge, there is no consensus on when to start screening or how often to do it.

Pregnancy

Menses tend to become regular after transitioning from short acting opioids (heroin or fentanyl) to long acting opioids like (methadone or buprenorphine). With this, pregnancy is not uncommon for women after initiating methadone. It is unclear if this is due to anything related to the medication, or more likely, due to changes in the patients' behavior. Due to this, it is important for women who start MOUD to also be offered an appropriate method of birth control. If pregnant, methadone is safe and poses no risk of congenital malformations to the fetus. In fact, methadone is much safer for the fetus, than that of experiencing withdrawal from tapering off methadone or the risk of relapsing with illicit opioids. During pregnancy, methadone is metabolized much more rapidly, and likely requires, twice a day dosing. At delivery, there is a risk of neonatal abstinence syndrome to the newborn, and this can be readily treated by neonatologists or pediatricians.

Interactions with other medications

Methadone has many interactions with other medications. Doctors should be aware of any medications a patient may be on, or that a patient gets prescribed while on methadone.

Buprenorphine

Many of the side effects of methadone are also applicable to buprenorphine, yet important differences apply. Most of the following is applicable to the sublingual versions of buprenorphine.

Dose related effects: Too low

Especially at the beginning of treatment with buprenorphine withdrawal signs may be an issue. These signs and symptoms may occur when the buprenorphine dose starts wearing off. Everybody has different tolerances to opioids and patients metabolize methadone differently. There is no way to know the exact dose a patient should start on. These symptoms may occur during the first few day of starting buprenorphine (induction) but should not be an issue once an adequate dose has been achieved. Signs of buprenorphine withdrawal (or that of any other opioid) include runny nose, yawning, high temperature but feeling cold and sweating with goosebumps, irritability and aggression, loss of appetite, nausea and vomiting, abdominal cramps and diarrhea, tremors, muscle spasms and jerking, back and joint aches, and cravings.

Dose related effects: Too high

Buprenorphine due to its particular pharmacology, does NOT have a risk for overdose on its own. After 24 mg (some say 32 mg), buprenorphine reaches a ceiling on its effects. This means that if a person takes more than this in a single day there are no more effects, and thus no risk of overdose. However, overdose on buprenorphine do occur when combined with other medications or substances, particularly with benzodiazepines (Xanax, Ativan, Valium) or alcohol.

Gastrointestinal

The most common side effect is constipation and sometimes bloating. This is common with the use of any opioid including illicit opioids like heroin and fentanyl. Recommendations include increasing water intake, eating a balanced diet which includes high amounts of fiber, exercise. Patients should generally avoid laxatives, but can use

over the counter medications like stool softners (ducosate, Dulcolax) or magnesium. If despite these recommendations, constipation is still an issue and impacts the patient's quality of life, doctors can prescribe specific medications that may also help.

Cardiac

Buprenorphine has little to no effect on heart conduction. Thus, there is little to no risk for QT prolongation and *torsades de pointes*. There is a theoretical risk for QT prolongation in combination with other medications, but this is also rare.

Pain

Buprenorphine is an opioid, and as such is expected to treat pain. Similar to methadone, buprenorphine has long acting effects on withdrawal and cravings (expected around 24 hours), however again, buprenorphine only treats pain for 8 to up to 12 hours. After this period pain returns until the next buprenorphine dose. This is a problem for patients with chronic pain syndromes. Ideally in this situation, the buprenorphine dose could be split in half providing adequate pain relief and treatment of OUD over 24 hours. This is much easier with buprenorphine as the patient controls his/her/their own dose. Additional approaches include using over the counter non-opioid pain relievers (acetaminophen or naproxen) or referring to the patient's doctor for better management of pain.

Metabolic

Buprenorphine (like other opioids) can alter sex hormones, although much less than methadone. This may lead to decreased decreased libido. This can be a big problem for a patients' quality of life due to issues in their sexual relationships, and in turn, lead to patients leaving MOUD. The most important thing to do is, let the patient know that this is a side effect, and that if it is a problem affecting his/her/they quality of life, he/she/they may ask their doctor to be screened for alterations in their sexual hormones, and treatment may improve their symptoms. Related to bone health, buprenorphine does not appear to lead to premature osteoporosis like other opioids may lead to.

Pregnancy

Menses tend to become regular after transitioning from short acting opioids (heroin or fentanyl) to long acting opioids like (methadone or buprenorphine). With this, pregnancy is not uncommon for women after initiating buprenorphine. It is unclear if this is due to anything related to the medication, or more likely, due to changes in the patients' behavior. Due to this, it is important for women who start MOUD to also be offered an appropriate method of birth control. If pregnant, there is a theoretical concern of the naloxone in the buprenorphine/naloxone product. Buprenorphine alone is safe and poses no risk of congenital malformations to the fetus. Thus, during pregnancy the buprenorphine monoproduct is preferred. As with methadone, buprenorphine is much safer for the fetus, than that of experiencing withdrawal from tapering off buprenorphine or the risk of relapsing with illicit opioids. There is a risk of neonatal abstinence syndrome, and this can be readily treated by neonatologists or pediatricians.

Naltrexone

Naltrexone is available in an oral and injectable extended release form. The extended release from is the only one approved for treatment of OUD. Common side effects of naltrexone include nausea, diarrhea, dizziness, headache, and insomnia. Typically, these annoying but not dangerous side effects appear early in treatment and tend to dissipate, so that often patients can be coached through them. If necessary, ancillary medications, such as anti-emetics, can be prescribed.

Liver function abnormalities

Oral naltrexone has a boxed warning for hepatic injury. However, in practice no serious or lethal hepatic toxicity has been observed. The extended release naltrexone does not have this boxed warning. Nevertheless, it is standard practice to obtain liver function tests prior to and during treatment. Should liver transaminases show a marked upward trend (5-10 times the upper limit of normal) in the absence of other potential etiologies, the provider should consider whether or not to continue naltrexone.

Psychiatric

Depression and suicidal ideation have also been reported. These psychiatric adverse events should be handled as they would for any other psychiatric patient by initiating antidepressants and/or psychotherapy for depression and potential hospitalization for suicidal ideation. If naltrexone is deemed causative, it clearly should be discontinued.

Overdose

Overdose is not a direct side effect of naltrexone. However, multiple studies have shown an increased risk of overdose after discontinuing long acting naltrexone. As naltrexone has no opioid agonist properties, tolerance to opioids rapidly decreases while on naltrexone. If a patient subsequently uses opioids at doses he/she/they was accustomed to prior to naltrexone therapy, the opioid dose may rapidly lead to overdose. All patients should be counseled on this, told that if relapse ever occurs to use a very small dose as tolerance has disappeared, and be provided with a naloxone for opioid reversal.

Injectable products: Buprenorphine and Naltrexone

The extended release injectable preparations have the additional potential side effect of injection site reactions. Mild injection site reactions can usually be managed with palliative measures like hot compresses and over-the-counter analgesics. In rare severe cases, antibiotics or minor surgical intervention might be necessary. Injection site reactions appear to be related to injection technique.

8.6 Topic 4: Housing, Food Security and Hygiene Module

KEY POINTS FOR CHAPTER 8, Topic 4

Topic 4 guides a session that discusses needs for stable housing and how to go about arranging this. Discusses ways to manage needs for food security and hygiene

- Begin the session by reviewing what has occurred since last session
- Check-in on MOUD, ART, PrEP
- Review housing status and plans
- Do case management and system navigation to arrange stable housing
- Introduce topic of food security
- Introduce topic of personal hygiene

Topics and Objectives:

- Develop a housing plan to move from unstable to stable housing
- Develop a housing plan that emphasizes safety and tolerance
- Develop a plan that addresses food security
- Develop a plan for personal hygiene

Module activity	Suggested script/Probes	Notes
Check-In	Welcome back. It's good to see you again. The last time we met individually, we *[SUMMARIZE LAST SESSION], then:* - Review goals and priorities regarding MOUD, ART and PrEP - Review importance of adherence to medications - Ask what the participant was able to accomplish - Congratulate participant on successes - Re-assure participant on any challenges faced - Problem-solve on how to accomplish next step in goals and objectives	Provide positive feedback for any progress. Find some success and reinforce it.
Goals and Priorities	Before we get started today, let's quickly review the areas to make sure that any urgent issue gets addressed in addition to today's topic. 1. MOUD status	During each module discuss the patient's goals. Discuss the concept of **goal setting** and **breaking larger goals into smaller steps**. Overall the modules aim to break down the goal setting process into

	2. PrEP or ART adherence status 3. Mental health status 4. Harm reduction status 5. STD test and treat 6. HCV testing and treat 7. Primary medical care status 8. Housing status 9. Food status 10. Hygiene needs	manageable steps, acknowledge and reward them for accomplishing these steps, and provide skills training and social support to achieve these steps. An important aspect of goal setting is rewards for all the small steps in achieving the goal. For example, if the participant has the goal of reducing drug use, one step would be to think about how they could avoid drug using friends. The navigator should encourage them for such a step, but these steps should be based on the participants' own goals and the steps that they decide to take to achieve these goals.
Housing	Using a motivational interview format, discuss history of housing stability. If housing is unstable, when in life did this start? What have been ways to find safe and decent places to live during periods of housing instability? This can include "couch surfing," moving in for short stays with people, other options? If living outdoors – in cars, under overpasses, in river bottoms, in tent encampments – how is personal safety maintained? How does substance use interact with unstable housing? Use of stimulants to stay awake through the night when people are more vulnerable outdoors? Discuss SMART goals for housing. What is Specific, Measurable, Attainable, Reasonable and Time Bound regarding housing? Reasons for continuing to accept unstable housing arrangements can be complex – and can cause some people great embarrassment or shame. Try to stay "strengths based" for this discussion and remain focused on solution to help participants reach their housing goals.	Use the Navigation Plan Document to update goals about housing stability
Food	Continue your interview about safe housing by turning to the topic of food security. Where and when does the participant eat?	Use the Navigation Plan Document to update goals about food security

	How regular are meals? What part does snacking play in the diet? This includes going to fast food joints, 7-11/convenience stores, pharmacies to purchase snack foods. What possible sources of healthy foods exist? This includes navigation to food banks, prepared meals at shelters or other facilities. Discuss the ways healthy foods improve physical and mental health. Using a motivational interview, get ratings of importance of healthy diet and use SMART goal setting if willing. Discuss SMART goals for food security. What is Specific, Measurable, Attainable, Reasonable and Time Bound regarding stable access to food? It can be embarrassing or cause shame to be hungry or admit one accepts benefits for food (WIC) or food stamps. Try to stay "strengths based" for this discussion and remain focused on solution to help participants reach their food security goals.	
Personal Hygiene	Finding access to clean water to drink and wash with can be an ongoing struggle. Access to toilets and laundry facilities are additional challenges if one is living outdoors or has other unstable housing arrangements. Dental hygiene is perhaps most tricky – as toothbrushes and toothpaste can get lost and during times of chaos, brushing and flossing ones' teeth may not be important. In continuing the motivational interview, discuss SMART goals for personal hygiene. What is Specific, Measurable, Attainable, Reasonable and Time Bound regarding personal hygiene? Reasons for letting personal hygiene become less important can be many and discussions about the issue can cause some people great embarrassment or shame. Try to stay "strengths based" for this discussion and remain focused on solution to help participants reach their hygiene goals.	Use information from this discussion to update information about personal hygiene on the Navigation Plan Document
COVID-19 Considerations	As COVID-19 continues to move across the country, please discuss what you might need to maintain good health for yourself and others.	

	As part of this plan, discuss what to do should the participant get sick – colds, flus and the like are uncomfortable in the best of situations. COVID-19 is a viral infection that is highly contagious and can cause a flu-like reaction that can become very severe. What are the plans for where you can be on quarantine if needed? What about if you get sick? Where would you go? Who can look after you to take you to hospital if you need?	
Goal Setting	For this goal setting exercise, let's list out goals for housing stability, food security and hygiene. Review housing situation and what possibilities exist for improving permanent and safe housing. Discuss whether housing situation supports ability to manage health threats.	
Summary	The point of this session is to develop near and mid-term goals for accessing housing, food and hygiene. It is likely that some part of each session needs to address these issues to make sure people are making progress in these areas.	

8.7 Topic 5: Sexual Risk Reduction

KEY POINTS FOR CHAPTER 8, Topic 5

Topic 5 reviews ways to reduce HIV transmission risks along sexual behaviors.

- Begin the session by reviewing what has occurred since last session on goal setting
- Present information about sex risks (U=U)
- Additional risks from drug use, intimate partner violence, and other factors
- Conduct activity with the risk ladder and see where participants place behaviors by risk
- Discuss personal sexual risk reduction plan

Topics and Objectives:

- Review information on sexual risk reduction
- Learn about different levels of HIV sex risk and options for reducing risk.

Module activity	**Suggested script/Probes**	**Notes**
Check-In	Welcome back. It's good to see you again. The last time we met individually, we *[SUMMARIZE LAST SESSION]. then* - *Review goals and priorities regarding MOUD, ART and PrEP* - *Review importance of adherence to medications* - *Ask what the participant was able to accomplish* - *Congratulate participant on successes* - *Re-assure participant on any challenges faced* - *Problem-solve on how to accomplish next step in goals and objectives*	Provide positive feedback for any progress. Find some success and reinforce it.
Introduction	Today we are going to talk about the different levels of risk associated with different sex behaviors. Talking about sex is sensitive and can be embarrassing for some people. However, what is discussed here today will remain confidential. Before we get started today, let's quickly review the areas to make sure that any urgent issue gets addressed in addition to today's topic.	Materials needed for this module include: • Blank risk reduction ladder poster • Sex behavior cards • Sexual risk ladder answer key

	1. MOUD status 2. PrEP or ART adherence status 3. Mental health status 4. Harm reduction status 5. STD test and treat 6. HCV testing and treat 7. Primary medical care status 8. Housing status 9. Food status 10. Hygiene needs	Please review the Navigation Plan Document to reflect changes
INFORMATION	Let's talk about that we mean about sex risks and HIV. *For those who are living with HIV,* it is important to consider protecting yourself from other sexually transmitted infections and also very importantly protecting your partners from HIV infection. *For those who are not living with HIV,* a top priority has to be protecting yourself from becoming infected with HIV, as well as other sexually transmitted infections. The most important piece of information, though, is that research now shows definitively that **Undetectable = Untransmittable.** What this means is that if you're living with HIV and have undetectable viral load measures, you cannot transmit HIV to others via sex. What is not known is whether the **U=U** concept also applies to people who inject drugs and share needles. It's always a great idea to keep up with your ART and keep your levels undetectable as the MOST IMPORTANT thing you can do for HIV prevention. For those who are HIV-negative, **U=U** can help reduce anxiety when having sex with people living with HIV who also maintain undetectable viral loads. Still ,it's always a good idea to use condoms when having sex with partners known as HIV-positive. Anxiety can be further reduced if HIV-negative individuals are on PrEP if they have sex with partners known as HIV-positive or with partners who are unaware of their HIV-status. Of course, condoms reduce risks for other sexually transmitted infections, including syphilis, gonorrhea and chlamydia. Sometimes there are risks you find out about when finding new sexual partners or even when continuing to have sex with a main partner. Those risks can involve	

Risks additional to sex and drugs	risks for HIV and other STDs, but the risks often can extend to include Intimate Partner Violence (IPV). *Intimate Partner Violence is more common that people like to admit. If your participant is experiencing something like IPV – even if it's with a main partner, please let the participant know we're here to talk about it.* *Have available resources for shelters and housing options for people with IPV in case this is an issue. For all participants who admit IPV, schedule a separate session to review the situation, make a case management plan and help the participant safely find a new place to be if s/he is willing.*	If there is no indication of IPV, skip this section and start the next one. It's always reassuring to participants, though if you conduct basic queries about IPV and if there is any suspicion of IPV provide resources for housing and the like.
Activity	There are different levels of risk associated with different sex behaviors. We are going to use a ladder to describe these different levels of risk. *Ladder materials provided in Section 8.12.2* [*Point out blank ladder poster*] – *It should have none of the steps on it but should indicate direction of highest and lowest risk.* *Pass out cards for sex risk ladder activity and describe direction* We are going to do an activity so that we can talk about the different levels or risk associated with different sex behaviors. I am going to give you cards with a behavior written on it. I want you to come up to the poster and place it on the ladder based on how risky you think it is. The higher up on the ladder the higher the HIV risk. Notice the higher up on this ladder the color gets red to indicate danger and as you go down the ladder the color becomes blue for less risk. *Rearrange sex behavior cards so that they are correct and summarize* Consider the risk level you have for the different sex acts. Where do you think your behavior places you on the risk ladder? *Give them card that has "Never"; "Rarely"; "Sometimes"; "Always" typed* Discuss whether participant changes risk levels by the type of sexual partner, e.g., main partner versus a casual partner? You did a wonderful job with this activity. The main point of this ladder is that there are many different options available for reducing HIV risk related to sex.	Explain sex risk reduction ladder. As the participant places the cards on the ladder, ask them to explain their reasons for the placement. Allow cards to be placed incorrectly so that there can be a good discussion. Use the sex risk ladder answer key to determine correct order of behavior cards on ladder. The risk behaviors on the ladder are not specific to any sexual orientation or identity.

	So let's walk through the different levels starting at the top of the ladder which is the highest risk. Having anal sex without a condom is the riskiest type of sex. Why do you think this is? [*Answer: Because the tissue in the anal area is sensitive and can easily tear which would either increase the chance that blood will be present or be an open cut*] Vaginal sex without a condom is also a very high risk behavior. The vaginal area is much stronger than the anal area but what body fluids are presented during unprotected vaginal sex? [*Answer: Vaginal secretions, semen, and possibly blood*] Farther down the ladder, a safer option is having vaginal or anal sex with a condom. Because a condom is a barrier, if you use it properly from start to finish, it greatly reduces HIV transmission and infection. Many people find using lubricants makes sex with a condom more pleasurable. Have you ever tried to use lubricants? However you need to use the correct lubricant. Farther down the ladder, an even safer option is performing oral sex, where your mouth is on someone's penis or vagina. IN fact, oral sex is about 20-50 times less risky than vaginal or anal sex. Using your hands to stimulate your partner is very low risk for HIV infection. Remember that vaginal secretions and semen can transmit HIV so be aware if you have cuts or sores on your hands. Do you have any questions about any of the behaviors and their levels of risk on the ladder? *Of course, COVID-19 complicates all kinds of things, including meeting new partners Please spend some time discussing how and where participants meet new sexual partners respecting COVID-19 restrictions.*	[Be sure to have condoms and lube available to participants when conducting this session]
Goals	What are some ways you think you can reduce your sexual risk? What do you think is the best way you can move down the ladder? What challenges do you think you will face in making these changes? How will you address these challenges? If COVID-19 restrictions are in place, where can you go to get free condoms? In continuing this session topic, discuss SMART goals for reducing sexual HIV risk behaviors. What is Specific, Measurable, Attainable, Reasonable and Time Bound regarding personal hygiene?	

	Reasons for not wanting to reduce HIV sexual risks can often be related to issues if participants are involved in providing sex services or exchange sex. There can also be relationship issues that interfere with making changes in risk behavior (i.e., it could increase suspiciousness among some main partners). Try to stay "strengths based" for this discussion and find ways that even when participants are not wanting to make big risk reductions, participants find small ways to reduce sexual risks (e.g., using 2-1-1 PrEP).	
Summary	The point of this activity was to point out the variety of options we can use for being safer when it comes to sex. Is there any information in this module that was not clear? Do you have any additional questions? What is your personal plan for HIV-risk reduction? How will you engage this plan respecting COVID-19 restrictions?	

8.8 Topic 6: Injection Risk Reduction and Drug Splitting

KEY POINTS FOR CHAPTER 8, Topic 6

Topic 6 guides discussion about reducing risks for infectious diseases when injecting drugs, including drug splitting.

- Begin the session by reviewing what has occurred since last session regarding personal plan for sexual risk reductions
- Continue with a check-in on MOUD, ART, PrEP
- Begin discussion in injection risks
- Conduct risk ladder exercise about injection behaviors
- Develop personalized risk reduction plan for injection behaviors
- Discuss drug splitting
- Conduct risk ladder exercise about drug splitting
- Develop personalized risk reduction plan for drug splitting

Topics and Objectives:

- Review progress towards and changes to participant's goals and priorities
- Review information on injection risks for disease transmission
- Learn about different levels of drug splitting risk and options to decrease risk

Module activity	**Suggested script/Probes**	**Notes**
Check-In	Welcome back. It's good to see you again. The last time we met individually, we *[SUMMARIZE LAST SESSION]* - *Review goals and priorities regarding MOUD, ART and PrEP* - *Review importance of adherence to medications* - *Ask what the participant was able to accomplish* - *Congratulate participant on successes* - *Re-assure participant on any challenges faced* - *Problem-solve on how to accomplish next step in goals and objectives*	Provide positive feedback for any progress. Find some success and reinforce it.

Assessment of needs	*Review the Navigation Plan Document, to help advise next modules.*	Please review the Navigation Plan Document and revise to reflect changes
	Before we get started today, let's quickly review the areas to make sure that any urgent issue gets addressed in addition to today's topic. 1. MOUD status 2. PrEP or ART adherence status 3. Mental health status 4. Harm reduction status 5. STD test and treat 6. HCV testing and treat 7. Primary medical care status 8. Housing status 9. Food status 10. Hygiene needs *Now is a good time to problem-solve on how to accomplish next step in goals and objectives*	
Goals and Priorities	*[Tailor to needs of client]*	During each topic discuss the patient's goals. Discuss the concept of **goal setting** and **breaking larger goals into smaller steps**. Overall the topics aim to breakdown the goal setting process into manageable steps, acknowledge and reward them for accomplishing these steps, and provide skills training and social support to achieve these steps. An important aspect of goal setting is rewards for all the small steps in achieving the goal. For example, if the participant has the goal of reducing drug use, one step would be to think about how they could avoid drug using friends. The navigator should encourage them for such a step, but these steps should be based on the participants' own goals and the steps that they decide to take to achieve these goals.

	DISCUSSION ON INJECTION RISKS	
Start Session	[Depending on the assessment of their needs, their priorities and next goals of participant, navigator may choose to go out of order for a more relevant session.]	
Module activity	**Suggested script/Probes**	**Notes**
Introduction	Today we are going to focus on ways we can help reduce HIV injection behaviors.	Materials needed for this module include: • Blank risk reduction ladder poster • Injection risk behavior cards • Injection risk ladder answer key
INFORMATION	Let's talk about that we mean about HIV injecting risk. There are many risks to be reduced besides those linked to transmitting HIV. There is the need to consider protecting yourself and your partners against other infections (such as Hepatitis). When you inject, it's important to reduce risks against soft skin and tissue injuries (like abscesses and sepsis) that can occur when injecting without using a new needle every time. These are both common infections in addition to HIV that can successfully be reduced by using careful behaviors when injecting and/or having sex. The easiest virus to transmit via use of injection drugs is Hepatitis C. It is so easy to transmit Hepatitis C, that some of the things you do to prevent spread of HIV may not prevent spread of Hepatitis C. Hepatitis C is spread easily through blood-to-blood contact – even a little bit. Sexual contact can spread HCV, but not as efficiently as needle use behaviors. The best way to prevent Hepatitis C transmission is to not share any injection equipment.	
Activity	There different levels or risk associated with different injection behaviors. We are going to use a ladder to describe these different levels of risk. *Risk ladder materials provided in Section 8.12.2* *[Point out blank ladder poster] – This should have none of the steps on it but should indicate direction of highest and lowest risk.* The higher up on the ladder the higher the HIV risk. Notice the higher up on this ladder the color gets read to indicate danger and as you go down the ladder the color becomes blue for less risk. The ground on this poster represents not injection. *[Pass out cards for injection risk ladder activity and describe direction]*	Explain risk reduction ladder. .

	We are going to do an activity so that we can talk about the different levels or risk associated with different injection behaviors. I am going to give you cards with a behavior written on it. I want you to come up to the poster and place it on the ladder based on how risky you think it is. *As the participant places the cards on the ladder, ask them to explain their reasons for the placement. Allow cards to be placed incorrectly so that there can be a good discussion.[Rearrange injection behavior cards so that they are correct and summarize]* Probe: Where do you think you are on the ladder? *[Give them frequency card that has "Never"; "Rarely"; "Sometimes"; "Always]* How frequently are you this step of the ladder when injecting? Does this change by who you are injecting with? You did a wonderful job with this activity. The main point of this ladder is that there are many different options available for reducing HIV risk related to injection behavior. So let's take a look at the different levels of risk and safer options. At the top of the ladder is injection with someone else's unclean needle. We know that there are people who do not use other people's needles, but may lend their unclean needle out. We think that this is just as harmful. Another high risk behavior is injection drugs that were in someone else's unclean cooker. Because there could be blood in the cooker, it could mix with your drugs. As we have talked about, blood is fluid that can transmit HIV. One way to reduce some of the harm of using an unclean needle is rinse out the needle with cold water (point to ladder). Cold water is better than hot water because it rinses the blood out better, hot water makes the blood stick to the syringe. Rising once will decrease your risk of transmitting HIV, but rinsing more than once will greatly decrease your risk of transmission. We recommend repeating rinses at least 5 times with clean cold water. Remember, clean cold water is effective at getting blood with HIV out of needles. After you remove the blood with water, it is also recommended to rinse with bleach if you have it. For example you could rinse once with water, then with bleach, then with water…etc. at least 5 times. One of the safest options is to use a brand new needle every time you inject.	Use an injection risk ladder answer key to determine correct order of behavior cards on ladder.

GOALS	How are some ways do you think you can reduce your injecting risk? What do you think is the best way you can move down the ladder? What challenges do you think you will face in making these changes? How will you address these challenges? [Give suggestions] In continuing this session topic, discuss SMART goals for reducing injection-related HIV risk behaviors. What is Specific, Measurable, Attainable, Reasonable and Time Bound regarding injection risk behavior reductions? Try to stay "strengths based" for this discussion and find ways that participants can feel good about making small steps towards harm reduction – especially steps to have new syringes, needles, and injection equipment as much as is possible.	
Summary	Do you have any questions about this ladder or where the different behaviors are place? Did anything surprise you? Is there any information in this module that was not clear? Do you have any additional questions?	

8.9 Topic 7: Use of Stimulants and other Substances

KEY POINTS FOR CHAPTER 8, Topic 7

Topic 7 guides discussion about use of stimulants and other substances.

- Begin the session by reviewing what has occurred since last session
- Check-in on MOUD, ART, PrEP
- Begin discussion about stimulants and how they are used by participant
- Do a motivational interview about stimulant use
- Consider links between trauma and stimulant use
- Harm reduction of Narcan, fentanyl test strips
- Considerations of change regarding stimulant use

Topics and Objectives:

- Review previous individual sessions
- Review progress towards and changes to participants goals and priorities
- Choose and conduct next module for counseling

Module activity	Suggested script/Probes	Notes
Check-In	Welcome back. It's good to see you again. The last time we met individually, we *[SUMMARIZE LAST SESSION]* Let's review your goals and priorities. Where are you regarding MOUD? Where are you regarding your goals for HIV treatment or PrEP? How many days have you missed medications for MOUD, for HIV care or for HIV PrEP since your last visit? What do you feel like you were able to accomplish regarding your MOUD, HIV and PrEP goals? *[congratulate client on any successes – find a success and reinforce it]* What challenges have you faced in approaching your goals regarding MOUD, HIV and PrEP?	Provide positive feedback.

	Before we get started today, let's quickly review the areas to make sure that any urgent issue gets addressed in addition to today's topic. 1. MOUD status 2. PrEP or ART adherence status 3. Mental health status 4. Harm reduction status 5. STD test and treat 6. HCV testing and treat 7. Primary medical care status 8. Housing status 9. Food status 10. Hygiene needs *[now is a good time to problem-solve on how to accomplish next step in goals and objectives]*	
Goals and Priorities	*Tailor to needs of the participant*	
Assessment of needs	*Review the Navigation Plan Document to help decide the next module.*	
Start Session	*Depending on the assessment of their needs, their priorities and next goals of participant, navigator may choose to go out of order for a more relevant session.* *Start this Topic with something like:* "Tell me about your use of stimulants…by stimulants I mean, cocaine, crack, methamphetamine and ecstasy"	
Stimulants	Let's talk about stimulants. Two of the stimulants most often used with opioids are methamphetamine (tina, glass, ice, meth, crystal) and cocaine in rock (crack, cheese, free base) and powder (coke, white, blow, lines) forms. People often have a preference for one or more stimulants. Which of these do you prefer? ☐ Powder Cocaine ☐ Rock Cocaine ☐ Methamphetamine ☐ Ecstasy ☐ Don't use stimulants	

	When you use stimulants do you use them □ With opioids □ By themselves □ With other drugs (like alcohol or pot) Everyone experiences these drugs differently. Let's talk about the pros – the good things that you get – when you use cocaine or methamphetamine. *If participant gets confused or quiet, offer a couple of suggestions like*, "For example, many people who use cocaine or methamphetamine like the feeling of energy they get. Some like the way it feels – the high – especially when combined with opioids and/or alcohol. Are these true for you? What about other things that are positives of using the drug? *If the participant doesn't mention sex, probe whether their stimulant changes their experiences with sex. As well, check to see if the participant uses the pros of stimulants to stay awake at night.* Now let's talk about the negatives, the "cons" of using stimulants. These are the downsides. *Probe for cons of stimulant use including financial cost, paranoia, skin problems.* Some people experience withdrawal symptoms from stimulants when they stop using. What is your experience when you stop using stimulants?	Take out a piece of paper or work on a computer and open up a table with two columns. One column should be titled "Pros" and the other column should be titled "cons". On the second column titled "cons" write down the list of negatives generated by the participant. Don't judge or comment on any of the points listed by the participant.
The Balance	Present the list of pros and cons to the participant and ask: Seeing these lists, what are your thoughts? *[Let silence happen, but you may need to open the conversation by simply noting the number of one list compared to the other.]* *Ask the question:* On balance, which of the two columns motivates you the most in your use of stimulants? If these were weights and you placed them on either side of a scale, which side would weigh the most in total? Do the pros outweigh the cons? Do the cons outweigh the pros? Maybe there're about equal.	
Trauma	*Not always, but sometimes stimulants are used in ways that are connected to trauma. The drugs absolutely have positive ability to build energy and a high. As well, stimulant use can interfere with being able to tolerate distress for very long – which can intensify arguments and contribute to risks for physical or sexual violence. Stimulants when used can also remind people of traumatic experiences that happened over the lifetime.* *INTEGRA focuses on medications for opioid use disorder and those medications can change experiences using stimulants (buprenorphine has an ability to cause a feeling*	For participants who report trauma and use stimulants to help cope, engage a discussion for referral to mental health clinician – either now or in future

	of "well-being" and of normal that can sometimes help people use stimulants less). As you discuss experiences with stimulant use, remember that for those who have histories of trauma, it is not helpful to explore trauma issues linked to stimulant use until well after a foundation of stable MOUD is in place.	
Decisions	Let's review your Balance exercise pros and cons of stimulant use. Your data (not your navigator's) on pros and cons give you an outstanding way to step back and to keep tabs on when stimulant use is working and when it no longer is. Based on your data, what, if anything, do you want to do regarding stimulant use. **[*If participant is fine with their stimulant use as is:]*** OK great. I'm noting that right now, you do not want to change your use of stimulants. That's fine. Let's talk about ways to minimize harms that might happen from your use of stimulants. Let's talk about: ☐ Ways to get the drug that reduces risk for police involvement ☐ Ways to address risks for fentanyl in the stimulants (have a narcan kit available) ☐ Ways to use the drug that minimizes risk for personal harm (use only with people you trust) ☐ If injecting, use a new needle every time. ☐ Ways to minimize risks for STIs and sexual harms Agree to check in from time to time to make sure that they are OK with their current use. ***If participant wants to make a change in their stimulant use:*** OK great. I'm noting that right now, you are thinking you want to change your use of stimulants. That's fine. Let's talk about ways that can happen. Let's talk about: ☐ Continuing to monitor the pros and cons of your stimulant use (let's see what happens). ☐ Trying to cut down the amount of stimulants you're using – if you are not interested in quitting altogether – but are interested in cutting down ☐ Attend a 12-step group – AA, NA, CMA or other anonymous group ☐ Attend Rational Recovery groups as an alternative to the 12-steps ☐ Consider an outpatient treatment for stimulant use	Monitoring a behavior is a first step to changing the behavior. 12-step groups are not treatment. They are a social fellowship. So people are welcome to attend, independent of their stimulant use goals Rational Recovery is a cognitive behavioral therapy approach to the 12-step strategy. It integrates CBT with 12 step principles Outpatient treatments for stimulant use work best with warm handoffs. Have agencies and numbers close by to facilitate linkages

	Remember that as you talk with participants that two defining features of addiction are: 1) *Continued use despite knowledge of negative consequences. This means that just talking about the pros and cons regarding stimulant use in a motivational interview is unlikely to change use much. It's often good to let participants know that YOU know this fact).* 2) *Inability to cut down or stop. So for those who want to cut down or quit, ask open ended questions about how this might best work for the participant as this is a tall order.* *For those participants willing to make change in their use of stimulants, discuss SMART goals for stimulant use reduction. What is Specific, Measurable, Attainable, Reasonable and Time Bound regarding reducing use of stimulants?* *Try to stay "strengths based" for this discussion and remain focused on solution to help participants reach their goals regarding reducing stimulant use. This can mean talking about outcomes other than complete abstinence from stimulants – there are benefits to health by reducing stimulant use. Find and record the specific goals participants might want regarding their stimulant use behaviors.*	Remember to mention mirtazapine treatment as an option for methamphetamine use
Summary	Review the information from the session with the participant and reinforce any positive behaviors – especially reinforce "change talk," which is shown in studies to link with reductions in drug use behaviors. "Change talk" are statements like, "I never stopped to look at my meth use in this way – it makes me stop and think." The statements don't have to state the overt desire to reduce/quit stimulant use. But it's OK if people do say that. Document if there are any changes in goals during the session.	

Methamphetamine Information and Resources

What is methamphetamine?

Methamphetamine is a powerful, highly addictive stimulant that affects the central nervous system. Also known as meth, chalk, ice, and crystal, among many other terms, it takes the form of a white, odorless, bitter-tasting crystalline powder that easily dissolves in water or alcohol.

Methamphetamine was developed early in the 20th century from its parent drug, amphetamine, and was used originally in nasal decongestants and bronchial inhalers. Like amphetamine, methamphetamine causes increased activity and talkativeness, decreased appetite, and a pleasurable sense of well-being or euphoria. However, methamphetamine differs from amphetamine in that, at comparable doses, much greater amounts of the drug get into the brain, making it a more potent stimulant. It also has longer-lasting and more harmful effects on the central nervous system. These characteristics make it a drug with high potential for widespread abuse.

What are the immediate (short-term) effects of methamphetamine abuse?

As a powerful stimulant, methamphetamine, even in small doses, can increase wakefulness and physical activity and decrease appetite. Methamphetamine can also cause a variety of cardiovascular problems, including rapid heart rate, irregular heartbeat, and increased blood pressure. Hyperthermia (elevated body temperature) and convulsions may occur with methamphetamine overdose, and if not treated immediately, can result in death.

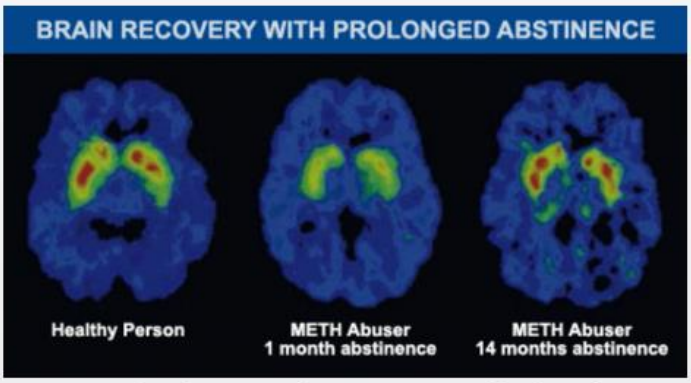
Short-term effects may include:
• **Increased attention and decreased fatigue**
• **Increased activity and wakefulness**
• **Decreased appetite**
• **Euphoria and rush**
• **Increased respiration**
• **Rapid/irregular heartbeat**
• **Hyperthermia**

Most of the pleasurable effects of methamphetamine are believed to result from the release of very high levels of the neurotransmitter dopamine. Dopamine is involved in motivation, the experience of pleasure, and motor function, and is a common mechanism of action for most drugs of abuse. The elevated release of dopamine produced by methamphetamine is also thought to contribute to the drug's deleterious effects on nerve terminals in the brain.

What are the long-term effects of methamphetamine abuse?

Long-term methamphetamine abuse has many negative consequences, including addiction. Addiction is a chronic, relapsing disease, characterized by compulsive drug seeking and use and accompanied by functional and molecular changes in the brain.

As is the case with many drugs, tolerance to methamphetamine's pleasurable effects develops when it is taken repeatedly. Abusers often need to take higher doses of the drug, take it more frequently, or change how they take it in an effort to get the desired effect. Chronic methamphetamine abusers may develop difficulty feeling any pleasure other than that provided by the drug, fueling further abuse. Withdrawal from methamphetamine occurs when a chronic abuser stops taking the drug; symptoms of withdrawal include depression, anxiety, fatigue, and an intense craving for the drug.



Recovery of Brain Dopamine Transporters in Chronic Methamphetamine (METH) Abusers

Methamphetamine abuse greatly reduces the binding of dopamine to dopamine transporters (highlighted in red and green) in the striatum, a brain area important in memory and movement. With prolonged abstinence, dopamine transporters in this area can be restored.

Long-term effects may include:
• **Addiction**
• **Psychosis, including:** ○ **Paranoia** ○ **Hallucinations** ○ **Repetitive motor activity**
• **Changes in brain structure and function**
• **Deficits in thinking and motor skills**
• **Increased distractibility**
• **Memory loss**
• **Changes in brain structure and function**
• **Aggressive or violent behavior**
• **Mood disturbances**
• **Severe dental problems**
• **Weight loss**

In addition to being addicted to methamphetamine, chronic abusers may exhibit symptoms that can include significant anxiety, confusion, insomnia, mood disturbances, and violent behavior. They also may display a number of psychotic features, including paranoia, visual and auditory hallucinations, and delusions (for example, the sensation of insects creeping under the skin). Psychotic symptoms can sometimes last for months or years after a person has quit abusing methamphetamine, and stress has been shown to precipitate spontaneous recurrence of methamphetamine psychosis in formerly psychotic methamphetamine abusers.

These and other problems reflect significant changes in the brain caused by abuse of methamphetamine. Neuroimaging studies have demonstrated alterations in the activity of the dopamine system that are associated with reduced motor speed and impaired verbal learning. Studies in chronic methamphetamine abusers have also revealed severe structural and functional changes in areas of the brain associated with emotion and memory, which may account for many of the emotional and cognitive problems observed in chronic methamphetamine abusers.

Methamphetamine abuse also has been shown to have negative effects on non-neural brain cells called microglia. These cells support brain health by defending the brain against infectious agents and removing damaged neurons. Too much activity of the microglial cells, however, can assault healthy neurons. A study using brain imaging found

more than double the levels of microglial cells in former methamphetamine abusers compared to people with no history of methamphetamine abuse, which could explain some of the neurotoxic effects of methamphetamine.

Some of the neurobiological effects of chronic methamphetamine abuse appear to be at least partially reversible. In the aforementioned study, abstinence from methamphetamine resulted in less excess microglial activation over time, and abusers who had remained methamphetamine- free for 2 years exhibited microglial activation levels similar to the study's control subjects. Another neuroimaging study showed neuronal recovery in some brain regions following prolonged abstinence (14 but not 6 months). This recovery was associated with improved performance on motor and verbal memory tests. But function in other brain regions did not recover even after 14 months of abstinence, indicating that some methamphetamine induced changes are very long lasting. Moreover, methamphetamine use can increase one's risk of stroke, which can cause irreversible damage to the brain. A recent study even showed higher incidence of Parkinson's disease among past users of methamphetamine.

In addition to the neurological and behavioral consequences of methamphetamine abuse, long-term users also suffer physical effects, including weight loss, severe tooth decay and tooth loss ("meth mouth"), and skin sores. The dental problems may be caused by a combination of poor nutrition and dental hygiene as well as dry mouth and teeth grinding caused by the drug. Skin sores are the result of picking and scratching the skin to get rid of insects imagined to be crawling under it.

What are effective treatments for methamphetamine reduction?

The most effective treatments for methamphetamine addiction at this point are behavioral therapies, such as cognitive-behavioral and contingency-management interventions. Currently, there are no pharmaceutical medications that can counteract the specific effects of methamphetamine or reduce the abuse of methamphetamine by an individual addicted to the drug.

Source: http://www.drugabuse.gov/publications/research-reports/methamphetamine/what-methamphetamine

What are harm reduction strategies when using methamphetamine?

In general, alcohol should be avoided when using methamphetamine. Also, you can try to reduce the amount you use. If you are living with HIV, you should plan to take any HIV medications before using methamphetamine so you do not forget.

What is "overamping"?

Overamping is the term we use to describe what one might consider an "overdose" on speed. Overamping means a different things to a lot of people. Sometimes it can consist of physical symptoms, like fast heart rate or irregular breathing. Or it can be psychological symptoms, such as paranoia, anxiety, or psychosis. It can also be a combination of both.

Overamping can happen for a lot of different reasons: you've been up for too long (sleep deprivation), your body is worn down from not eating or drinking enough water, you're in a weird or uncomfortable environment or with people that are sketching you out, you did "that one hit too many," you mixed some other drugs with your speed that have sent you into a bad place — whatever the reason, it can be dangerous and scary to feel overamped.

What can be done to handle physical aspects of overamping?

Medical attention should be sought immediately if someone using is experiencing:

- Nausea and/or vomiting
- Falling asleep/passing out (but still breathing)
- Chest pain or a tightening in the chest

- High temperature/sweating profusely, often with chills
- Fast heart rate, racing pulse
- Irregular breathing or shortness of breath
- Seizure/convulsions
- Stroke
- Limb jerking or rigidity
- Feeling paralyzed but you are awake
- Severe headache
- Hypertension (elevated blood pressure)
- Teeth grinding
- Insomnia or decreased need for sleep
- Tremors

What can be done to handle psychological aspects of overamping?

If someone is experiencing anxiety or other psychological symptoms of overamping, here are some strategies to help reduce the symptoms:

- Drink water (but not too much) or a sports drink
- Eat some food
- Try to sleep
- Switch how you're doing speed; sometimes if you're shooting, switching to smoking can help
- Change your environment or the people you're with
- Do breathing or meditation exercises
- Create physical contact, like massaging yourself or having someone else do it for you
- Go walking, walking, walking — walk it off!
- Take a warm shower
- Get some fresh air

Source: http://harmreduction.org/issues/overdose-prevention/overview/stimulant-overamping-basics/what-is-overamping/

8.10 Topic 8: Alcohol, Benzos and other Downers

KEY POINTS FOR CHAPTER 8, Topic 8

Topic 8 guides discussion about use of alcohol, benzodiazepines and other downer drugs.

- Begin the session by reviewing what has occurred since last session
- Check-in on MOUD, ART, PrEP
- Recognize how many people use alcohol in the U.S.
- Identify amount of alcohol that is risky and consequences to alcohol use for those living with HCV.
- Discuss use of benzodiazepines, barbiturates and other drugs that are used to manage anxiety
- Discuss ways these drugs interact with opioids to increase risks for overdose
- Discuss whether or not to change use of these drugs, including drink/drug refusal skills.
- Developing alternatives to drinking
- Setting goals regarding drinking and use of downer drugs

Module activity	Suggested script/Probes	Notes
Check-In	Welcome back. It's good to see you again. The last time we met individually, we *[SUMMARIZE LAST SESSION]* - *Review goals and priorities regarding MOUD, ART and PrEP* - *Review importance of adherence to medications* - *Ask what the participant was able to accomplish* - *Congratulate participant on successes* - *Re-assure participant on any challenges faced* - *Problem-solve on how to accomplish next step in goals and objectives*	Provide positive feedback especially if goal activities were not directly addressed.

Check-In	Work with participant to re-iterate goals for the *following:* • *MOUD and [PrEP/HIV] medical care* • *MOUD and [PrEP/HIV] adherence status* • *Drug treatment status* • *Current Drug Use?* • *Currently sexually active?* • *Current levels of alcohol use?* • *Housing/food/hygiene* • *STDs and treatment* • *Need for harm reduction* • *Primary care* • *Mental health/depression* *Congratulate participant on successes* *Re-assure participant on any challenges they faced, and* *Problem-solve on how to accomplish next step in goals and objectives*	Provide positive feedback. Find a success and reinforce it.
Introduction	In this topic, we are going to focus on alcohol use. We will also talk about other substances that are "downers". Alcohol is used by a lot of Americans for lots of different reasons. How do you use alcohol? Other drugs are "downers," too. Benzodiazepines (benzos), barbiturates (barbs), and some other drugs are out there to dampen mood, energy and anxiety. Today we'll talk the risks associated with hazardous or binge drinking and use of the "downer" drugs. We'll also talk about strategies to minimize harm linked to these substances.	
INFORMATION	Let's begin. Tell me about your drinking. *Quantity*: How many alcoholic drinks do you usually consume on days you drink alcohol (use standard drinks). *Frequency:* How many days during a two-week period do you usually drink alcohol? *Hazardous/binge drinking:* How many days out of the past 30 days did you drink 6 or more drinks on any day? *Suggested Probes:*	Use the standard drink tool (Section 8.12.3) to clarify how many drinks we're talking about. It's also good to review the answers to the AUDIT screener from the enrollment visit in the Behavior CRF. Use the participant's own data from baseline to compare. Note whether these are the same, more or less. But don't try to make meaning of any outcome, one way or another. Just note whether drinking is the same, more or less.

	In general, what types of drinks do you have? On average, how many drinks per day would you have? Describe a typical situation when you decide to drink.	
Activity #1 Low-risk drinking & effects of high-risk drinking	Thank you for sharing that information with me. I now want to discuss with you about low-risk drinking. Reducing or stopping alcohol use can reduce harm for people who have OUD and/or HIV because drinking can make it harder to take your medications as prescribed, and can make your HIV worse by interfering with medication adherence – people who drink heavily can forget to take their daily medications. Heavy alcohol use can also cause problems in your relationships – drinking heavily and frequently can lead friends, family members and others who don't drink heavily to reduce the amount of support they are willing to give you and cut themselves off. Of course, one of the greatest risks of heavy alcohol drinking is that it contributes to respiratory depression and death for people who use opioids. Drinking heavily while combining benzodiazepines and opioids is a truly deadly combination. Many people who have histories of injection drug use, whether opioids or stimulants, become infected with Hepatitis C virus (HCV). As we talked about earlier, HCV is easier to transmit and to acquire than HIV. That's why many PWID become infected with HCV within the first 6 months of using injection methods during drug use – it just happens that people share drugs and injection equipment – often share HCV exposure and for many, becoming HCV positive. For people living with HCV, alcohol is a real threat because heavy drinking can damage your liver more than HCV alone. Your liver is the organ in your body that has the job of clearing your body of alcohol when you drink (and of clearing almost every other drug, medication, or poison, too). If you liver has to break down a lot of alcohol when it's already been weakened by HCV, it becomes damaged. For people living with OUD and HCV (or OUD, HCV and HIV), liver damage can be a real health problem when they drink alcohol. If the participant is living with HCV, encourage decision to get treated for HCV. Treatments available today can cure HCV and OUD is not a problem for those seeking the HCV treatment. *Check in with participant:* If you are not interested in stopping drinking altogether, you might consider cutting back. To do	Supplemental materials to be used for this activity are found in Section 8.12.3: • What's a Standard Drink? • Effects of High-Risk Drinking

	that, it's important to keep track of how much alcohol is in each beverage you usually drink, so you can know how much you reduce the amount you drink. [*Use "What's a standard drink" sheet. Define standard drink with participant*] Most bottles and cans of beer have about the same amount of alcohol as a glass of wine or one shot of distilled spirits. When you think about how much you drink, be sure to count standard drinks. *Review the NIAAA definitions on what defines low-risk alcohol drinking which are:* - *Men: 2 drinks a day or 14 drinks total over 7 days* - *Women: 1 drink a day or 7 drinks total over 7 days* If you have been drinking above these limits, you risk causing harm to yourself and others Fortunately, most people can stop or reduce their drinking if they decide to do so and work hard at changing their drinking habits.	
Other Downers	Other downers are important to pay attention to as well as alcohol (and especially their combination). The primary risk to your health when you use opioids (heroin, fentanyl, oxys) is respiratory depression…that is, your breathing slows down until it just stops. This risk gets way bigger when opioids or opioid agonists (like methadone) are combined with any and all of the downers. Benzos and barbs slow breathing. When you combine benzos, barbs and/or alcohol with opioids, people feel a slushy high, but they also experience exaggerated depression of the breathing centers. This increases the risks for overdose and death a great deal. This risk is not a joking matter. More than 60,000 Americans every year are losing their lives to the opioid epidemic. When people die due to overdose, it's because their breathing centers stop working due to opioids and/or the combination of opioids and other drugs and alcohol. Check-in about anxiety and using alcohol and downers to cope with anxiety. People who inject opioids often have long-standing problems with anxiety that range from moderate to severe. Some of those anxiety problems started before use of injection opioids. Other anxiety problems are linked to opioid withdrawal – problems that get worse to the point people seek medical care. For many with this severe anxiety, doctors prescribe benzos (like Ativan, Klonopin, Xanax) in order to medicate the	

	anxiety and to help individuals to function in spite of the anxiety. Discuss with participant non-medical ways to manage anxiety. This includes things like meditation, physical exercise, and mindful breathing. All of these are intentional activities – something to do to handle anxiety as compared to using medications. The important factor here, though, is doing something to reduce your anxiety. It will work, if you work it!	
PLAN	Now let's talk about your use of alcohol and other downer drugs. [*Take time to review participants' goals and substance use information*] Are you interested in controlling or reducing your alcohol use? [***If yes -*** *continue to activity 2*] [***If no****, follow probes below and do motivational interviewing below*] • What do you enjoy about drinking? • What are the problems that arise from your drinking? • What do you think are the negatives if you were to reduce or quit drinking? [*Assess with participant if they are interested in doing anything to reduce drinking or addressing some of the barriers to changing their alcohol use*]	Conduct motivational interview if not interested in reducing alcohol use
Activity #2 Stopping or cutting back	When people successfully change their habits they usually follow a simple plan. If possible, try to get somebody to help you. Perhaps a friend or a relative, a health worker, or your supporter for this study would be willing and able to help you work out a plan and stick to it. The reason for getting somebody else to help is simply that two heads are better than one. Also, they will be able to provide support. Of course, many people change their habits without help from others. So it is OK if you don't have somebody who would be a good helper for this . *Talk with the participant about the following aspects of drinking behaviors and use the information to guide your recommendations on whether or not it is safe to reduce/stop drinking behaviors. Do not encourage someone who is drinking heavily to stop drinking abruptly. Instead help such a person to find a medically supervised detox.*	There may be substantial health hazards to completely stopping alcohol use if you are a dependent user. If the participant drinks large amounts daily or almost daily they are at risk for alcohol dependence. If alcohol treatment is available you can refer them to treatment. If there is no treatment available, inform participants who drink a large amount daily that it can be dangerous if they quit drinking immediately and completely ('cold turkey'). It is advisable for them to reduce alcohol consumption by 10% each day for 10 days. For sites that do have alcohol detox programs, remember to provide

	• *For participants who drink heavily sometimes or otherwise do not drink heavily daily, it is appropriate to discuss their interests in reducing drinking* *Review with participant a list of benefits that s/he can reasonably expect from reducing or stopping alcohol drinking.* *See if one or more of these benefits can be endorsed by the participant.* *Alcohol drinking within low-risk limits:* • *Extends life - probably between five and ten years.* • *Improves sleep.* • *Saves money otherwise spent on alcohol.* • *Improves relationships with family, friends, co-workers.* • *Reduces fights with others and risks for run-ins with the police.* • *Risks for death due to liver disease dramatically reduced (12 times less likely)* • *Risks for death by auto accident reduced (3 times less likely).*	participant referrals so that they may utilize these medical services. As well, medically supervised outpatient detoxification for alcohol is often offered by addiction medicine practices.
Activity #3 Refusal skills	Even when committed to changing your drinking, our culture is set up with "social pressure" to drink by friends, family members or others. That can make it hard to cut back or quit. The first step to building alcohol refusal skills is to become aware of the two different types of social pressure to drink alcohol—direct and indirect. • **Direct social pressure** is when someone offers you a drink or an opportunity to drink. • **Indirect social pressure** is when you feel tempted to drink just by being around others who are drinking—even if no one offers you a drink. Take a moment to think about situations where you feel direct or indirect pressure to drink or to drink too much. Knowing what type of situations you may face is the first step to developing strategies to say no. For some situations, your best strategy may be avoiding them altogether (which we can discuss below in activity #4). If you feel guilty about avoiding an event or turning down an invitation, remind yourself that you are not necessarily talking about "forever." When you have confidence in your refusal skills, you may decide to ease gradually into situations you now choose to	

	avoid. In the meantime, you can stay connected with friends or family by suggesting alternate activities that don't involve drinking. *Know your "no"* When you know alcohol will be present, it's important to have some resistance strategies lined up in advance. If you expect to be offered a drink, you'll need to be ready to deliver a convincing "no thanks." Your goal is to be clear and firm, yet friendly and respectful. Avoid long explanations and vague excuses, as they tend to prolong the discussion and provide more of an opportunity to give in. Here are some other points to keep in mind: • Don't hesitate, as that will give you the chance to think of reasons to go along • Look directly at the person and make eye contact • Keep your response short, clear, and simple The person offering you a drink may not know you are trying to cut down or stop, and his or her level of insistence may vary. It's a good idea to plan a series of responses in case the person persists, from a simple refusal to a more assertive reply. Consider a sequence like this: • No, thank you. • No, thanks, I don't want to. • You know, I'm (cutting back/not drinking) now (to get healthier/to take care of myself/because my doctor said to). I'd really appreciate it if you'd help me out. You can also try the "broken record" strategy. Each time the person makes a statement, you can simply repeat the same short, clear response. Script and practice your "no" Many people are surprised at how hard it can be to say no the first few times. You can build confidence by scripting and practicing your lines. First, tell me of a situation where a person may be offering you a drink. Now, let's think of how you'll respond.	It may be helpful to do <u>role playing</u> here. Pretend to be the person offering the drink and have the participant practice out loud their refusal strategy. Let the participant know that practice will help them gain confidence and feel better about refusing.
Activity #4 alternatives to drinking	Your desire to drink heavily probably changes according to your moods, the people you are with, and whether or not alcohol is easily available. Think about the last time you drank too much and try to work out what things contributed to your drinking. What situations will make you want to drink heavily in the future?	

	Some examples may include: • Situations in which other people are drinking and I am expected to drink. • Feeling bored and depressed, especially on weekends. • After a family argument. • When drinking with my friends. • When feeling lonely at home. Alcohol use also fills a lot of time. Let's think about some ways to fill that time with activities that are fun/reinforcing that would otherwise be spent drinking. Let's think of as many activities as we can that might hold your interest over binge drinking or hazardous drinking and then select 2 of them to try. • What types of things have you enjoyed learning in the past? (e.g., sports, crafts, languages) • What types of trips have you enjoyed in the past? (e.g., to the ocean, to the mountains, to the country) • What types of things do you think you could enjoy if you had no worries about failing? (e.g., painting, dancing) • What have you enjoyed doing alone? (e.g., long walks, playing a musical instrument, sewing) • What have you enjoyed doing with others? (e.g., talking on the telephone, playing a game, having sex) • What have you enjoyed doing that costs no money? (e.g., playing with your children) • What have you enjoyed doing that costs very little (e.g., going to a park) What 2 activities should you try the next time you think about drinking?	
Goals	How are some ways you think you can reduce your alcohol use? What do you think is the best way you can reduce your alcohol from the strategies we have discussed? *[Probe: suggest some strategies just discussed]* What challenges do you think you will face in making these changes? How will you address these challenges? *[Give suggestions]* *For those participants willing to make change in their use of alcohol and benzodiazepines, discuss SMART goals for reduction of these substances. What is Specific, Measurable, Attainable, Reasonable and*	

	Time Bound regarding reducing use of alcohol and/or benzodiazepines? *Try to stay "strengths based" for this discussion and remain focused on solution to help participants reach their goals regarding reducing alcohol and/or benzodiazepines. There are benefits to health by reducing alcohol use – especially for those with HIV and HCV. Find and record the specific goals participants might want regarding their use of alcohol and/or benzodiazepines.*	
Summary	The point of this activity was to discuss the risks associated with high-risk drinking and review strategies to help stop or cut back on drinking. Is there any information in this module that was not clear? Do you have any additional questions? A few key points to remember: • Remember that every time you are tempted to drink too much and are able to resist, you are breaking your habit. • Whenever you feel very uncomfortable, distressed or miserable, keep telling yourself that it will pass. If you crave a drink, pretend that the craving is like a sore throat that you have to put up with until it goes away. • If you have a helper, tell that person honestly how much you had to drink each day and when you have been successful or have drunk too much. • Finally, it is likely that you will have some bad days on which you drink too much. When that happens, DON'T GIVE IN. Remember that people who HAVE learned to drink at low-risk levels had many bad days before they were finally successful. It will get easier in time.	

Benzodiazepines Information and Resources

What are benzodiazepines?

Benzodiazepines are prescription medicines most commonly used to treat anxiety and sleep disorders. Doctors may also prescribe them as muscle relaxants, or to treat epilepsy, alcohol withdrawal or panic disorders. Some people use benzodiazepines illegally to experience their effects and become intoxicated.

Chemical/Generic name	Brand name
Alprazolam	Xanax
Clobazam	Frisium
Clonazepam	Rivotril
Diazepam	D-Pam, Propam, Diazemuls, Stesolid Rectal, Valium
Flunitrazepam	Rohypnol
Lorazepam	Ativan, Lorapam, Lorzem
Lormetazepam	Noctamid
midazolam	Hypnovel
Nitrazepam	Insoma, Nitrados
Oxazepam	Ox-Pam, Serepax, Benzotran
temazepam	Normison, Somapam, Euhypnos
triazolam	Halcion, Hypam, Trycam
zopiclone	Imovane

Benzodiazepines are a depressant. They work by slowing down the messages travelling around the central nervous system. This makes the user feel relaxed and calm, but tolerance builds quickly, and the dosage required to deliver the same effect increases. For this reason, benzodiazepines are intended to provide short-term, temporary relief, while the underlying causes of the anxiety or sleep disturbance are treated.

Benzodiazepines are prescribed in tablet form and come in a variety of shapes, sizes, and colors. There are many types and brand names of benzodiazepine.

Once taken benzodiazepines take effect within 30 minutes. Lasting effects depend on the type of benzodiazepines used, the dosage, the condition being treated, and the presence or absence of other drugs.

Benzodiazepines are sometimes used illegally (without a prescription) to become intoxicated or as a substitute for opiate drugs when these are unavailable or when a person is trying to stop using opiates. They are sometimes used with opiate drugs to enhance their effects, and some people use benzodiazepines to help alleviate the ‘come down’ from stimulant drugs like amphetamines or MDMA (ecstasy) and to help them sleep.

What are the short-term effects of benzodiazepine mis-use?

When benzodiazepines are taken at higher doses, effects similar to those of alcohol can be produced including:

- drowsiness and sleepiness, leading to an induced state of sleep
- over-sedation
- cognitive and coordination impairment
- mood swings
- aggressive outbursts.

It is common for recreational users to take high doses of benzodiazepines as they are not always aware of recommended dosages and are administering the drug to achieve a state of intoxication.

What are the long-term effects of benzodiazepine mis-use?

Long-term use (exceeding one month) of benzodiazepines daily is not recommended and should be monitored by a doctor. Long-term use of benzodiazepines may cause:

- drowsiness and sleepiness, leading to an induced state of sleep
- lack of motivation
- unclear thoughts, memory loss
- behavioural and personality changes
- anxiety, irritability or aggression
- difficulty sleeping and disturbing dreams
- nausea, headaches
- skin rash
- menstrual and sexual problems
- greater appetite, weight gain
- lack of coordination, vulnerability to accidents
- depression
- slurred speech

Long-term use of benzodiazepines commonly causes similar conditions to those which the drug has been prescribed to relieve. What that means is anxiety actually increases with regular long-term use of benzodiazepines.

Reported adverse reactions from mixing Benzodiazepines with other drugs

Drug	Effect
Cannabis	Increased drowsiness Paradoxical agitation (opposite effect of the normally expected results) Nervous tension, irritability, nervousness
Alcohol	Increased drowsiness Hypotension (low blood pressure) Fainting Cessation of breathing DANGEROUS
Stimulants (Cocaine/ Amphetamine/ Ecstasy etc.	Reduced effectiveness of Benzodiazepines
Heroin / Methadone and other opiates	Increased drowsiness Risk of decreased rate of breathing DANGEROUS
Tobacco	Possible excessive lowering of blood pressure

What happens if benzodiazepines are mixed with other substances?

When used alone benzodiazepines have a low risk of acute toxicity (poisonous effect). However, when used with other types of medication (which is often the case) including other drugs, the toxicity of benzodiazepines can be increased.

Fatal overdoses in addicted patients often involve a combination of benzodiazepines and alcohol.

Opioid users (including methadone users) who also use benzodiazepines have an increased risk of fatal overdose.

Dosage escalation can result in excessive sedation and lead to falls, road traffic accidents and other accidents (especially when combined with alcohol).

What are the effects of injecting benzodiazepines?

Benzodiazepine tablets or capsules are intended for oral use only. However some people inject benzodiazepines which can be very dangerous and has the potential to cause serious health problems.

Health problems associated with injecting benzodiazepines include:

- collapsed veins
- clotting of veins
- red, swollen, infected skin
- amputation of limbs due to poor circulation
- stroke or even death.

- sharing injecting equipment exposes users to the risk of blood borne viruses like hepatitis B, hepatitis C, and HIV

What are effective treatments for benzodiazepine reduction?

If you have been taking benzodiazepines for an extended period of time (a month or more) you should seek medical advice before stopping or reducing use. A medical professional will help you to manage any possible withdrawal symptoms.

Gradual dosage reduction is seen as a key strategy for successful discontinuation of the medication. Research suggests that those who unable to discontinue can switch to a lower dose but longer acting benzodiazepines with the help of a medical professional.

What are harm reduction strategies when using benzodiazepine?

In general, injection of benzodiazepine should be avoided in order to prevent infections, such as Hepatitis C.

How do benzodiazepines affect HIV treatment?

Benzodiazepines likely reduces the effect of HIV treatment. Therefore, use of benzodiazepines should be avoided when taking ART treatment.

Sources: http://www.benzoguide.co.uk/basic-harm-reduction.aspx

https://www.drugfoundation.org.nz/benzodiazepines/reducing-the-harm

Liebrenz, M., Schneider, M., Buadze, A., Gehring, M. T., Dube, A., & Caflisch, C. (2016). Attitudes towards a maintenance (-agonist) treatment approach in high-dose benzodiazepine-dependent patients: a qualitative study. Harm Reduct J, 13(1), 1.

doi:10.1186/s12954-015-0090-x

8.11 Topic 9: Depression and Stigma

KEY POINTS FOR CHAPTER 8, Topic 9

Topic 9 guides discussion about identifying and managing impact of depression and stigma on the lives of participants

- Begin the session by reviewing what has occurred since last session
- Check-in on MOUD, ART, PrEP
- Provide information about depression and how to identify it
- Learn techniques (and practice them, if possible) that help stop depression feelings
- Discuss stigma experiences that occur from using drugs, from HIV, or aspects of living with these conditions

Module activity	Suggested script/Probes	Notes
Check-In	Welcome back. It's good to see you again. The last time we met individually, we *[SUMMARIZE LAST SESSION]* - *Review goals and priorities regarding MOUD, ART and PrEP* - *Review importance of adherence to medications* - *Ask what the participant was able to accomplish* - *Congratulate participant on successes* - *Re-assure participant on any challenges faced* - *Problem-solve on how to accomplish next step in goals and objectives*	Provide positive feedback even if homework was not accomplished.
Goals and Priorities	Before we get started today, let's quickly review the areas to make sure that any urgent issue gets addressed in addition to today's topic. 1. MOUD status 2. PrEP or ART adherence status 3. Mental health status 4. Harm reduction status 5. STD test and treat 6. HCV testing and treat	During each module discuss the patient's goals. Discuss the concept of **goal setting** and **breaking larger goals into smaller steps**. Overall the modules aim to breakdown the goal setting process into manageable steps, acknowledge and reward them for accomplishing these steps, and provide skills training and social support to achieve these steps.

	7. Primary medical care status 8. Housing status 9. Food status 10. Hygiene needs	An important aspect of goal setting is rewards for all the small steps in achieving the goal. For example, if the participant has the goal of reducing drug use, one step would be to think about how they could avoid drug using friends. The navigator should encourage them for such a step, but these steps should be based on the participants' own goals and the steps that they decide to take to achieve these goals.
Assessment of needs	*Make changes to the Navigation Plan Document, to help decide on next module.*	
Choose Module Content	*Depending on the assessment of their needs, their priorities and next goals of participant choose from the modules below.*	*Refer to the navigation plan document to help decide which module is most appropriate*

DEPRESSION Module

Module activity	**Suggested script/Probes**	**Notes**
Introduction	Today we are going to focus on depression and discuss techniques to help manage your moods. We are also going to talk about stigma related to MOUD, HIV and drug use and how this may affect you.	
INFORMATION ON DEPRESSION	Feeling depressed from time to time is normal. But having a depressive disorder, which often co-occurs with OUD and HIV, means that symptoms of depression are long lasting (2 weeks or more) and cause interference in the ability to function (e.g., get out of bed, talk to your partner/family, care about your physical presentation). Trauma and stress in peoples' lives also contribute negatively to the experience of depressive disorder. For people with OUD and HIV, depression and sadness also may be caused by feeling sick or by a wide range of other reasons. Here is a list of sign and symptoms of depression. Let's discuss these and figure out which ones cause distress for you: • Symptoms last 2 weeks or more and are present most of the day, nearly every day. • Sad, anxious, or empty feelings • Loss of interest in activities or hobbies once enjoyable, including sex • Feeling guilty, worthless, or helpless • Feeling irritable or restless	Note regarding participants with moderate to severe depression: If medications for depression are available and depression is severe then navigator should refer participants and encourage them to talk to their doctors about medications. Many depression medications (SSRIs) can have very strong negative effects if doses are missed and their dose should be slowly increased and slowly decreased. It can take several weeks for them to be effective and most are statistically significantly better than placebos for severe depression. However, for mild to moderate depression behavioral approaches are effective.

	• Feeling tired all the time • Difficulty concentrating, remembering details, or making decisions • Difficulty falling asleep or staying asleep, a condition called insomnia, or sleeping all the time • Overeating (or loss of appetite) – often marked by weight gain (or weight loss) • Thoughts of death and suicide or suicide attempts *When participants started the study they completed a depression measure – the CES-D as part of the behavioral questionnaire. Before starting the session, look up the CESD score for the participant and use it to check in to see how people feel today regarding their depression symptoms.* There is a great deal of overlap in behaviors you can do to treat depression and to treat OUD. One thing to do is to do something. Behavioral activation means getting out of bed by a set time, getting involved with a scheduled activity, exercising or visiting with friends. Using cognitive behavioral therapy (CBT) skills, changing the way you think can change the way you feel. Things you can DO include: • Exercise – this raises dopamine levels (which lifts mood) and helps you feel better in your body • Spend more time with supportive people and doing things that are pleasurable – this counteracts the pull to isolate when depressed • Give rewards to yourself to interrupt the loop of negative thoughts à negative feelings • Thought-stop negative thoughts. Negative thoughts lead to negative feelings. Stop the thoughts. It changes the feelings.	
Activity	Here are some steps for thought stopping. The **STOP technique** for dealing with depression. *"S" stands for slow down.* Slowing ourselves down allows us to take a break so that we can take a look at what is happening. When something stressful happens such as an argument or bad experience. This may include taking a deep breath, having a drink of water, going for a walk, taking time to read, saying a prayer, daily exercise, watching a funny TV show. *[interviewers and counselors should add to this list]* *The T in STOP stands for Thoughts*: Are they negative or positive? This is your chance to notice the types of thoughts	

	you may be having. Here are some examples of negative thoughts: • Nobody cares about me, • I should just keep to myself • I'm just a burden • Everyone is getting sick and tired of my problems • I might as well go get high so I can forget all of this. *The "O" stands for Options*. When we get stuck in a negative thinking pattern we tend to see the world as "all or nothing". The "O" in STOP is a reminder to take a different perspective and look at options that you have that may help you to feel better. In some cases the options may not seem like good ones – but they are options. Many people find that they feel better when they are with other people who are supportive. When feeling depression we are more likely to isolate ourselves – and avoid contact with people who support and care for us. We also tend to feel uncomfortable around people and are more likely to think we are being judged and criticized by others. When you are feeling sad, it is important to not isolate yourself. • Think of someone who you enjoy spending time with. • Think of someone who has given you support or encouragement, or someone that you would like to spend more time with? • Who could you spend more time with who is supportive? Another option is spending time in more positive places. Sometimes there are places that you can go that are relaxing and enjoyable. • Are there places that you can go to relax? • Are there places where you can go to be around other people? • Are there people who you can be around who do not use drug but are supportive of you? What types of things can you do that may be enjoyable or relaxing such as talking a walk or listening to music? Some people find that exercise can make them feel better. • What type of physical exercise do people do in your community?	Ask the participant if they are willing to share recent negative thoughts they have been experiencing. This also could be a support group. If the person says no one, the navigator can ask about places where people gather where they could spend time. There may be volunteer activities, religious activities, where they can interact with other people.

	• Is this something you might be interested in doing? Finally, *the P in STOP stands for Practice*. Practice rewarding yourself, saying positive things to yourself and give yourself credit for trying something new. Here are some example of things that you can say to yourself. • I did it before I can do it again • I may not do everything right but I am a worthy person • Things are rough now but I am going to keep trying • I am a survivor - Look how far I have come. • I am a good and caring person who helps others What types of positive statements do you think you would like to try to make to yourself? Even when things do not work out for us it is important to think about what did go well and praise yourself for things that you accomplished. For example, if you needed to get documents to go to the MOUD or HIV clinic. You get your documents together and head out but when you get to the clinic it was closed. You could say to yourself: • I am frustrated but at least I accomplished my goal of getting my papers together. • I am disappointed but I am proud of myself for doing something positive. • At least I won't have to start the process over again now that I have my papers together. • I am disappointed but I am going to use this time to do something that I enjoy. What are some of the things that you could say to yourself that are positive? It is useful to practice saying these things to yourself?	Develop a list of relaxing and pleasurable activities In piloting the module the navigators should record other positive statements that participants may want to use. It is important to perhaps use site/cultural specific statements. [explore whether physical exercise is possible and develop a plan for trying to exercise. This plan should include small and increasing goals for exercise. The first goal may be to get a pair of shoes for exercising. Encourage participants to start slowly.]

STIGMA Module

INFORMATION ON STIGMA	Sometimes people who use drugs or who have HIV are treated poorly by others. What you have been taught today can also be used when people treat you poorly. Have you ever been treated poorly because of your HIV or drug use? Can you give me an example of what happened?	

	If someone says something rude to you such as "(*navigators fill in examples*)." You can use the STOP technique. Slow down and take some time before you react. Examine what are you thinking right after this experience? Does what the person says or did lead you to have negative thoughts? What are you options? Can you come up with other thoughts that may counteract any negative thoughts, such as I am a good person, or I am helpful to my friends and family" The last step in STOP is Plan. What sort of plan can you make? [*talk to someone about it, rehearse what you could say back, find some pleasant or relaxing activities*]	
Goals	For this goal setting exercise, let's list out goals of using several techniques for Slowing down, planning to spend time with people, places or doing pleasurable activities, and several positive statements that you can say to yourself. Let's review our list of things that you can do to slow down, some of the negative thoughts that you have that need to be counteracted, people that you can interact with who are positive, places you can go, and activities that you can do that are pleasurable. We also have a list of things that you can say to yourself as a reward. For those participants willing to make change by increasing their activities, by using their thoughts to help them better their moods, by agreeing to engage activities that can help improve moods, discuss SMART goals for improving mood. What is Specific, Measurable, Attainable, Reasonable and Time Bound improving mood using thoughts or behaviors? Try to stay "strengths based" for this discussion and remain focused on solution to help participants reach their goals regarding improving their moods. There are benefits to health by improving mood – so many benefits - especially for those with HIV and opioid use. Find and record the specific goals participants might want regarding something THEY can do to actively improve their moods.	
Summary	The point of this activity was to learn about depression and discuss strategies for stopping depression symptoms. Is there any information in this module that was not clear? Do you have any additional questions?	

8.12 Additional Materials for Sessions.

8.12.1 Pile Sorting Cards on Barriers

Card	Notes (responses/probes)
I don't have time to go to the clinic.	
I don't have the energy or motivation to go to the clinic	This could be an indicator that drug use/ alcohol/mental health issues are a challenge
I missed an appointment, and I am embarrassed/ashamed to go back	
I have been too sick to go to the clinic.	
My drug use (finding money for drugs, or time taken getting drugs)	
I am worried about the unwanted side effects or complications	Often people have side effects from medications. Usually these become less strong after a few weeks. There are treatments for some of the side effects and sometimes doctors will change your medications
My drinking	
I don't have family or friends to help me	
I don't want anyone to know I have HIV	It is certainly possible that other people will find out about your HIV. You may also find out about friends HIV. Knowing other people who have HIV can help you find support and you can help them as well.
I don't have the necessary materials needed by the clinic: - paperwork - identification - test results	
ART is too expensive.	HIV medical care is free. If there are tests that costs we can work with you about figuring out a way to pay for them.
ART was not available at the clinic	
My doctor would not give me treatment	
I don't know how to get or where to go	
I don't have any transport to clinic	

I have been traveling	
I have been in jail or incarcerated	
I am scared of being arrested for drug use	
I want to get my drug use under control first	While you are working to control your drug use you can still get into HIV care. It is very hard to quit using drugs. We will help you with your drug use, but at the same time we encourage you to get into HIV care.
I don't deserve HIV treatment / I don't want to waste my families time and money on treatment	As a drug user you can still be a productive family member and community member. You can do many things to help your family and the community. We will also work with you to stop or slow down your drug use if that's what you want.
Doctors will treat me poorly / Doctors have treated me poorly in past	If you are not treated well at the HIV clinic please tell us. We can accompany you to the clinic and talk to the health care providers.

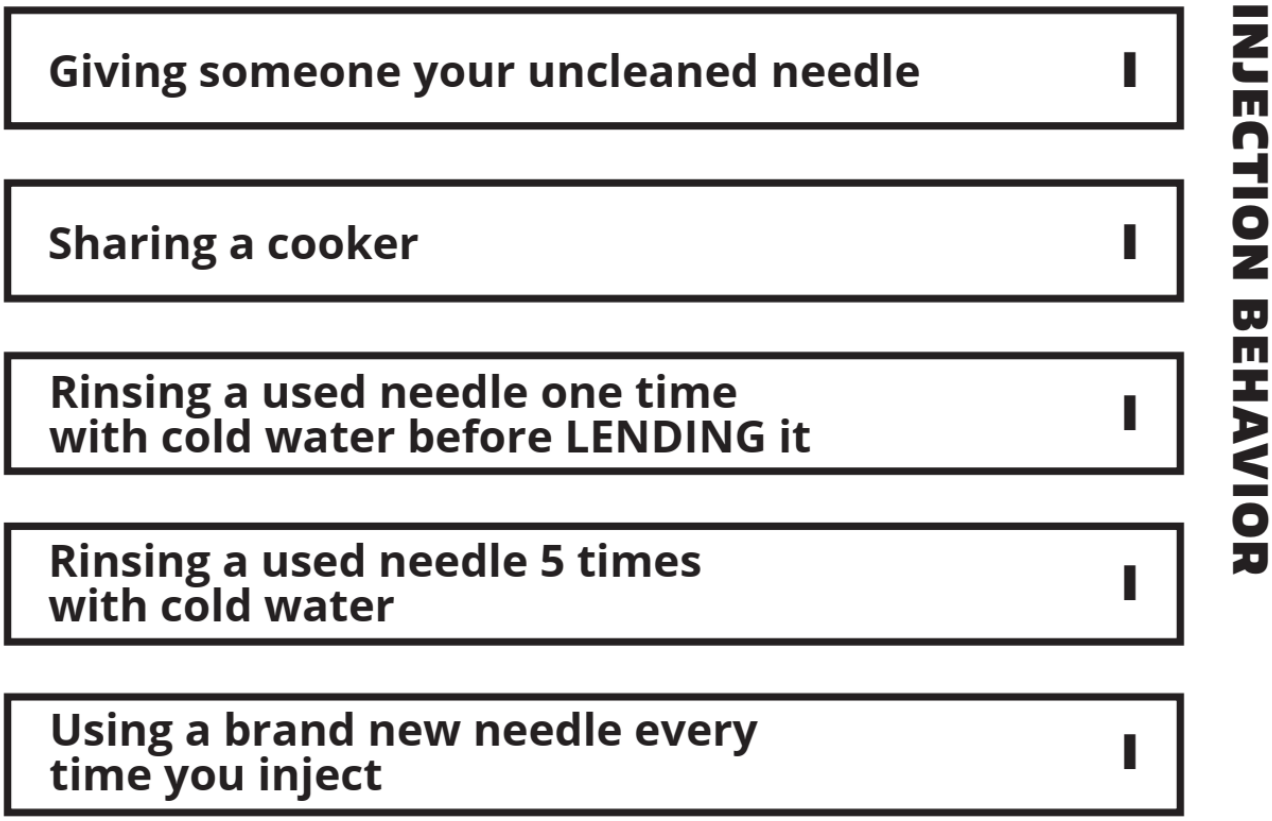
8.12.2 Risk Ladders

Sexual Risk Ladder - Sexual behavior cards

These cards are used for the sexual risk ladder activity. Have participant place cards on the ladder according to their perceived level of risk. Use the sexual risk ladder answer key for correct order of behaviors cards on ladder.

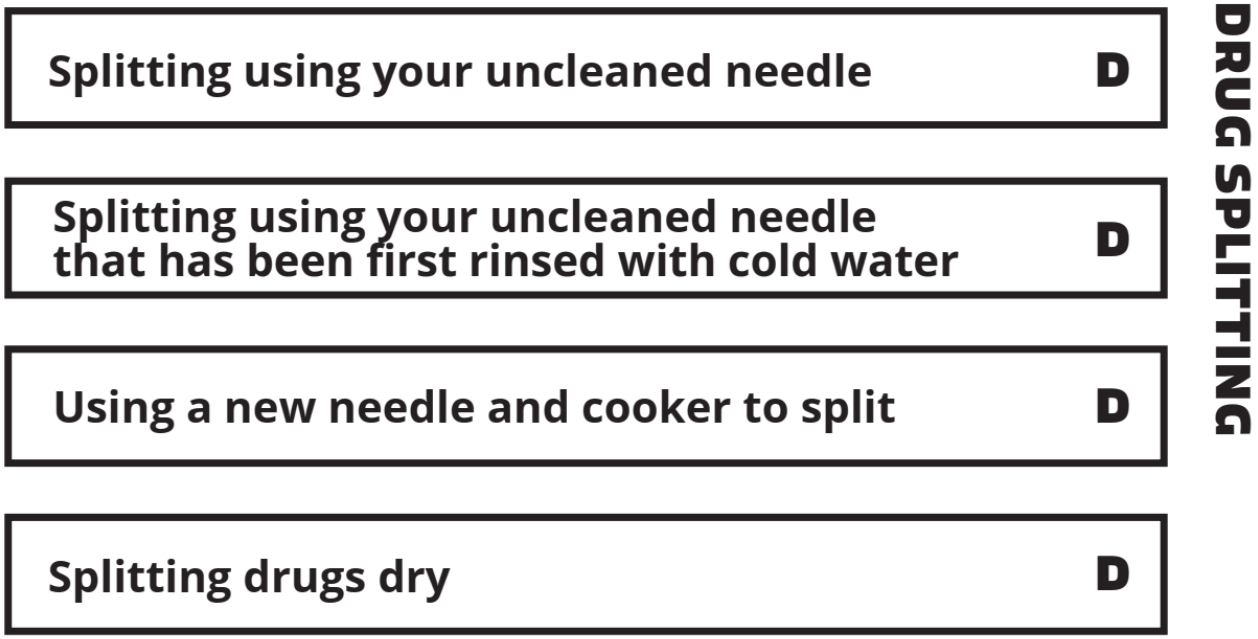
Injection Risk Ladder - Injection behavior cards

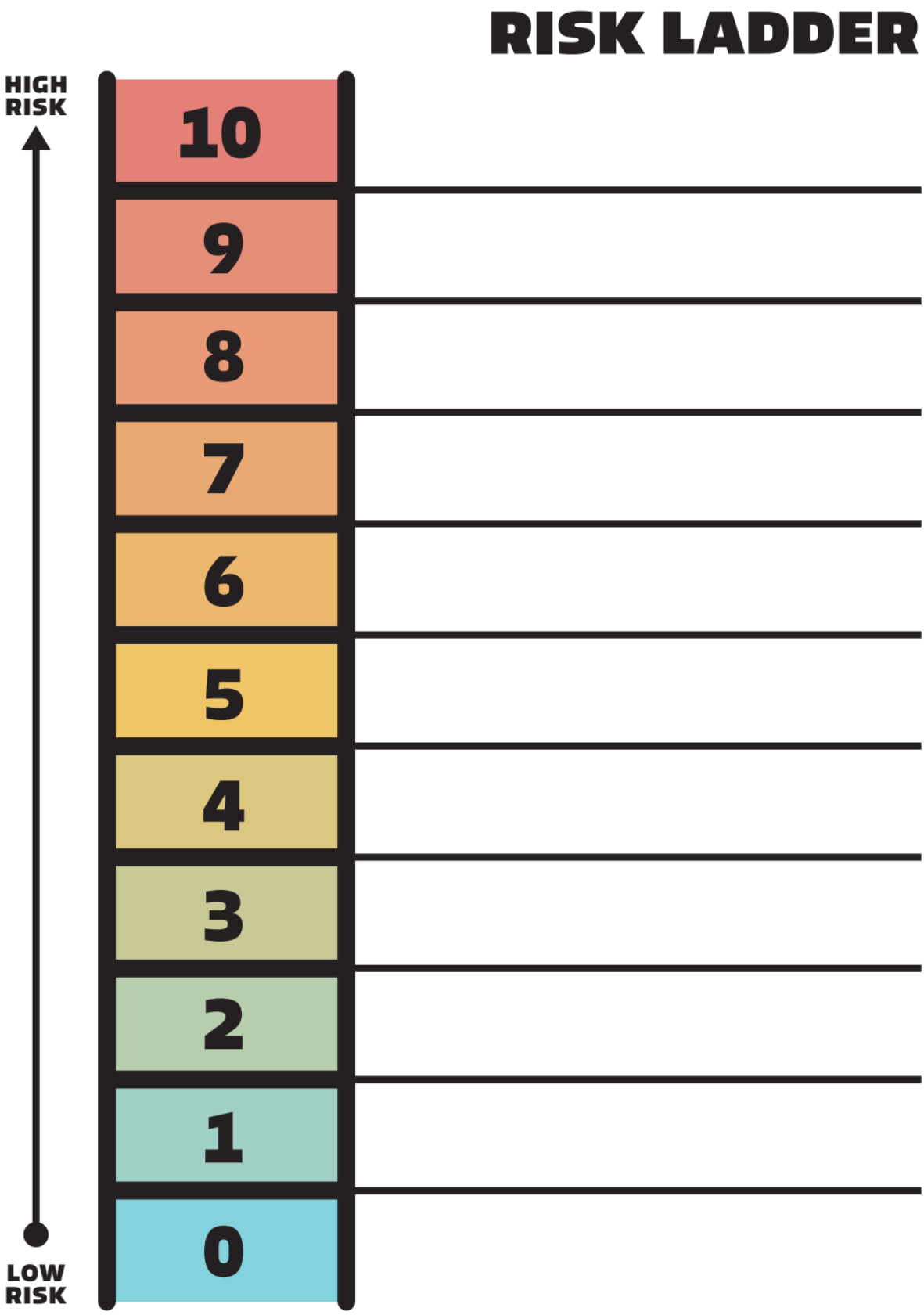
These cards are used for the injection risk ladder activity. Have participant place cards on the ladder according to their perceived level of risk. Use the injection risk ladder answer key for correct order of behaviors cards on ladder.



Drug Splitting Risk Ladder - Drug splitting cards

These cards are used for the drug splitting risk ladder activity. Have participant place cards on the ladder according to their perceived level of risk. Use the drug splitting risk ladder answer key for correct order of behaviors cards on ladder.




RISK LADDER
HIGH RISK
10
9
8
7
6
5
4
3
2
1
0
LOW RISK

8.12.3 Alcohol use module supplementary materials

WHAT IS A STANDARD DRINK?

ONE STANDARD DRINK EQUALS:

ONE CAN OF ORDINARY BEER
(e.g. 330 mL at 5%)

or

ONE SINGLE SHOT OF SPIRITS
Whiskey, gin, vodka, etc.
(e.g. 40 mL at 40%)

or

ONE GLASS OF WINE
OR SMALL GLASS OF SHERRY
(e.g. 140 mL at 12% or 90 mL at 18%)

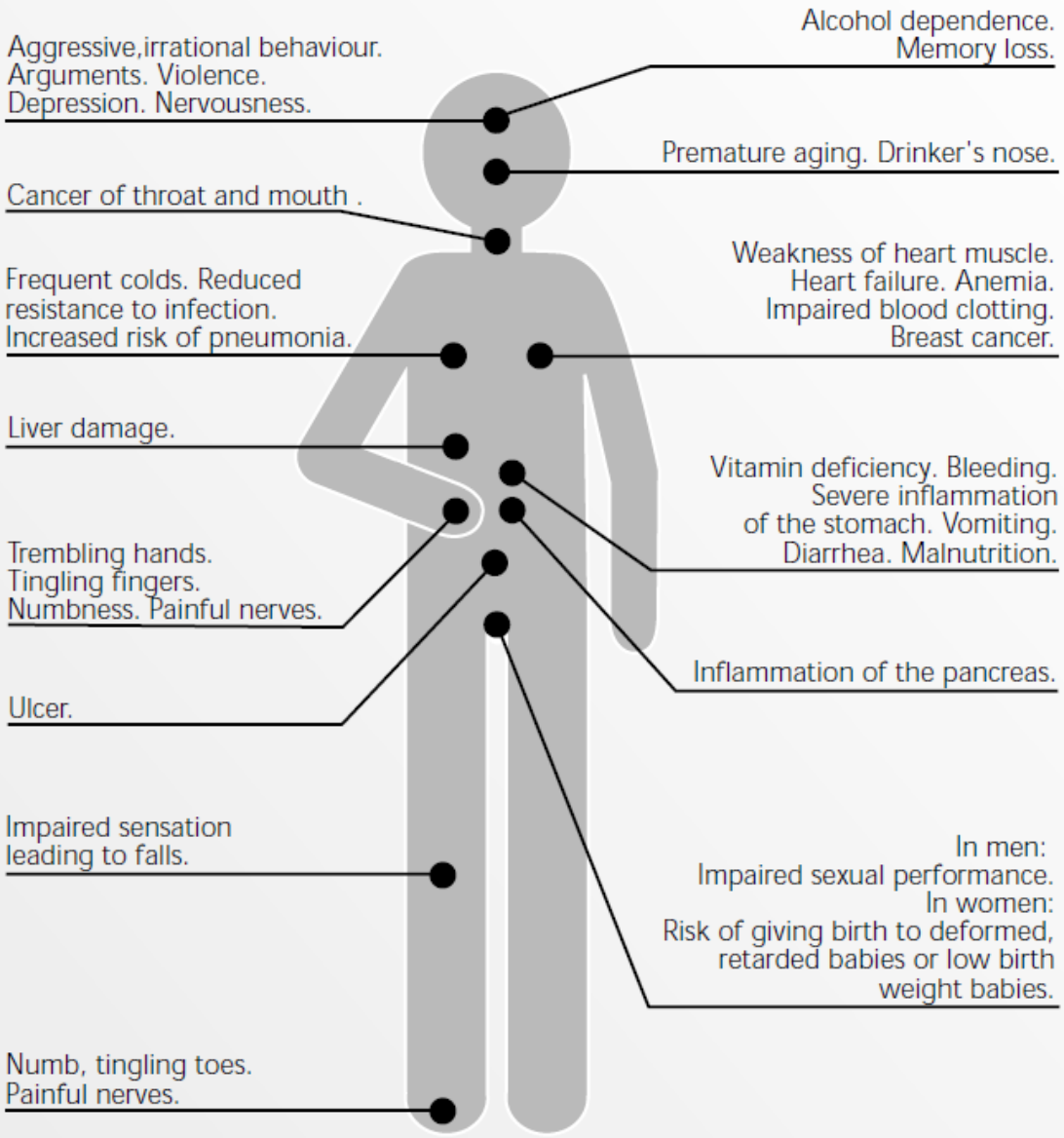
or

ONE SMALL GLASS OF LIQUEUR
OR APERITIF
(e.g. 70 mL at 25%)

or

ONE CUP OF TRADITIONAL
OR HOME BREW
(e.g. 85 mL, >20%)

Effects of High-Risk Drinking



High-risk drinking may lead to social, legal, medical, domestic, job and financial problems. It may also cut your lifespan and lead to accidents and death from drunken driving.

Recommendations for Family Planning and HIV

Family planning

Advances in HIV treatment and prevention make starting a family a safe, exciting option for many women or men who are living with or have partners living with HIV. There are a number of options available for serodiscordant couples (when one partner is HIV-positive and the other is HIV-negative) who want to have a family. There are also a number of options available for HIV-positive couples who want to have a family.

It is important to plan your pregnancy to protect your partner and baby from HIV. Your healthcare professional can direct you to family planning services.

It is also important to take ART as directed to obtain undetectable viral load to maintain your health to take care of your future child.

What are the options for serodiscordant couples having a family?

Many studies show that with a lower viral load, you are less likely to pass HIV to your partner. Having an undetectable HIV viral load (so low the test cannot detect HIV in your blood even though it is still present in your body) dramatically lowers the risk of you passing HIV. Poorly controlled HIV can also be associated with decreased fertility, making it more difficult to get pregnant. Therefore, it is very important to take your ART as directed.

While active drug use provides no interference with fertility per se, sharing of injection drug equipment with others who are HIV-positive or serostatus unknown carries high risk for HIV transmission. As well, non-injection substance use, especially nicotine, alcohol, methamphetamine and cocaine can change likelihood to keep viral load levels undetectable (and can cause damage to fetus during development). The protective effects of MOUD for HIV are extensive and highly valued when family planning in the setting of one or more partners living with HIV.

It is important for both you and your partner to get tested and treated for STIs before trying to get pregnant. Many STIs don't cause symptoms. These infections can increase the chances of your partner getting HIV, may lower your chances of her getting pregnant, and may be dangerous during pregnancy and delivery.

Having a HIV-negative baby is possible with careful planning. Your conception options will vary depending on which partner is HIV-positive. Also, some of these options may not be readily available but may be helpful to know when you discuss with your care provider.

Here are steps any serodiscordant couple can take to prevent the HIV negative partner getting HIV when having unprotected sex so as to get pregnant:

- The HIV-positive partner can take HIV treatment to lower their viral load to an undetectable level before having unprotected sex.
- Both partners can add protection by being consistently involved in MOUD.
- The HIV-negative partner can take PrEP prior to unprotected sex in some cases *(however, the risk of HIV infection still exists)*.
- Get tested and treated for STIs to reduce the risk of HIV transmission.
- Monitor your viral load closely if having unprotected sex.
- Only have unprotected sex whilst the female partner is ovulating.
- *Remember*: Unprotected sex still risks passing HIV to the negative partner.

There are additional options available for serodiscordant couples.

If the female is HIV-positive and the male is HIV-negative:

- Artificial insemination

- Artificial insemination protects the male partner from HIV-infected bodily fluids. His sperm is inserted into the woman's vagina using a syringe. You can do this at home, but with medical advice.
- Artificial insemination is most effective when a woman is ovulating (releasing an egg). Ovulation occurs about 14 days after a woman's period starts.
- Ovulation varies between women, seek advice from your doctor.

If the male is HIV-positive and the female is HIV-negative

- Sperm washing
  - 'Semen' is the fluid that comes from a man's penis when he ejaculates
  - HIV-infected semen cannot infect your baby, but can infect your female partner
  - Sperm washing is a procedure that separates HIV-free sperm from the HIV-infected seminal fluid
  - HIV-free sperm can be inserted into the woman's vagina by artificial insemination – eliminating any risk of HIV infection
  - Sperm washing is not something you can do at home…it is something a doctor would do.
- Timing of unprotected sex (with professional advice)
  - Timed unprotected sex is unlikely to pass HIV to the female partner, if the male partner has:
    - undetectable viral load for 6 months
    - good adherence to their treatment
    - no sexually transmitted infections (STIs).

What are the options for couples who are both HIV-positive having a family?

If both partners are HIV-positive, HIV treatment and planned unprotected sex can reduce the chances of the baby becoming infected. However, a small risk of transmission to the baby cannot be ruled out. All pregnant HIV-infected women should receive ART to prevent perinatal transmission regardless of plasma HIV RNA levels or CD4 cell count. The goal of ART is to maintain a viral load below the limit of detection throughout pregnancy.

In general, the same ART regimens recommended for treatment of non-pregnant adults can be used in pregnant women unless there are known adverse effects for women, fetuses, or infants that outweigh benefits. Frequent and consistent monitoring of HIV RNA levels and CD4 cell count is important throughout the pregnancy.

Sources:

- https://www.avert.org/learn-share/hiv-fact-sheets/mixed-status-couples
- http://www.hiveonline.org/for-you/fertility/
- Recommendations for Use of Antiretroviral Drugs in Pregnant HIV-1-Infected Women for Maternal Health and Interventions to Reduce Perinatal HIV Transmission in the United States: http://aidsinfo.nih.gov/guidelines

APPENDIX I- The Navigation Plan Document

OVERVIEW: The Navigation Plan Document provides a record of the agreement on goals and outcomes between the navigator and the participant and describes the type, timing and scope of services, the referrals to the services (and if possible, referral to the service provider), and measurable outcomes to be reached for each goal listed in this Navigation Plan Document.

This Navigation Plan Document will be reviewed on a regular, but not less than monthly basis between the participant and the navigator. It is expected that the Navigation Plan Document will be reviewed at the start of each navigation session, with changes made as appropriate. The navigator supervisor would also have access to the Plan document during supervision.

For the next six months, the participant and navigator agree to engage a help-intended process that is driven by the goals, needs and wants of the participant. The program of services to be navigated include: MOUD, ART (or PrEP if HIV-negative), sexually transmitted infections, Hepatitis C, primary care, harm reduction and housing.

FREQUENCY: The navigator meets with participants, either face-to-face, on Zoom or on telephone at a frequency that is appropriate for meeting my needs. These sessions can last from 15 to 45 minutes each. With unpredictable COVID-19 restrictions, this contact may be conducted using Zoom sessions or telehealth visits via phone. Any deviations from agreed upon scheduled sessions will be discussed by both, with agreements on whether to schedule, to reschedule or to cancel sessions by both parties. When there are events that interfere with our meetings, I understand I must cancel the session fully 24 hours in advance.

DECISION MAKING: A central part of navigation involves joint goal-setting and meeting of commitments by navigators, providers and participants. A key to reaching this goal involves discussions and skills training in making and keeping commitments. For these sessions, the emphasis is placed on making sure to make commitments that can be kept (i.e., not cancelling or no-showing for appointments). Self-advocacy skills training will used. Client-centered goal setting will be the process used to determine the case management plan.

FOCUS of NAVIGATION: This program of navigation involves health-intended conversations with navigators as well as making linkages to the range of services to be provided in integrated care: MOUD, ART (or PrEP if HIV-negative), sexually transmitted infections, Hepatitis C, primary care, harm reduction and housing. The first goal of this integrated strategies approach is to make sure participants have insurance covering treatments for each of the elements of the integrated strategies.

Steps and Deadlines to Arrange Insurance Status: _____

Treatment for Opioid Use Disorder. The foundation of this treatment is medication for opioid use disorder.

Goals for MOUD are:

- ☐ Methadone
- ☐ Buprenorphine
- ☐ Naltrexone/Vivitrol
- ☐ Not ready to start MOUD

These commitments are agreed upon:

- ☐ Methadone: _____Target Date: _____
- ☐ Buprenorphine: _____ Target Date: _____
- ☐ Naltrexone/Vivitrol: _____ Target Date: _____

Stimulant/Poly-Substance Use. Treatment approaches are entirely behavioral in nature. Goals for this treatment are as noted below.

- ☐ 12-step: (website)_____ Target Date: _____
- ☐ Rational Recovery: _____ Target Date: _____
- ☐ Outpatient Counseling: _____ Target Date: _____
- ☐ Rehab: _____ Target Date: _____
- ☐ Mirtazapine for meth: _____ Target Date: _____

Treatment for HIV. The foundation of this treatment is antiretroviral therapy access. Goals for this treatment are as noted below.

- ☐ HIV Care Clinic: _____ Target Date: _____
- ☐ Mobile Unit: _____ Target Date: _____

PrEP. The foundation for this treatment involves arranging physical exam and labs for PrEP medications. Goals for this treatment are as noted below.

- ☐ Prescribing Clinician/Clinic: _____Target Date: _____
- ☐ Mobile Unit: _____ Target Date: _____

Sexually Transmitted Infections. Goals for this treatment are as noted below.

- ☐ STD Clinic: _____ Target Date: _____
- ☐ Mobile Unit: _____ Target Date: _____

Hepatitis C. Testing and treatment for HCV. Goals for this treatment are as noted below.

- ☐ Prescribing Clinician/Clinic: _____ Target Date: _____
- ☐ Mobile Unit: _____ Target Date: _____

Primary Care. Getting medical care. Goals for this treatment are as noted below.

- ☐ Provider/Clinic: _____ Target Date: _____
- ☐ Mobile Unit: _____ Target Date: _____

Harm Reduction. Provision of narcan kit(s). Provision of injection equipment.

- ☐ SEP: _____ Target Date: _____
- ☐ Narcan kits: _____Target Date: _____
- ☐ Condoms & Lube: _____Target Date: _____
- ☐ Mobile Unit: _____ Target Date: _____

Mood Management. Assessment of mood disorders, especially depressive disorders, will be ongoing. Referrals to persons who provide treatments for mood disorders will be provided. This will involve using cognitive behavioral therapy (for depression) and may involve use of medications. Ongoing discussions will ensure that the right level of intensity is provided to manage moods.

- ☐ Referral for antidepressants: _____Target Date: _____
- ☐ Provision of CBT/counseling for depression: _____ Target Date: _____

Housing. Stable housing is the strong foundation needed to build stability for all health behaviors. Goals for making arrangements for stable housing, which can range from moving from tents, streets and encampments to transitional housing, “couch surfing,” or other forms of housing that can lead to permanent housing. These are the goals for Housing.

- ☐ From streets, tents and encampments to indoor housing of any kind (shelters, motel vouchers, friends couch, transitional housing): _____ Target Date: _____

- ☐ From non-permanent indoor housing to permanent housing (sharing room, apartment, subsidized housing): _____Target Date: _____
- ☐ From current permanent housing to more stable/safer permanent housing: _____Target Date: _____

Food Security. Access to food security is another cornerstone of good health. These are the goals for ensuring consistent access to healthy foods.

- ☐ Sign up for programs that provide direct food assistance (food stamps) Target Date: _____
- ☐ Commit to visiting food banks and other sources for immediate access to food Target Date: _____
- ☐ Commit to reducing intake of fast foods Target Date: _____

Hygiene. Personal hygiene is important and can be one of the toughest to arrange, particularly in the setting of housing and food instability. These are the hygiene goals.

- ☐ Commit to laundering clothes weekly Target Date: _____
- ☐ Commit to personal hygiene at least @ 2 days/week Target Date: _____
- ☐ Commit to oral hygiene/brushing teeth Target Date: _____

This Navigation Plan Document may be modified, and additional recommendations may be made as the intervention progresses through the Program.

APPENDIX II – Supervision Session Debrief Form for Supervisors

Date:

Attendees:

Instructions: Supervisors fill out this form during supervision meetings.

1. In the prior week through your interactions with participants, supporters, and the health system, what unique experiences did you learn about barriers and facilitators to MOUD, ART for HIV care and prevention, services for hepatitis, STI testing and treatment, primary care, harm reduction, stable housing, food security, personal hygiene?

2. After your supervision session, rate whether or not you observed navigators describing use of the model and the navigation skills described in the manual.

Navigation Skill	**Observed (Y/N)**
Motivational Interviewing	Yes/No
Cognitive Behavioral Skills	Yes/No
Problem Solving	Yes/No
Case Management	Yes/No
Social Support	Yes/No
Interpersonal/Process Issues	Yes/No
Cultural Competency	Yes/No

3. Which of the following skills need additional training/support by the navigators?
    a. Motivational Interviewing
    b. Cognitive Behavioral Skills
    c. Problem Solving
    d. Case Management
    e. Social Support
    f. Interpersonal/Process Issues
    g. Cultural Competency

4. What is the plan to provide support and/or training experiences needed by your navigators?

APPENDIX III - Supervision Session Debrief Form for Navigators

Date:

Supervisor:

Instructions: Navigators fill out this form during supervision meetings.

1. In the prior week through your interactions with participants, supporters, and the health system, what unique experiences did you learn about barriers and facilitators to MOUD, ART for HIV care and prevention, services for hepatitis, STI testing and treatment, primary care, harm reduction, stable housing, food security, personal hygiene?

2. Please rate yourself in how often you use the following interventions using the theory-driven model to participants

Motivational Interviewing	Not at all	Some	A lot
Cognitive Behavioral Skills	Not at all	Some	A lot
Problem Solving	Not at all	Some	A lot
Case Management	Not at all	Some	A lot
Social Support	Not at all	Some	A lot
Interpersonal/Process Issues	Not at all	Some	A lot
Cultural Competency	Not at all	Some	A lot

3. What support or training experiences would help you to do your job as navigator?

    a. More information about interventions (list) _____
    b. More training on interventions (list) _____
    c. Change in number of participants (higher/lower)
    d. Getting participants with fewer comorbidities (yes/no)
    e. Help with managing difficult participants (list how) _____
    f. Changing the process of supervision (list how) _____
    g. More information on resources in area _____