

HPTN 074

Qualitative Methods Handbook

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1 Overview

The purpose of this manual is to provide guidance on the implementation of the qualitative component of the HPTN 074 Study, as described in Section 5.8 of the study protocol. This manual describes procedures for all three sites of HPTN 074.

To assess the feasibility of the intervention provided in HPTN 074, individual semi-structured interviews will be conducted with 4-10 stakeholders at each site (minimum=12, maximum=30 across all sites) and 4-15 index participants randomized to the intervention during (1) the initial stages of enrollment and the (2) final stages of follow-up. Stakeholders will include navigators and counselors at the research sites as well as key clinic personnel at the HIV care and substance use treatment sites. The clinic (non-study) personnel will include HIV care and substance use treatment providers and supervisors. Intervention participants will include those who were randomized to receive the HPTN 074 intervention.

Please note: This manual is not intended to be a comprehensive explanation of qualitative methods. Staff involved in this component of the study are expected to have the knowledge and skills necessary to successfully implement qualitative research and should follow the HPTN 074 protocol, Study Specific Procedures (SSP) manual, this manual and site study operating procedures (SOPs) as needed. If at any time any of these materials conflict with the protocol, the protocol should be followed. Questions may be directed to the Qualitative PI.

Semi-structured interviews will explore the heterogeneity of availability and accessibility of treatment services. This will include objective measures such as hours of clinic operations, differences in rules for termination of substance use treatment, and any costs to participants. Additionally, interviews will elicit what clinic personnel believe are the common barriers and/or facilitators for them as providers – as well as their clients - to the intervention outcomes: initiation of HIV care and substance use treatment, as well as medication adherence. Lastly, interviews will explore the sustainability, strengths and weaknesses of the HPTN 074 intervention in addressing the barriers and/or enhancing the facilitators.

Interviews will be conducted using a standard guide (see Appendix A) that includes site-specific probes and a combination of client- and provider-centered queries. An example of a client-centered query is stakeholders' perception of why participants may not be able or willing to initiate HIV or substance use care. An example of a provider-centered query is staffing at methadone maintenance therapy and ART sites and scalability of the intervention.

Interviews may take place at a location identified by study staff that assures adequate privacy and confidentiality. All interviews must be conducted by a staff member who does not have a supervisory or lateral position with the participant and will be recorded and transcribed by qualified personnel and identifying information removed.

Data collected from the interviews will be used to characterize provider opinion on participant experiences with the access to and quality of treatment services, as well experiences with the HPTN 074 intervention. Data analytic methods are fully described in Section 5 of this manual.

2 Study Timeline

Interviews will take place in two phases: **Phase 1** will occur between 1-3 months after the first participant is enrolled in the intervention and **Phase 2** will take place 1-3 months prior to the last participant completing follow-up. In both phases, semi-structured interviews will be conducted with the same systems navigators, counselors, clinic personnel, and participants at each site. Sites can decide which order to interview stakeholders in, but there it is not necessary to interview groups of stakeholders (e.g. all

systems navigators) before proceeding to interview others (e.g. clinic personnel). Recruitment may begin up to 1-3 weeks prior to the interviews.

3 Recruitment

Participation of stakeholders and intervention participants will be entirely voluntary. If a stakeholder chooses not to participate, he/she will experience no penalty or loss of benefits. Furthermore, procedures will be undertaken to ensure that supervisors are not informed of a stakeholder's decision regarding participation. To ensure protection of stakeholder participation or refusal interviewers should not be in supervisory or lateral position to the interviewee. Similarly, should an intervention participant decide not to participate it will not affect his/her receipt of intervention services or any other health care services. Intervention participants will be reminded that participating in an interview will not affect their care or relationship with their provider.

Recruitment may begin up to 1-3 weeks prior to the interviews. Methods or criteria used to identify stakeholders to approach for an interview should be clearly documented and shared between sites, to coordinate a consistent strategy, prior to approaching the first participant. The number of participants approached and outcome (agreement to participate/ refusal, etc.) should be document at the site.

3.1 Eligibility Criteria

Eligible interview participants for stakeholder interviews are systems navigators and counselors at research sites and key clinic personnel at HIV care and substance use treatment sites. Each site will conduct interviews with 4-10 stakeholders (three sites combined minimum=12, maximum=30), aiming for equal distribution of systems navigators, counselors, clinic personnel at HIV care sites, and clinic personnel at substance use treatment sites. Participants for counselor/systems navigator interviews should be current HPTN psychosocial counselors and/or systems navigators (at least 0.5 FTE employee) and have had "encounters" with at least 5 HPTN participants. Participants for clinic personnel interviews should be current ART or substance use care clinic staff (at least 0.5 FTE employee) and have served in their current position for at least 1 year.

In some cases, systems navigators and psychosocial counselor responsibilities may fall to one person, and one person may be able to be interviewed for both purposes. Similarly, some sites may have integrated HIV and substance use care and clinic personnel may speak to both roles if relevant. Site staff can consult Site and Qualitative PIs on adapting this breakdown based on each site's specifications.

Eligible interview participants for participant interviews are intervention participants who have been randomized to receive the HPTN 074 intervention. Each site will conduct interviews with 4-15 intervention participants (three sites combined minimum=12, maximum= 45), aiming for an equal distribution of gender, age, and any other demographic characteristics identified by the Site PI. Participants will be purposively sampled to include those who have been successful at ART uptake and adherence and those who have been unsuccessful at ART uptake and adherence. Participants should have participated in the initial mandatory intervention sessions and preferably a few individual sessions with intervention counselors.

3.2 Informed Consent Procedures and Documentation

Once study staff has determined whether or not a participant is eligible for the qualitative component, he or she should be approached and scheduled for an interview. Upon attendance for an interview, staff should complete the qualitative informed consent procedure using the appropriate language IRB-approved consent forms. Written consent must be obtained prior to participation in the interview. The informed consent process should be documented at the site according to source documentation procedures

outlined in the HPTN 074 SSP and site SOPs. Participants should provide informed consent for this component directly prior to participation (see Appendix C for Sample Informed Consent).

3.3 Interviews with Systems Navigators and Counselors

Interviews with systems navigators and counselors will take place during initial stages of enrollment (1-3 months after first participant is enrolled) and with the same participants at the conclusion of follow up (1-3 months prior to last participant concluding follow up). Participation is voluntary and interviewer should not be in a supervisory position to the interviewee. Semi-structured interviews should follow the interview guide for system navigators/counselors found in Appendix A.

Systems navigators and counselors will be asked for insight on provider and client-level facilitators and barriers. Consequently, ideal participants for interview are characterized by their abilities to articulate experiences, attitudes, and beliefs. Individuals who are both a system navigator and counselor may be interviewed about either or both of their roles. If interviewing an individual in both roles, sites can adjust the interview guide to avoid repeating questions.

Systems navigators and counselors should have prior experience working with affected populations. In addition to previous experience, navigators/counselors should spend at least half-time (0.5 FTE) of their time working directly with patients in the navigator/counselor role.

3.4 Interviews with Clinic Personnel

Interviews will be conducted with key clinic personnel at HIV care and substance use treatment sites at initial stages of enrollment (1-3 months after participant is enrolled) and *the same personnel* at the conclusion of follow up (1-3 months prior to last participant concluding follow up). Semi-structured interviews should follow the interview guide in Appendix A. Sites should aim for an equal distribution of HIV and substance use clinic personnel, with the understanding that at some sites clinical care occurs at the same location and some personnel may be in both roles. Interview participants can include medical doctors, nurses, substance use counselors, or other key clinic personnel at the discretion of each site PI. Participants will be asked for insight on provider and client-level facilitators and barriers. Consequently, ideal participants for interview are characterized by their abilities to articulate experiences, attitudes, and beliefs. Consequently, participants should be experienced, well established, and have a breadth of experience with different types of clients.

3.5 Interviews with Intervention Participants

Interviews will be conducted with intervention participants who have been randomized to receive the HPTN 074 intervention. Interviews will take place at initial stages of enrollment (1-3 months after participant is enrolled) and conclusion of follow up (1-3 months prior to last participant concluding follow up). Participation is entirely voluntary in each phase of interviews and interviewers should remind participants that participation will not affect participants' receiving intervention or any other health care services. Sites should aim to interview the same participants in both interview phases; however, if a participant drops out of the intervention, sites can replace him/her with another participant. Semi structured interviews should follow the interview guide in Appendix A.

To assess feasibility and acceptability of the HPTN 074 intervention, participants will be asked to reflect on their experiences with ART access in order to identify barriers to access and assess how the intervention can facilitate ART access and adherence. Participants should have attended the required introductory sessions and, if possible, several additional sessions. Sites should aim for an equal distribution in gender, age, and home community when recruiting participants. Participants should be

purposely sampled to include those who have been successful at ART uptake and adherence and those who have been unsuccessful at ART uptake and adherence. Ideal participants are characterized by their ability to articulate personal experiences as well as beliefs and attitudes.

4 Interview Procedures

4.1 Interview Guides

Interview Guides can be found in Appendix A of this manual. Guides are separated by type of stakeholder (e.g. system navigator, counselor, clinic personnel, intervention participant). Guides should be repeated for both phases of interviews (initial enrollment and conclusion of follow up). For the interviews occurring during conclusion of follow-up, questions may be adjusted based on site-specific issues that occurred during intervention implementation. Sites may adjust the guides to be culturally and site appropriate. Final guides should be sent to the Qualitative PI for final approval prior to use. Sites are responsible for making sure all appropriate IRB approvals have been obtained prior to use of these guides. Sites teams will work closely with each other and the Qualitative PI to finalize their guides prior to submitting for IRB review and approval.

4.2 Interview Set-Up and Materials

In an effort to streamline study procedures on the day of the actual interview, sites should consider space, set-up, and materials well in advance. The informed consent process and interviews will be conducted in a location that assures adequate privacy and confidentiality, such as a non-study related office. Prior to the interview, staff should make sure that they have all necessary materials. A suggested materials list can be found in Appendix B and should be modified for site-specific needs.

4.3 Documentation Requirements for Interviews

As with other study visits, the qualitative component should follow the guidelines for source and essential documentation as outlined in the HPTN 074 SSP and in site specific SOPs. Source documentation for interviews may consist of checklists, recruitment logs, and transcripts.

4.4 Data Collection

No personal identifiers will be retained on the collected data to assure privacy and confidentiality for stakeholder participants. Reports and publications will be carefully redacted to ensure that identities cannot be discerned.

Semi-structured interviews with systems navigators, psychosocial counselors, clinic personnel, and intervention participants will be based on a standard field guide that will be used at all sites (12-30 stakeholder interviews, 4-15 intervention participants). All interviews will be audiotaped, transcribed and translated into English at each study site by qualified personnel. All participant identifiers will be removed from transcripts. Transcripts will be analyzed in two phases: topical and interpretive.

4.4.1 Interviewer

All interviews should be led by someone who has training and/or experience in qualitative methods. All staff conducting or attending the interviews should not have a role of influence with interviewee. Each site will assign a letter code first starting with I for interviewer, followed then by an A, B, C, or D depending on the number of unique interviewers used at each site. Interviewer codes will be included on the file name of the transcripts. Each site will keep a record of the staff members and their assigned codes.

4.4.2 Recording

Interviews will last approximately one hour. All interviews will be audio recorded, transcribed, and translated by qualified personnel. Electronic recordings, transcriptions, and translation files should be transferred using secure methods. All participant identifiers will be removed from transcripts.

All interviews will be audio-recorded using digital recorders, which provide very detailed, high fidelity reproduction of the interview for transcription and analysis. Study staff are encouraged to always have extra batteries, and when possible, an extra digital recorder on hand. Site teams are highly encouraged to use two tape recorders for every interview, as a back up. Staff should test the recording device and external microphone (if applicable) prior to the beginning of each interview. Prior to initiating the interview staff should record at the beginning of the digital file the date, location, and the participant and interviewer ID codes. This information should also be documented on recruitment logs, checklists, participant chart notes and other forms.

Once the interview has been completed, the digital recordings should be reviewed and backed-up by the local qualitative team within 48 hours of the interview or focus group. Backup to a secure computer should use the following labeling approach- the participant's ID number (interview) code, the date of the interview, and the interviewer or facilitator ID code. The unique participant ID number will be assigned to each participant prior to first interview being conducted. No other identifying information, such as participant or staff name, should be included in the file name. All audio files should be maintained until after analysis is complete.

4.4.3 Demographic Data Collection

After reviewing and obtaining informed consent with the participant (stakeholder), interviewers should complete the Participant Demographics form provided in Appendix D.

4.4.4 Post-Interview Field Summary

Following the completion of the interview, interviewers should summarize their impressions and key points gathered from the participant. Summary forms for each type of participant interview are provided in Appendix E. The goal of post-interview summaries is to provide feedback or lessons learned to the Site Team to improve intervention reach and quality.

For provider interviews, interviewers should record suggestions or feedback that would be useful to systems navigators/psychosocial counselors in working with intervention clients to access ART and/or substance use treatment. For systems navigators/psychosocial counselors interviews, interviewers should note if participants described strategies that were particularly helpful or culturally inappropriate. For intervention participant interviews, interviewers should briefly summarize the interview including barriers and facilitators identified by the participant.

Site staff should review these forms at the completion of each round of interviews, summarize key points, and give this information back to the peer navigator and counselor supervisors. At the conclusion of each round of interviews (e.g. early recruitment, final follow up) a short summary document of lessons learned should be shared with Qualitative PI and across sites.

4.4.5 Transcription and Translation

Site staff is responsible for transcription and translation, either using internal staff resources or commercial services. If using internal team to transcribe and/or translate, staff interviews should be compiled only by those who do not have a role of influence with the staff member interviewed, as voice

in the audio recording will likely disclose the identity of the staff member. Electronic recordings, transcriptions, and translation files should be transferred using secure methods.

Transcripts should note participants' nonverbal cues, such as extended pauses, shoulder shrugs, or facial expressions and indicate these using italicized or bracketed text. Any identifying information should be removed at the time of transcription. Identifying information should be replaced with a description holder indicating what type of information was removed. Examples of text with identifying information, as well as the de-identified version are included below.

| Identifier | De-identified |
|--|---|
| I don't use the tablets with Sean, my boyfriend. | I don't use the condoms with [name of boyfriend], my boyfriend. |
| I've been living at the corner of Park and Vine for 5 years. | I've been living at the corner of [name of intersection] for 5 years. |

Once transcripts have been completed, they should be reviewed and corrected as needed by the appropriate staff person for accuracy against the source documentation (recordings, notes) within two working days of receipt. Each site will determine appropriate timeline for transcription. However, all interviews conducted should be transcribed within two weeks of the final interview conducted at the end of each phase (i.e. enrollment and follow-up).

If using external services, site staff should carefully monitor transcription and translation to ensure fidelity and confidentiality. Any transcripts sent to external services will only contain the de-linked identification numbers. For translation, site staff should work closely with translators to identify tone that accurately reflect participant's intentions and vocabulary. Any cultural terms or expressions without equivalent English translations should be noted using the original wording and additional notes to explain meaning and tone, instead of literal translation.

4.4.6 Final Submission of Staff Transcripts

Sites should select one contact person who is responsible for submitting all final translated interview transcripts to the Qualitative PI. In addition the steps outlined above, prior to email submission sites should also check for spelling and grammar errors and remove any editing mark-up in the document.

4.4.7 Confidentiality and Privacy

Audio files will be saved on a password-protected, access-limited computer and any physical copies of the file (e.g. burned onto compact disc for transcription) will be kept in a locked, limited-access storage location like a file cabinet when not in use. Any other files related to the qualitative component, including, but not limited to, hard copies of transcriptions, written consent forms, link and recruitment logs will be handled and stored according to the study protocol and SSP.

5 Data Analysis

Data analysis will take place in two phases: topical and interpretative. In the first phase, topical analyses will identify content categories a priori and will cull data into units that reflect core content categories for summary. A centralized team will develop a codebook consisting of main topics of interest (e.g., utilization of systems navigators and counselors, uptake of ART, pill-taking patterns, uptake of substance use treatment, and provider burden).

A standardized workshop will train local staff in the codebook, the application of codes and the use of Atlas ti. Interviews will be indexed by pre-determined topics through the application of topical codes by trained teams of 2-3 site-level coders. Specifically, coders will review transcript content for references to

barriers and facilitators of both the intervention (engagement in counseling and utilization of systems navigators) and uptake of HIV and substance use treatment services from both client and provider perspectives. Each identified barrier and facilitator will be further coded for content that is motivational, behavioral skills related, or informational.

To maintain coding quality, each coder will complete a certification exercise prior to initiating the work, qualitative supervisors will regularly review coded transcripts and senior data analysts will spot check coded transcripts from each site. The team anticipates that these data will provide nuanced information about the feasibility of and barriers to the various components of the intervention as well as HIV and drug treatment services. Data that are topically coded will be used to generate code reports for each of the feasibility endpoints across sites at the central level. Based on these code reports, detailed summary reports will note insights, key themes and patterns that emerge from the data.

The second phase of analyses is interpretative and will occur at the central level. The team will use an iterative, inductive process of reviewing content and identifying themes within, across and outside of topical codes that characterize, qualify or define the phenomenon of interest. This phase of analyses will begin with an iterative review of site-specific topical code reports by senior data analysts familiar with the phenomenon of interest to ensure an adequate level of sensitivity in the development of coding schemes. In addition to descriptions of the phenomenon identified through topical coding, the team will explore the context in which it occurs, specific conditions in which it occurs, activities done in response to the phenomenon and outcomes of the activities. This process will produce a set of general categories that describe the characteristics and patterns both within and across sites and topical codes. Given the interview objectives, the team anticipates that a priori phenomena would include utilization of systems navigators and counselors, uptake of ART, pill-taking patterns, uptake of substance use treatment, and provider burden. However, additional phenomena that may emerge from the interview data will also be included. Codes will then be consolidated into a final coding system that can be compared across sites. Through this process, critical aspects of intervention delivery as well as uptake of services along the HIV treatment cascade will be defined both a priori and through the identification of emerging phenomena that may not have been anticipated.

APPENDIX A Interview Guide

Introduction script (*All participants*)

Thank you for participating in this interview. My name is *[introduce self and role]*. The goal of today's interview is to learn more about your work and the clients you serve *[for participant interviews: your experience accessing ART]*. We hope to understand barriers and facilitators for clients, particularly people who inject drugs, to get HIV tests, access ART, and maintain their ART adherence. Your input will help us improve programs and services for PLWH in the community.

Anything that you say to me will be kept confidential. What we discuss is audio recorded and then transcribed. When it is written out, all information that could identify you to someone reading the words (anything said with names or locations or that kind of thing) are completely removed. The material from our interview is saved with your participant number but not your name. The research team members reviewing this text will not link who you are to that ID and will not tell anyone on site about your specific feedback. There are other people doing interviews as well, and we will put all those documents together and look at main topics people talked about. We will not identify or share anything you say as a comment linked to your name or ID number.

Your input is crucial to help us understand how to make HIV and Substance Use services and programs most accessible and appropriate for people living in this community. There are no wrong or right answers to any of the questions here. Also, please don't feel like you have to answer only the questions I ask -- anything that you think of is really welcome and useful to our discussion.

You have signed the informed consent form in which you consented to audio record this discussion. I may also be taking notes on the things you are saying to help me follow the discussion. Please recall that when these tapes are not being reviewed, they will be stored in a locked location and will be destroyed after analyses are completed.

I would like to start recording. Before we do this, do you have any questions or concerns?

Are you ready to begin?

INTERVIEWER TURNS ON THE TAPE RECORDER TO START THE DISCUSSION

[Round 1] Stakeholder Interview Guide: Clinic Personnel

Objectives: *Identify client- and provider-level barriers and/or facilitators to uptake of HIV testing, initiation of HIV care and substance use treatment, and medication adherence, and assess the degree to which HPTN 074 interventions address barriers and/or enhance facilitators.*

Interviewer Note: *Each section is marked as appropriate for each type of participant. If participants work at a clinic that provides both HIV and substance use treatment, ask them both sets of questions.*

Introduction (All participants)

1. Tell me about your role in the clinic.
 - a. Probe: How long have you worked here?
 - b. Probe: What services does this clinic provide? (Hint: ART, MMT, etc.)
 - c. Probe: About how many clients do you see on a typical day?

2. What are some of the challenges you face in your role?
 - a. Hint: limited staff/financial resources, bureaucracy, patient's adherence to treatment, cultural norms/stigma
 - b. Hint: feeling discouraged by lack of improvement in patient outcomes, hearing about problems PWID have to deal with on a daily basis

Initiating HIV Care (ART providers)

Thank you for your insight on the barriers to HIV testing in this clinic. I'd like to now shift to talking about how clients initiate their HIV treatment here.

Interviewer Note: **If the provider works only with substance use treatment (e.g. MMT), skip this section and proceed to the substance use questions.**

1. Imagine a client has just been told they tested positive for HIV, what would he/she need to do to start ART?
 - a. Probe: Who tells them their next steps for getting onto ART?
 - b. Probe: Where do they go to get CD4 count?
 - c. Probe: How long do they have to wait for an appointment?
 - d. Probe: What days/times can they come back for an appointment?
 - e. Probe: What additional tests do clients need to start ART?
 - f. Probe: What paperwork is required for each of these steps?
 - g. Probe: Which services do clients have to pay for? And how much do they have to pay?

2. Of the process you just described, which step(s) do you think are the most difficult for clients?
 - a. Probe: Can you describe why this step (s) is particularly difficult for people who inject drugs?

3. What are the biggest barriers to clients accessing ART?
 - a. Hint: navigating the system, taking time off work, low motivation to seek care, lack of knowledge about ART, stigma in the community, etc.

4. Do you know of any programs or strategies that could reduce these barriers?
 - a. Probe: How could barriers be reduced at the clinic level (e.g. administrative requirements, better outreach in the community, additional staff)?

- b. Probe: How could barriers be reduced at the individual client level (e.g. more patient navigators, bringing spouses or family to the visit)?
 - c. What advice do you give clients to overcome these barriers?
5. What motivates clients who are PWID to get onto ART
- a. Hint: feeling sick, have children and want to get better

ART Adherence (*ART providers*)

Lets talk about the clients who are on ART and the challenges and successes they experience when adhering to ART.

6. What do you tell clients about ART adherence?
- a. Probe: How often do you discuss ART adherence with your clients?
 - b. Probe: How do clients respond to this discussion?
7. Can you tell me a little about the patterns of ART adherence you see in the clinic?
- a. Hint: most clients don't skip at all; most clients skip once or twice, but are otherwise adherent; many who skip, skip several days in a row.
8. In your opinion, what are the most common reasons clients do not adhere to their treatment?
- a. Hints: Running out of pills, forgetting to take medication, embarrassed to take medication, alcohol use, feeling better, don't like side effects.
9. How often do clients have to come to the clinic to get their medicines?
- a. Probe: Do staff remind clients about getting their medicines? If so, how?
10. Who (e.g. friends, family, sexual partner, injecting partner) helps clients take ART?
- a. Probe: How are these people helpful?
 - b. Probe: Do you recommend clients identify someone to help with ART adherence?
11. What are some of the strategies that you recommend for patients to remember to take ART?
- a. Probe: What helpful things do they do at home to remember to take medication?
 - b. Probe: How do you encourage them to remember to take their medication?
 - c. Probe: In your opinion, how can counselors or system navigators assist patients with medication adherence?

Initiating Substance Use Treatment (*Substance use providers*)

Thank you for your insight on the challenges to initiating HIV treatment for people who inject drugs. I'd also like to understand the barriers for initiating substance use treatment.

12. What are some reasons that injectors seek care for their substance use?
- a. Hint: pressure from family, police mandate, own desire to stop using.
13. Can you tell me the range of services available to someone who wants to seek care for their substance use? How does an injector decide on which services to attend?
- a. Hint: 06/07 centers, community detoxification, substance use treatment.

14. In your experience, what are some of the reasons people who inject drugs come here, to the substance use clinic, to begin treatment?
 - a. Hint: wanted to stop injecting, influenced by friends/family, recently found out they have HIV
15. What are the barriers to going to substance use treatment?
 - a. Hint: did not know about substance use treatment, stigma around treatment, does not know how to navigate system, financial.
16. Can you tell me more about the process to start substance use treatment? If someone wanted to sign up for substance use treatment, what would they need to do?
 - a. Probe: Where do clients get the information they need for registering at the substance use treatment clinic?
 - b. Probe: What paperwork are clients required to bring?
 - c. Probe: Once the required paperwork is in, is there a process for selecting clients? Is there a waiting list? Are some injectors more likely to get registered into treatment than others?
 - d. Probe: How long do they have to wait to get their methadone dose each time they come into the clinic?
 - e. Probe: What times can they come back for an appointment; can they select their times?
 - f. Probe: Which services do clients have to pay for? And how much do they have to pay?
17. Of the process you just described, which step(s) do you think are the most difficult for clients?
 - a. Probe: Can you describe why this step (s) is particularly difficult for people who inject drugs?
18. Once on treatment, how often do people skip doses? What are the biggest barriers to clients adhering to substance use treatment?
 - a. Hint: taking time off work, low motivation to seek care, stigma in the community, etc.
19. Do you know of any programs or strategies that could reduce these barriers?
 - a. Probe: How could barriers be reduced at the clinic level (e.g. administrative requirements, better times to come in to take dose, more convenient location, additional staff)?
 - b. Probe: How could barriers be reduced at the individual client level (e.g. more patient navigators, bringing spouses or family to the visit)?
 - c. Probe: Do you think counseling programs can effectively reduce these barriers? Why or why not?
 - d. Probe: What advice do you give clients to overcome these barriers?

Conclusion *(All participants)*

Thank you for sharing your perspective. Before we conclude, is there anything else you would like to share about your role as a provider in this area? And/or anything we should consider as we improve the HPTN 074 program?

[Round 1] Stakeholder Interview Guide: Systems Navigators/Counselors

Objectives: *Identify client- and systems-level barriers and/or facilitators to uptake of HIV testing, initiation of HIV care and substance use treatment, and medication adherence, and assess the degree to which HPTN 074 interventions address barriers and/or enhance facilitators.*

Introduction

1. Tell me about your role in the clinic.
 - a. Probe: How long have you worked here?
 - b. Probe: About how many clients do you see on a typical day?
2. Can you describe some of your typical clients?
 - a. Probe: Where do they live?
 - b. Probe: How are their relationships with their families and/or communities?
 - c. Probe: What is their education/employment status?
 - d. Probe: What do they value?

Identifying Barriers to ART Access and Adherence

As you know, we are working to improve access to HIV and substance use services for people who inject drugs. Let's begin by identifying the most common challenges and issues for people who inject drugs, and then we'll move on to how you work with them to overcome these obstacles.

3. In general, how easy or difficult is it for people who inject drugs to get health care services, such as HIV testing or ART medication?
 - a. Probe: What services are easiest to access?
 - b. Probe: What services are most difficult to access?
4. Imagine a client has just been told they tested positive for HIV, what is the process to start ART?
 - a. Probe: Who tells them their next steps for getting onto ART?
 - b. Probe: Where do they go to get CD4 count?
 - c. Probe: How long do they have to wait for an appointment?
 - d. Probe: What days/times can they come back for an appointment?
 - e. Probe: What additional tests do clients need to start ART?
 - f. Probe: What paperwork is required for each of these steps?
 - g. Probe: Which services do clients have to pay for? And how much do they have to pay?
5. Based on your experiences as a navigator/counselor, of the process you just described, which step(s) do you think are most difficult for people who inject drugs?
 - a. Probe: Can you describe why this step(s) is particularly difficult for people who inject drugs?
 - b. Probe: Are some steps particularly difficult for men or women? What about people from ethnic minorities?
6. In your opinion, what are the greatest barriers to accessing ART?
 - a. Hint: navigating the system, taking time off work, low motivation to seek care, lack of knowledge about ART, stigma in the community, etc.

7. In your opinion, what are the greatest barriers to adhering to ART?
 - a. Hint: lack of knowledge about ART, low motivation, stigma in the community, difficulty consistently getting ART, mental health, drug use, alcohol use.
 - b. Probe: How are these barriers similar or different to initial ART access?

Addressing Barriers to ART Access and Adherence

Thanks for explaining the challenges and barriers to me. Now I want to move to understand how you are working with clients to improve their access to ART. I want to remind you that this discussion is not a reflection of how well you are doing your job -- it is for me to understand how well the counseling and navigation program is going. Please share with me honestly what you think is helpful or not helpful for your clients so that we can work together to improve programs for people who inject drugs.

8. Tell me about your experience working with people who inject drugs to increase their access and adherence to ART.
 - a. Probe: How do people who inject drugs react to your advice?
 - b. Probe: Are there differences in how people respond to advice initially compared to later (after there is established relationship)?
 - c. Probe: What are the challenges to working with people who inject drugs?

Interviewer note: Repeat questions 9 and 10 for 2-3 of the specific barriers they identified in the first part of the interview.

9. I'd like to go back to discussing [*identified barrier*], what do you advise people who inject drugs to overcome this issue?
 - a. Probe: Can you give me an example of advice you gave a client that was successful.
 - b. Probe: Why do you think this was helpful to the client? [Hint: client was motivated, strategy is always successful, I knew this worked with other clients]
 - c. Probe: Can you give me an example of advice you gave a client that was not successful.
 - d. Probe: Why do you think this was not helpful? [Hint: this strategy never works for clients or this type of client, client was not motivated, barriers were too difficult to overcome]
 - e. Probe: Are certain strategies more successful for certain types of clients? [Hint: men/women, age, socioeconomic status, clients' community, more/less social support]
10. In your opinion, what additional resources or strategies could help reduce barriers?
 - a. Hint: clinic structure, additional staff, more motivated patients, reduced stigma in the community

Identifying Barriers to Substance Use Treatment

Now I'd like to shift our conversation to talk about substance use treatment. The questions are similar to the ones I just asked you about ART, but please take some time to consider how your responses may be similar or different when thinking about people who inject drugs accessing substance use treatment.

11. In general, what are some reasons that injectors seek care for their substance use?
 - a. Hint: pressure from family, police mandate, own desire to stop using.
12. Can you tell me the range of services available to someone who wants to seek care for their substance use?
 - a. Probe: How does an injector decide on which services to attend?

- b. Hint: 06/07 centers, community detoxification, MMT.
 - c. Probe: What services are easiest to access?
 - d. Probe: What services are most difficult to access?
 - e. Probe: How is this similar or different from accessing general health care services? From accessing HIV testing/ART?
13. Can you tell me about the process to initiate substance use treatment? If someone wanted to sign up for MMT, what would they need to do?
- a. Probe: Where do clients get the information they need for registering at the MMT clinic?
 - b. Probe: What paperwork are clients required to bring?
 - c. Probe: Once the required paperwork is in, is there a process for selecting clients? Is there a waiting list? Are some injectors more likely to get registered into MMT than others?
 - d. Probe: How long do they have to wait to get their methadone dose each time they come into the clinic?
 - e. Probe: What times can they come back for an appointment; can they select their times?
 - f. Probe: Which services do clients have to pay for? And how much do they have to pay?
14. Of the process you just described, which step(s) do you think are most difficult for people who inject drugs?
- a. Probe: Can you describe why this step(s) is particularly difficult for people who inject drugs?
 - b. Probe: Are some steps particularly difficult for men or women? What about people from ethnic minorities?
15. In your opinion, what are the greatest barriers to going to MMT?
- a. Hint: navigating the system, taking time off work, low motivation to seek care, lack of knowledge about MMT, stigma in the community, mental health, drug use, alcohol use.
16. Once on MMT, how often do people skip doses? What are the biggest barriers to clients adhering to MMT?
- a. Hint: taking time off work, low motivation to seek care, stigma in the community, etc.

Addressing Barriers to ART Access

As before, I want to discuss how you are working with clients to improve their access to substance use treatment. Again, it will be helpful for me to know what is or is not working, so please share your honest opinions with me.

17. In general, what has been your experience working with people who inject drugs to increase their access to substance use treatment?
- a. Probe: How do people who inject drugs react to your advice?
 - b. Probe: What are the challenges to working with people who inject drugs?
 - c. Probe: How is this similar or different than counseling/navigating to increase ART access and adherence?

Interviewer note: Repeat question 18 and 19 for several of the specific barriers they identified in the first part of the interview.

18. I'd like to go back to discussing [*identified barrier*], what do you advise people who inject drugs to overcome this issue?
- Probe: Can you give me an example of advice you gave a client that was successful.
 - Probe: Why do you think this was helpful to the client? [Hint: client was motivated, strategy is always successful, I knew this worked with other clients]
 - Probe: Can you give me an example of advice you gave a client that was not successful.
 - Probe: Why do you think this was not helpful? [Hint: this strategy never works for clients or this type of client, client was not motivated, barriers were too difficult to overcome]
 - Probe: Are certain strategies more successful for certain types of clients? [Hint: men/women, age, socioeconomic status, clients' community, more/less social support]
19. In your opinion, what additional resources or strategies could help reduce barriers?
- Hint: clinic structure, additional staff, more motivated patients, reduced stigma in the community

Evaluating the Counselor/Navigator Role

Lastly, I want to discuss your thoughts on your role as a systems navigator/counselor. Again, your opinion is very valuable for us to help improve these programs. It is just as important for me to understand what is not going well as it is to know what is going well. Your responses will be kept private, so do not worry about what others would think about what you say.

20. In your opinion, do you think your role as counselor/navigator was helpful to your clients?
- Probe: Why or why not?
21. In your opinion, what are some of the challenges of being a counselor/navigator?
22. In what ways do you think you may have helped participants with accessing HIV testing? ART? ART adherence? MMT?
- Probe: At what point was your role most helpful?
 - Probe: In your opinion, what additional services would have been helpful to participants to engage them in HIV/Substance Use care?
23. Imagine a new counselor/navigator was starting this job. What advice would you give him/her to work in this role?
- Probe: What would you tell them about working with people who inject drugs?
 - Probe: What would you tell them about their relationship with clients? With other staff in the clinic?
 - Probe: What would you tell them about the counseling strategies or content?
24. You've worked with a range of participants. Can you describe participants who were more likely to benefit from your role?
- Probe: Why do you think they were more likely to benefit?
 - Probe: When you are working with a client, what are some signs that a client will be successful in accessing ART or substance use services?
25. What are some of the reasons participants are less likely to benefit from your role?
- Probe: Why do you think they were less likely to benefit?

- b. Probe: When you are working with a client, are there any signs that a client will be less successful?

[Round 1] Stakeholder Interview Guide: Intervention Participants

Objective: *Identify client- and systems-level barriers and/or facilitators initiation and adherence to HIV care and substance use treatment. Assess the feasibility and acceptability of HPTN 074 intervention to address these barriers and/or facilitators with index participants randomized to the intervention program.*

Introduction

1. Tell me a little bit about your community. By community, I mean the people you interact with on a routine basis, including neighbors, friends, and colleagues. *[Please feel free to replace the word community to denote this concept.]*
 - a. Probe: What do people in your community value? (Hint: family, religion, money)
 - b. Probe: What is your relationship with your family?
 - c. Probe: What is your relationship with your community?
 - d. Probe: What do people in your community do for work?
2. Can you tell me a little about what it's like being a drug user in your community?
 - a. Probe: How long have you been using drugs?
 - b. Probe: Do you feel people treat you differently because you are a drug user? (Hint: family, friends, colleagues)
 - c. Probe: Do you talk with your friends about using drugs? What do you talk about?
 - d. Probe: Do your friends use drugs? Have they used drugs in the past?

Identifying Barriers to ART Access and Adherence

As you know, we are working to improve access to HIV and substance use services for people who inject drugs. I want to ask you about common challenges and issues for people who inject drugs.

3. In general, what are some reasons that people who inject drugs seek HIV testing or ART medication?
 - c. Hint: pressure from family, own desire to feel better.
4. In your opinion, how easy or difficult is it for people who inject drugs to get health care services, such as HIV testing? How easy or difficult is it for people who inject drugs to get ART medication?
 - a. Probe: What services are easiest to access?
 - b. Probe: What services are most difficult to access?
5. Let's go back to when you tested positive for HIV and were recommended to start treatment. Can you walk me through the process of beginning ART?
 - a. Probe: How did you feel about beginning ART?
 - b. Probe: What were you told about beginning ART?
 - c. Probe: When did you come back for an appointment? How long did you have to wait?
 - d. Probe: What types of paperwork were required?
 - e. Probe: What additional tests did you have to take to start ART?
 - f. Probe: Which services did you have to pay for? How much did they cost?

Thank you for sharing your personal experience. It's really helpful for me to understand the process that people who inject drugs go through.

6. Based on what you know about people who inject drugs, do you feel that your experience of beginning ART has been similar or different to the experience of other people who inject drugs?

- a. Probe: What have other people who inject drugs told you about their experience of beginning ART? (Hint: required paperwork, cost for services, counseling support)
7. Based on the experience you just described and what you know about people who inject drugs, which step(s) do you think are most difficult for people who inject drugs?
 - a. Probe: Can you describe why this step(s) is particularly difficult for people who inject drugs?
 - b. Probe: Are some steps particularly difficult for men or women? What about people from ethnic minorities?
 8. In your opinion, what are the greatest barriers to accessing ART?
 - a. Hint: navigating the system, taking time off work, low motivation to seek care, lack of knowledge about ART, stigma in the community, etc.

Interviewer Note: Choose question 7 OR 8 depending on a participant's ART status. Do NOT ask both questions in one interview.

For participants who are not yet taking ART or have been on ART less than 2 months:

I'd like to move to discussing your experience taking the medication. I want to remind you that everything you say is just between us. I won't be sharing this information with the program counselors or your doctor, so please feel free to share with me honestly.

9. In your opinion, what do you think may be challenging about taking ART?
 - a. Hint: lack of knowledge about ART, low motivation, stigma in the community, difficulty consistently getting ART, mental health, drug use, alcohol use.

For participants who have been on ART more than 2 months:

Now that you've been on ART for a few months, I'd like to ask you about your experience taking the medication. I want to remind you that everything you say is just between us. I won't be sharing this information with the program counselors or your doctor, so please feel free to share with me honestly.

10. In your opinion, what are the greatest barriers to adhering to ART?
 - a. Hint: lack of knowledge about ART, low motivation, stigma in the community, difficulty consistently getting ART, mental health, drug use, alcohol use.
 - b. Probe: How are these barriers similar or different to initial ART access?

Identifying Barriers to Substance Use Treatment

Now I'd like to shift our conversation to talk about substance use treatment. The questions are similar to the ones I just asked you about ART, but please take some time to consider how your responses may be similar or different when thinking about people who inject drugs accessing substance use treatment.

11. In general, what are some reasons that injectors seek care for their substance use?
 - a. Hint: pressure from family, police mandate, own desire to stop using.
12. Can you tell me the range of services available to someone who wants to seek care for their substance use?
 - a. Probe: How does an injector decide on which services to attend?
 - b. Hint: 06/07 centers, community detoxification, MMT.
 - c. Probe: What services are easiest to access?

- d. Probe: What services are most difficult to access?
 - e. Probe: How is this similar or different from accessing general health care services? From accessing HIV testing/ART?
13. Can you tell me about the process to initiate substance use treatment? If someone wanted to sign up for MMT, what would they need to do?
- g. Probe: Where do they get the information they need for registering at the MMT clinic?
 - h. Probe: What paperwork are clients required to bring?
 - i. Probe: Once the required paperwork is in, is there a process for selecting clients? Is there a waiting list? Are some injectors more likely to get registered into MMT than others?
 - j. Probe: How long do they have to wait to get their methadone dose each time they come into the clinic?
 - k. Probe: What times can they come back for an appointment; can they select their times?
 - l. Probe: Which services do clients have to pay for? And how much do they have to pay?
14. Of the process you just described, which step(s) do you think are most difficult for people who inject drugs?
- c. Probe: Can you describe why this step(s) is particularly difficult for people who inject drugs?
 - d. Probe: Are some steps particularly difficult for men or women? What about people from ethnic minorities?
15. In your opinion, what are the greatest barriers to going to MMT?
- b. Hint: navigating the system, taking time off work, low motivation to seek care, lack of knowledge about MMT, stigma in the community, mental health, drug use, alcohol use.
16. Once on MMT, how often do people skip doses? What are the biggest barriers to clients adhering to MMT?
- b. Hint: taking time off work, low motivation to seek care, stigma in the community, etc.

Evaluating the HPTN 074 Intervention

Thank you for helping me understand the challenges that people who inject drugs face with taking ART. Now I'd like to shift our conversation to discussing strategies to improve this process. I want to remind you that your opinion is very helpful for us to improve these programs. It is just as important for me to understand what is not going well as it is for me to know what is going well. Your responses will be kept private so do not worry about what others would think about your opinion.

17. In your opinion, have your sessions with a systems navigator and/or peer counselor been helpful?
- a. Probe: Why or why not?
 - b. Probe: Tell me about a time when the navigator/peer counselor was helpful. What made this successful?
 - c. Probe: Tell me about a time when the navigator/peer counselor was not helpful. What could s/he have done to make this instance better?
 - d. Probe: How would you describe your relationship with the navigator/peer counselor?
18. Walk me through your most recent visit with the systems navigator and/or peer counselor.
- a. Probe: What did you discuss?
 - b. Probe: What advice or strategies did s/he recommend?

- c. Probe: In what way was the advice helpful?
 - d. Probe: Did you have any remaining questions after the visit?
 - e. Probe: Are there any strategies that you have not found helpful? Why not?
 - f. Probe: In what way have these visits addressed the barriers you mentioned earlier?
19. Can you tell me about when you might ask a systems navigator/peer counselor for help with something?
- a. Probe: Sometimes we try to do things on our own or with our own friends/family members and other times we ask for help. Thinking about ART services and drug abuse services, at what point might you ask for help from your systems navigator/peer counselors?
 - b. Probe: Are there other people you might go to for advice or help in accessing HIV or drug abuse care? Why or why not?
20. In your opinion, what additional resources or strategies (outside of peer counselors/systems navigators) could help reduce some of the challenges you mentioned?
- a. Hint: reorganizing clinic, reducing wait time, reducing stigma in the community
21. Imagine your friend was recommended to start ART and/or MMT tomorrow. What would you advise them?
- a. Probe: Would you recommend they meet with a navigator and/or counselor? Why or why not?
 - b. Probe: What would you tell them about your relationship with your navigator and/or counselor?
 - c. Probe: What would you tell them about the counseling strategies or content?
 - d. Probe: How would your advice be similar or different if they were starting MMT instead of ART?

Thank you so much for your thoughts. Is there anything else you want to share about your experience in the ART program?

[Round 2] Stakeholder Interview Guide: Clinic Personnel

Objectives: *Identify client- and provider-level barriers and/or facilitators to initiation of HIV care and substance use treatment, and medication adherence, and assess the degree to which HPTN 074 interventions address barriers and/or enhance facilitators.*

Interviewer Note: Each section is marked as appropriate for each type of participant. If participants work at a clinic that provides both HIV and substance use treatment, ask them both sets of questions.

Introduction (*All participants*)

It is nice to see you again, I hope you are well. Thank you for taking the time to talk again.

3. Can you please remind me about your role in the clinic?
 - a. Probe: How many clients have been referred to you by **[name of systems navigator/counselor]**?
4. Are you aware of the HPTN 074 project? If so, what do you know about it?
 - a. Probe: Have you heard about the systems navigators/counselors working on the HPTN 074 project? If so, what do you know about their role?
5. How are the clients who have been referred to you by **[name of systems navigator/counselor]** different from your other clients?
 - a. Probe: How are the challenges they face the same? How are they different?
6. When a client is referred to you by **[name of systems navigator/counselor]**, how does your treatment of the client compare to your treatment of other clients?

Barriers and Facilitators to ART Access (*ART Providers*)

*As you know, we are working to improve access to HIV and substance use services for people who inject drugs. I want to focus our conversation on the clients who were referred to you by **[name of systems navigator/counselor]**. Let's begin by identifying the most common challenges and issues for these clients to access ART and the strategies used to address these issues.*

Interviewer Note: If the provider works only with substance use treatment (e.g. MMT), skip this section and proceed to the substance use questions.

7. What were some barriers the clients referred to you by **[name of systems navigator/counselor]** faced to initiate ART?
 - c. Probe: Of the barriers you listed, which ones surprise you? Why?
 - d. Probe: How do these barriers differ from the barriers that your other clients face?
8. How did you advise these clients to overcome the barriers?
 - a. Probe: How did these clients respond to your advice?
 - b. Probe: Did your advice to these clients about the barriers change over time? Why or why not?
9. Some of the clients referred to you by **[name of systems navigator/counselor]** started taking ART during the last year. Why did these clients start taking ART?
 - a. Probe: How do these reasons differ from those that your other clients give?

- b. *[Only ask if the clinician is aware of the systems navigators/counselors.]* Probe: In your opinion, how did the counselors/navigators support clients to get on ART?
 - i. How do you think they helped your clients?
 - ii. How do you think they were unhelpful to your clients?

Barriers and Facilitators to ART Adherence (ART Providers)

As you know, we are working to improve access to HIV and substance use services for people who inject drugs. Let's begin by identifying the most common challenges and issues for your clients to adhere to ART and the strategies used to address these issues.

Interviewer Note: If the provider works only with substance use treatment (e.g. MMT), skip this section and proceed to the substance use questions.

- 10. Some of your clients who were referred to you by **[name of systems navigator/counselor]** may be better at adhering to ART than others. What were some barriers these clients faced to initiate ART?
 - e. Probe: Of the barriers you listed, which ones surprise you? Why?
 - f. Probe: How do these barriers differ from the barriers that your other clients face?
- 11. How did you advise these clients to overcome the barriers?
 - a. Probe: How did these clients respond to your advice?
 - b. Probe: Did your advice to these clients about the barriers change over time? Why or why not?
- 12. Since the last time we talked, were you involved in successfully helping one of the clients referred to you by **[name of systems navigator/counselor]** improve their ART adherence? If so, what did you do to help?
 - a. Probe: Why do you think this was helpful?
 - b. *[Only ask if the clinician is aware of the systems navigators/counselors.]* Probe: In your opinion, how did the counselors/navigators support clients to adhere to ART?
 - i. How do you think they helped your clients?
 - ii. How do you think they were unhelpful to clients?
- 13. Do you have any clients who are still not adhering to ART? If so, why do you think these clients are having difficulty adhering to ART?
 - a. Probe: What type of advice do you give these clients?
 - b. Probe: How is your advice similar or different to advice you have given other clients?

Barriers and Facilitators to Substance Use Treatment (Substance Use Providers)

*As you know, we are working to improve access to HIV and substance use services for people who inject drugs. I want to focus our conversation on the clients who were referred to you by **[name of systems navigator/counselor]**. Let's begin by identifying the most common challenges and issues for your clients to access substance use treatment and the strategies used to address these issues.*

Interviewer Note: If the provider works only with HIV care (i.e. ART), skip this section and proceed to the ART and substance use treatment questions.

- 14. Why do you think the clients who were referred to you by **[name of systems navigator/counselor]** started to take substance use treatment?

- a. Probe: How do these reasons differ from those that your other clients give?
15. Do you have any clients who have been taking substance use treatment for longer than 3-6 months and continue to use drugs? If so, why do you think these clients are having difficulty quitting drugs?
- a. Probe: What type of drugs do these clients use? Why?
 - b. Probe: What type of advice do you give these clients?
16. Since the last time we talked, were you involved in successfully helping a client reduce their injection drug use? If so, what did you do to help?
- a. Probe: Why do you think this was helpful?
 - b. **[Only ask if the clinician is aware of the systems navigators/counselors.]** Probe: In your opinion, how did the counselors/navigators support clients to reduce their drug use?
 - i. How do you think they helped your clients?
 - ii. How do you think they were unhelpful to your clients?

ART and Substance Use Treatment *(All participants)*

Now, I am going to ask you a couple questions about the challenges involved with taking ART and substance use treatment at the same time.

17. How did your clients feel about taking ART and substance use treatment at the same time?
- a. Probe: What advice did you give to clients who did not know how to take both ART and substance use treatment at the same time?
18. **[Only ask if participants live in a district that has ART and substance use treatment available.]** Were you involved in successfully helping a client take substance use treatment and ART at the same time? If so, what did you do to help?
- a. Probe: Why do you think this was helpful?
 - b. **[Only ask if the clinician is aware of the systems navigators/counselors.]** Probe: In your opinion, how did the counselors/navigators support clients to take substance use treatment and ART at the same time?
 - i. How do you think they helped your clients?
 - ii. How do you think they were unhelpful to your clients?

Evaluating the Counselor/Navigator Role *(All participants)*

As you know, we are working to improve access to HIV and substance use services for people who inject drugs. [Name of systems navigator/counselor] was a health professional who provided the clients with psychosocial counseling and also helped to facilitate the clients' initiation of HIV care and substance use treatment.

19. Currently, your only interactions with [name of systems navigator/counselor] are through the referrals. What are other things that you think [name of systems navigator/counselor] could do to improve the clients' access to HIV care? What about access to substance use treatment?

Conclusion

20. In your opinion, what additional resources or strategies (outside of counselors/systems navigators) could help reduce some of the challenges you mentioned?

a. Hint: reorganizing clinic, reducing wait time, reducing stigma in the community

21. How have your views on the best way to help people who inject drugs engage with HIV care changed over time? How about with substance use treatment?

Thank you for sharing your perspective. Before we conclude, is there anything else you would like to share about your role as a provider in this area? And/or anything we should consider as we improve the HPTN 074 program?

[Round 2] Stakeholder Interview Guide: Clinic Personnel (VIETNAM SITE ONLY)

Objectives: *Identify client- and provider-level barriers and/or facilitators to initiation of HIV care and substance use treatment, and medication adherence, and assess the degree to which HPTN 074 interventions address barriers and/or enhance facilitators.*

Interviewer Note: Each section is marked as appropriate for each type of participant. If participants work at a clinic that provides both HIV and substance use treatment, ask them both sets of questions.

Introduction (*All participants*)

It is nice to see you again, I hope you are well. Thank you for taking the time to talk again.

22. Can you please remind me about your role in the clinic?
 - a. Probe: How many clients have been referred to you by **[name of systems navigator/counselor]**?
23. Are you aware of the HPTN 074 project? If so, what do you know about it?
 - a. Probe: Have you heard about the systems navigators/counselors working on the HPTN 074 project? If so, what do you know about their role?
24. How are the clients who have been referred to you by **[name of systems navigator/counselor]** different from your other clients?
 - a. Probe: How are the challenges they face the same? How are they different?
25. When a client is referred to you by **[name of systems navigator/counselor]**, how does your treatment of the client compare to your treatment of other clients?

Barriers and Facilitators to ART Access (*ART Providers*)

*As you know, we are working to improve access to HIV and substance use services for people who inject drugs. I want to focus our conversation on the clients who were referred to you by **[name of systems navigator/counselor]**. Let's begin by identifying the most common challenges and issues for these clients to access ART and the strategies used to address these issues.*

Interviewer Note: If the provider works only with substance use treatment (e.g. MMT), skip this section and proceed to the substance use questions.

26. What were some barriers the clients referred to you by **[name of systems navigator/counselor]** faced to initiate ART?
 - g. Probe: Of the barriers you listed, which ones surprise you? Why?
 - h. Probe: How do these barriers differ from the barriers that your other clients face?
27. How did you advise these clients to overcome the barriers?
 - a. Probe: How did these clients respond to your advice?
 - b. Probe: Did your advice to these clients about the barriers change over time? Why or why not?
28. Some of the clients referred to you by **[name of systems navigator/counselor]** started taking ART during the last year. Why did these clients start taking ART?

- c. Probe: How do these reasons differ from those that your other clients give?
- d. **[Only ask if the clinician is aware of the systems navigators/counselors.]** Probe: In your opinion, how did the counselors/navigators support clients to get on ART?
 - i. How do you think they helped your clients?
 - ii. How do you think they were unhelpful to your clients?

Barriers and Facilitators to ART Adherence (ART Providers)

As you know, we are working to improve access to HIV and substance use services for people who inject drugs. Let's begin by identifying the most common challenges and issues for your clients to adhere to ART and the strategies used to address these issues.

Interviewer Note: If the provider works only with substance use treatment (e.g. MMT), skip this section and proceed to the substance use questions.

- 29. Some of your clients who were referred to you by **[name of systems navigator/counselor]** may be better at adhering to ART than others. What were some barriers these clients faced to initiate ART?
 - i. Probe: Of the barriers you listed, which ones surprise you? Why?
 - j. Probe: How do these barriers differ from the barriers that your other clients face?
- 30. How did you advise these clients to overcome the barriers?
 - e. Probe: How did these clients respond to your advice?
 - f. Probe: Did your advice to these clients about the barriers change over time? Why or why not?
- 31. Since the last time we talked, were you involved in successfully helping one of the clients referred to you by **[name of systems navigator/counselor]** improve their ART adherence? If so, what did you do to help?
 - g. Probe: Why do you think this was helpful?
 - h. **[Only ask if the clinician is aware of the systems navigators/counselors.]** Probe: In your opinion, how did the counselors/navigators support clients to adhere to ART?
 - i. How do you think they helped your clients?
 - ii. How do you think they were unhelpful to clients?
- 32. Do you have any clients who are still not adhering to ART? If so, why do you think these clients are having difficulty adhering to ART?
 - i. Probe: What type of advice do you give these clients?
 - j. Probe: How is your advice similar or different to advice you have given other clients?

Structural change

ONLY for clients who are NOT taking ART at Thai Nguyen Health Center

In July 2016, the health center was integrated into the hospital. Let's begin by talking about this change in service delivery.

- 26. Can you tell me about the process of integrating the health center into the hospital?
 - a. Probe: How long did it take?
 - b. Probe: What was the first step in the process? What happened next?
 - c. Probe: How did clients learn about the change?
 - d. Probe: How did clients respond when they first learned about the change?
- 27. When the health center became a part of the hospital, how did things change for you as a provider?

- e. Probe: How do you think things changed for clients when the health center became part of the hospital?
- f. Probe: How do you think your clients' ability to access HIV services changed?
- g. Probe: Can you describe the change in barriers to accessing HIV services for clients who moved from the health center to the hospital?

33. How did you advise your clients to overcome the barriers?
- a. Probe: How did your clients respond to your advice?

Insurance change

If you are doing the interview in 2017, ask the insurance change questions in past tense as the insurance change will have already been made.

34. In January 2017, clients will be required to get health insurance to get HIV services for free. How do you feel about this change?
- h. Probe: Why do you feel that way?
35. How do you think your clients' access to HIV services will change once health insurance is required? Why?
36. What are barriers you think your clients will face to access HIV service once health insurance is required?
37. What support will your clients need to overcome these barriers?

Barriers and Facilitators to Substance Use Treatment (*Substance Use Providers*)

As you know, we are working to improve access to HIV and substance use services for people who inject drugs. I want to focus our conversation on the clients who were referred to you by [name of systems navigator/counselor]. Let's begin by identifying the most common challenges and issues for your clients to access substance use treatment and the strategies used to address these issues.

Interviewer Note: If the provider works only with HIV care (i.e. ART), skip this section and proceed to the ART and substance use treatment questions.

38. Why do you think the clients who were referred to you by [name of systems navigator/counselor] started to take substance use treatment?
- k. Probe: How do these reasons differ from those that your other clients give?
39. Do you have any clients who have been taking substance use treatment for longer than 3-6 months and continue to use drugs? If so, why do you think these clients are having difficulty quitting drugs?
- l. Probe: What type of drugs do these clients use? Why?
 - m. Probe: What type of advice do you give these clients?
40. Since the last time we talked, were you involved in successfully helping a client reduce their injection drug use? If so, what did you do to help?
- n. Probe: Why do you think this was helpful?
 - o. ***[Only ask if the clinician is aware of the systems navigators/counselors.]*** Probe: In your opinion, how did the counselors/navigators support clients to reduce their drug use?

- i. How do you think they helped your clients?
- ii. How do you think they were unhelpful to your clients?

ART and Substance Use Treatment *(All participants)*

Now, I am going to ask you a couple questions about the challenges involved with taking ART and substance use treatment at the same time.

41. How did your clients feel about taking ART and substance use treatment at the same time?
- p. Probe: What advice did you give to clients who did not know how to take both ART and substance use treatment at the same time?
42. **[Only ask if participants live in a district that has ART and substance use treatment available.]**
Were you involved in successfully helping a client take substance use treatment and ART at the same time? If so, what did you do to help?
- q. Probe: Why do you think this was helpful?
 - r. **[Only ask if the clinician is aware of the systems navigators/counselors.]** Probe: In your opinion, how did the counselors/navigators support clients to take substance use treatment and ART at the same time?
 - i. How do you think they helped your clients?
 - ii. How do you think they were unhelpful to your clients?

Evaluating the Counselor/Navigator Role *(All participants)*

As you know, we are working to improve access to HIV and substance use services for people who inject drugs. [Name of systems navigator/counselor] was a health professional who provided the clients with psychosocial counseling and also helped to facilitate the clients' initiation of HIV care and substance use treatment.

43. Currently, your only interactions with **[name of systems navigator/counselor]** are through the referrals. What are other things that you think **[name of systems navigator/counselor]** could do to improve the clients' access to HIV care? What about access to substance use treatment?

Conclusion

44. In your opinion, what additional resources or strategies (outside of counselors/systems navigators) could help reduce some of the challenges you mentioned?
- s. Hint: reorganizing clinic, reducing wait time, reducing stigma in the community
45. How have your views on the best way to help people who inject drugs engage with HIV care changed over time? How about with substance use treatment?

Thank you for sharing your perspective. Before we conclude, is there anything else you would like to share about your role as a provider in this area? And/or anything we should consider as we improve the HPTN 074 program?

[Round 2] Stakeholder Interview Guide: Systems Navigators/Counselors

Objectives: *Identify client- and systems-level barriers and/or facilitators to initiation of HIV care and substance use treatment, and medication adherence, and assess the degree to which HPTN 074 interventions address barriers and/or enhance facilitators.*

Introduction

It is nice to see you again, I hope you are well. Thank you for taking the time to talk again.

28. Can you please remind me about your role as a counselor/systems navigator?
 - a. Probe: How long have you worked as a counselor/systems navigator?
 - b. Probe: About how many clients have you seen as a counselor/systems navigator?

29. Tell me about your clients as a counselor/systems navigator.
 - a. Probe: Did anything about your clients surprise you? Why or why not?
 - b. Probe: Since we last talked, how have your views of clients changed?

Barriers and Facilitators to ART Access

As you know, we are working to improve access to HIV and substance use services for people who inject drugs. Let's begin by identifying the most common challenges and issues for your clients to access ART and the strategies used to address these issues.

30. Some of your clients were not taking ART at the start of the project. What were some barriers your clients faced to initiate ART?
 - k. Probe: Of the barriers you listed, which ones surprise you? Why?
 - l. Probe: In your opinion, how do these barriers differ from the barriers that your non-drug using clients face?

31. How did you advise clients to overcome these issues?
 - a. Probe: How did your clients respond to your advice?
 - b. Probe: Did your advice to clients about these issues change over time? Why or why not?
 - c. Probe: How did you tailor your advice for each client? (Hint: family context, drug use history, employment status, health condition, etc.)

32. Some of your clients initiated ART during your time with them. Why did these clients start taking ART?
 - a. Probe: How do these reasons differ from those that your non-drug using clients give?
 - b. *[Skip this question if the participant is an ARV doctor.]* Probe: In your opinion, how did ARV doctors support your clients?
 - i. How do you think they helped your clients?
 - ii. How do you think they were unhelpful to your clients?

33. Since the last time we talked, how were you involved in helping a client initiate ART? (Hint: counseling sessions, sessions with a supporter, phone calls, guidance in clinics, providing access to free examinations, help with access to treatment for other health conditions [TB, etc.])
 - a. Probe: Why do you think this was helpful?
 - b. Probe: Are there strategies you tried with this client that were not helpful? Why?

34. *[Only ask about clients who have attended both counseling sessions.]* Do you have any clients who are still not on ART? If so, why do you think these clients are having difficulty initiating ART? (Hint: need to treat TB, fear of side effects, drug use, going to rehabilitations, feeling healthy, etc.)
- Probe: What type of advice do you give these clients?
 - Probe: How did you tailor your advice for these clients? (Hint: family context, drug use history, employment status)
 - Probe: How does it differ from the advice you give non-drug using clients?

Barriers and Facilitators to ART Adherence

As you know, we are working to improve access to HIV and substance use services for people who inject drugs. Let's begin by identifying the most common challenges and issues for your clients to adhere to ART and the strategies used to address these issues.

35. Some of your clients who are on ART may be better at adhering to ART than others. Why do you think some of your clients did not adhere to ART?
- Probe: Of the barriers you listed, which ones surprise you? Why?
 - Probe: How do these barriers differ from the barriers that your non-drug using clients face?
36. How did you advise clients to overcome these issues?
- Probe: How did your clients respond to your advice?
 - Probe: Did your advice to clients about these issues change over time? Why or why not?
 - Probe: How did you tailor your advice for each client? (Hint: family context, drug use history, employment status, health condition, etc.)
37. Since the last time we talked, were you involved in helping a client improve their ART adherence? If so, what did you do to help? (Hint: counseling sessions, sessions with a supporter, phone calls, guidance in clinics, other)
- Probe: Why do you think this was helpful?
 - Probe: Are there strategies you tried with this client that were not helpful? Why?
 - [Skip this question if the participant is an ARV doctor.]* Probe: In your opinion, how did ARV doctors support your clients?
 - How do you think they helped your clients?
 - How do you think they were unhelpful to your clients?
38. *[Only ask about clients who have attended both counseling sessions.]* Do you have any clients who are still not adhering to ART? If so, why do you think these clients are having difficulty adhering to ART?
- Probe: What type of advice do you give these clients?
 - Probe: How did you tailor your advice for these clients? (Hint: family context, drug use history, employment status)
 - Probe: How does it differ from the advice you give to non-drug using clients?

Barriers and Facilitators to Substance Use Treatment

As you know, we are working to improve access to HIV and substance use services for people who inject drugs. Let's begin by identifying the most common challenges and issues for your clients to access substance use treatment and the strategies used to address these issues.

39. Some of your clients were taking substance use treatment and some were not. Why do you think some of your clients were not taking substance use treatment?
 - o. Probe: Of the barriers you listed, which ones surprise you? Why?
40. How did you advise clients to overcome these issues?
 - a. Probe: How did your clients respond to your advice?
 - b. Probe: Did your advice to clients about these issues change over time? Why or why not?
 - c. How did you tailor your advice for each client? (Hint: family context, drug use history, employment status)
41. Some of your clients started taking substance use treatment during your time with them. Why do you think these clients started to take substance use treatment?
42. Since we last talked, were you involved in helping a client take substance use treatment? If so, what did you do to help?
 - a. Probe: Why do you think this was helpful?
 - b. ***[Skip this question if the participant is an MMT doctor.]*** Probe: In your opinion, how did MMT doctors support your clients?
 - i. How do you think they helped your clients?
 - ii. How do you think they were unhelpful to your clients?
43. ***[Only ask about clients who have attended both counseling sessions.]*** Do you have any clients who are still not taking substance use treatment? If so, why do you think these clients are having difficulty taking substance use treatment?
 - a. Probe: What type of advice do you give these clients?
 - b. Probe: How did you tailor your advice for these clients? (Hint: family context, drug use history, employment status)
44. ***[Only ask about clients who have attended both counseling sessions.]*** Do you have any clients who have been taking substance use treatment for longer than 3-6 months and continue to use drugs? If so, why do you think these clients are having difficulty quitting drugs?
 - a. Probe: What type of drugs do these clients use? Why?
 - b. Probe: What type of advice do you give these clients?
 - c. Probe: How did you tailor your advice for these clients? (Hint: family context, drug use history, employment status)

ART and Substance Use Treatment

Now, I am going to ask you a couple questions about the challenges involved with taking ART and substance use treatment at the same time.

45. How did your clients feel about taking ART and substance use treatment at the same time?

- a. Probe: What advice did you give to clients who did not know how to take both ART and substance use treatment at the same time?
46. Were you involved in successfully helping a client take substance use treatment and ART at the same time? If so, what did you do to help?
- a. Probe: Why do you think this was helpful?
 - b. *[Skip this question if the participant is an ARV doctor.]* Probe: In your opinion, how did ARV doctors support clients to take substance use treatment and ART at the same time?
 - i. How do you think they helped your clients?
 - ii. How do you think they were unhelpful to your clients?
 - c. *[Skip this question if the participant is an MMT doctor.]* Probe: In your opinion, how did MMT doctors support clients to take substance use treatment and ART at the same time?
 - i. How do you think they helped your clients?
 - ii. How do you think they were unhelpful to your clients?

Evaluating the Counselor/Navigator Role

Lastly, I want to discuss your thoughts on your role as a systems navigator/counselor. Again, your opinion is very valuable for us to help improve these programs. It is just as important for me to understand what is not going well as it is to know what is going well. Your responses will be kept private, so do not worry about what others would think about what you say.

47. During your time working with the clients, how did your role as counselor/navigator change over time?
- a. Probe: How did your relationship with clients change over time?
 - b. Probe: How did the type of support or advice you provided your clients change over time?
 - c. Probe: Do you think you became better at your job over time? Why or why not?
48. How do you think the counselor and systems navigator roles overlap?
49. Some clients requested additional (booster) sessions after attending two counseling sessions. Did any of your clients receive additional (booster) sessions (i.e. about depression, drug treatment, risk reduction, etc.)? Why or why not?
- a. *If yes:* In your opinion, why were these additional topics interesting to some of your clients?
 - i. Which topics were the most helpful? Why?
 - b. *If no:* In your opinion, why do you think some clients were uninterested in attending additional (booster) sessions?
50. Which sessions were most helpful to clients? Which sessions were least helpful? Why?
- a. Probe: How can the sessions be improved?
51. Tell me about any topics that you felt were missing from the sessions. Why would those topics be helpful?

52. *[Only ask if the person is both a counselor and a systems navigator.]* You played the role of both a counselor and a systems navigator. Did you feel more helpful as a counselor or as a systems navigator? Why?
- a. What type of client is a counselor most helpful for?
 - b. What type of client is a systems navigator most helpful for?
53. How would you change the role of the counselor to improve your ability to help clients? How about the role of the systems navigator?

Conclusion

54. In your opinion, what additional services (outside of peer counselors/systems navigators) would have been helpful to clients to engage them in HIV care? How about for substance use treatment?
55. How have your views on the best way to help people who inject drugs engage with HIV care changed over time? How about with substance use treatment?

Thank you for sharing your perspective. Before we conclude, is there anything else you would like to share about your role as a provider in this area? And/or anything we should consider as we improve the HPTN 074 program?

[Round 2] Stakeholder Interview Guide: Systems Navigators/Counselors (VIETNAM SITE ONLY)

Objectives: *Identify client- and systems-level barriers and/or facilitators to initiation of HIV care and substance use treatment, and medication adherence, and assess the degree to which HPTN 074 interventions address barriers and/or enhance facilitators.*

Introduction

It is nice to see you again, I hope you are well. Thank you for taking the time to talk again.

56. Can you please remind me about your role as a counselor/systems navigator?
- a. Probe: How long have you worked as a counselor/systems navigator?
 - b. Probe: About how many clients have you seen as a counselor/systems navigator?
57. Tell me about your clients as a counselor/systems navigator.
- a. Probe: Did anything about your clients surprise you? Why or why not?
 - b. Probe: Since we last talked, how have your views of clients changed?

Barriers and Facilitators to ART Access

As you know, we are working to improve access to HIV and substance use services for people who inject drugs. Let's begin by identifying the most common challenges and issues for your clients to access ART and the strategies used to address these issues.

58. Some of your clients were not taking ART at the start of the project. What were some barriers your clients faced to initiate ART?
- p. Probe: Of the barriers you listed, which ones surprise you? Why?
 - q. Probe: In your opinion, how do these barriers differ from the barriers that your non-drug using clients face?
59. How did you advise clients to overcome these issues?
- a. Probe: How did your clients respond to your advice?
 - b. Probe: Did your advice to clients about these issues change over time? Why or why not?
 - c. Probe: How did you tailor your advice for each client? (Hint: family context, drug use history, employment status, health condition, etc.)
60. Some of your clients initiated ART during your time with them. Why did these clients start taking ART?
- a. Probe: How do these reasons differ from those that your non-drug using clients give?
 - b. *[Skip this question if the participant is an ARV doctor.]* Probe: In your opinion, how did ARV doctors support your clients?
 - i. How do you think they helped your clients?
 - ii. How do you think they were unhelpful to your clients?
61. Since the last time we talked, how were you involved in helping a client initiate ART? (Hint: counseling sessions, sessions with a supporter, phone calls, guidance in clinics, providing access to free examinations, help with access to treatment for other health conditions [TB, etc.]
- a. Probe: Why do you think this was helpful?

b. Probe: Are there strategies you tried with this client that were not helpful? Why?

62. *[Only ask about clients who have attended both counseling sessions.]* Do you have any clients who are still not on ART? If so, why do you think these clients are having difficulty initiating ART? (Hint: need to treat TB, fear of side effects, drug use, going to rehabilitations, feeling healthy, etc.)

a. Probe: What type of advice do you give these clients?

b. Probe: How did you tailor your advice for these clients? (Hint: family context, drug use history, employment status)

c. Probe: How does it differ from the advice you give non-drug using clients?

Barriers and Facilitators to ART Adherence

As you know, we are working to improve access to HIV and substance use services for people who inject drugs. Let's begin by identifying the most common challenges and issues for your clients to adhere to ART and the strategies used to address these issues.

63. Some of your clients who are on ART may be better at adhering to ART than others. Why do you think some of your clients did not adhere to ART?

r. Probe: Of the barriers you listed, which ones surprise you? Why?

s. Probe: How do these barriers differ from the barriers that your non-drug using clients face?

64. How did you advise clients to overcome these issues?

a. Probe: How did your clients respond to your advice?

b. Probe: Did your advice to clients about these issues change over time? Why or why not?

c. Probe: How did you tailor your advice for each client? (Hint: family context, drug use history, employment status, health condition, etc.)

65. Since the last time we talked, were you involved in helping a client improve their ART adherence? If so, what did you do to help? (Hint: counseling sessions, sessions with a supporter, phone calls, guidance in clinics, other)

a. Probe: Why do you think this was helpful?

b. Probe: Are there strategies you tried with this client that were not helpful? Why?

c. *[Skip this question if the participant is an ARV doctor.]* Probe: In your opinion, how did ARV doctors support your clients?

i. How do you think they helped your clients?

ii. How do you think they were unhelpful to your clients?

66. *[Only ask about clients who have attended both counseling sessions.]* Do you have any clients who are still not adhering to ART? If so, why do you think these clients are having difficulty adhering to ART?

a. Probe: What type of advice do you give these clients?

b. Probe: How did you tailor your advice for these clients? (Hint: family context, drug use history, employment status)

c. Probe: How does it differ from the advice you give to non-drug using clients?

Structural change

ONLY for clients who are NOT taking ART at Thai Nguyen Health Center

In July 2016, the health center was integrated into the hospital. Let's begin by talking about this change in service delivery.

67. Can you tell me about the process of integrating the health center into the hospital?
 - a. Probe: How long did it take?
 - b. Probe: What was the first step in the process? What happened next?
 - c. Probe: How did clients learn about the change?
 - d. Probe: How did clients respond when they first learned about the change?

68. When the health center became a part of the hospital, how did things change for you as a systems navigator/counselor?
 - i. Probe: How do you think things changed for clients when the health center became part of the hospital?
 - j. Probe: How do you think your clients' ability to access HIV services changed?
 - k. Probe: Can you describe the change in barriers to accessing HIV services for clients who moved from the health center to the hospital?

69. How did you advise your clients to overcome the barriers?
 - b. Probe: How did your clients respond to your advice?

Insurance change

If you are doing the interview in 2017, ask the insurance change questions in past tense as the insurance change will have already been made.

70. In January 2017, clients will be required to get health insurance to get HIV services for free. How do you feel about this change?
 - l. Probe: Why do you feel that way?

71. How do you think your clients' access to HIV services will change once health insurance is required? Why?

72. What are barriers you think your clients will face to access HIV service once health insurance is required?

73. What support will your clients need to overcome these barriers?

Barriers and Facilitators to Substance Use Treatment

As you know, we are working to improve access to HIV and substance use services for people who inject drugs. Let's begin by identifying the most common challenges and issues for your clients to access substance use treatment and the strategies used to address these issues.

74. Some of your clients were taking substance use treatment and some were not. Why do you think some of your clients were not taking substance use treatment?
 - t. Probe: Of the barriers you listed, which ones surprise you? Why?

75. How did you advise clients to overcome these issues?
 - a. Probe: How did your clients respond to your advice?
 - b. Probe: Did your advice to clients about these issues change over time? Why or why not?

- c. How did you tailor your advice for each client? (Hint: family context, drug use history, employment status)
76. Some of your clients started taking substance use treatment during your time with them. Why do you think these clients started to take substance use treatment?
77. Since we last talked, were you involved in helping a client take substance use treatment? If so, what did you do to help?
- a. Probe: Why do you think this was helpful?
 - b. **[Skip this question if the participant is an MMT doctor.]** Probe: In your opinion, how did MMT doctors support your clients?
 - i. How do you think they helped your clients?
 - ii. How do you think they were unhelpful to your clients?
78. **[Only ask about clients who have attended both counseling sessions.]** Do you have any clients who are still not taking substance use treatment? If so, why do you think these clients are having difficulty taking substance use treatment?
- a. Probe: What type of advice do you give these clients?
 - b. Probe: How did you tailor your advice for these clients? (Hint: family context, drug use history, employment status)
79. **[Only ask about clients who have attended both counseling sessions.]** Do you have any clients who have been taking substance use treatment for longer than 3-6 months and continue to use drugs? If so, why do you think these clients are having difficulty quitting drugs?
- a. Probe: What type of drugs do these clients use? Why?
 - b. Probe: What type of advice do you give these clients?
 - c. Probe: How did you tailor your advice for these clients? (Hint: family context, drug use history, employment status)

ART and Substance Use Treatment

Now, I am going to ask you a couple questions about the challenges involved with taking ART and substance use treatment at the same time.

80. How did your clients feel about taking ART and substance use treatment at the same time?
- a. Probe: What advice did you give to clients who did not know how to take both ART and substance use treatment at the same time?
81. Were you involved in successfully helping a client take substance use treatment and ART at the same time? If so, what did you do to help?
- a. Probe: Why do you think this was helpful?
 - b. **[Skip this question if the participant is an ARV doctor.]** Probe: In your opinion, how did ARV doctors support clients to take substance use treatment and ART at the same time?
 - i. How do you think they helped your clients?
 - ii. How do you think they were unhelpful to your clients?
 - c. **[Skip this question if the participant is an MMT doctor.]** Probe: In your opinion, how did MMT doctors support clients to take substance use treatment and ART at the same time?

- i. How do you think they helped your clients?
- ii. How do you think they were unhelpful to your clients?

Evaluating the Counselor/Navigator Role

Lastly, I want to discuss your thoughts on your role as a systems navigator/counselor. Again, your opinion is very valuable for us to help improve these programs. It is just as important for me to understand what is not going well as it is to know what is going well. Your responses will be kept private, so do not worry about what others would think about what you say.

82. During your time working with the clients, how did your role as counselor/navigator change over time?
 - a. Probe: How did your relationship with clients change over time?
 - b. Probe: How did the type of support or advice you provided your clients change over time?
 - c. Probe: Do you think you became better at your job over time? Why or why not?
83. How do you think the counselor and systems navigator roles overlap?
84. Some clients requested additional (booster) sessions after attending two counseling sessions. Did any of your clients receive additional (booster) sessions (i.e. about depression, drug treatment, risk reduction, etc.)? Why or why not?
 - a. *If yes:* In your opinion, why were these additional topics interesting to some of your clients?
 - i. Which topics were the most helpful? Why?
 - b. *If no:* In your opinion, why do you think some clients were uninterested in attending additional (booster) sessions?
85. Which sessions were most helpful to clients? Which sessions were least helpful? Why?
 - a. Probe: How can the sessions be improved?
86. Tell me about any topics that you felt were missing from the sessions. Why would those topics be helpful?
87. **[Only ask if the person is both a counselor and a systems navigator.]** You played the role of both a counselor and a systems navigator. Did you feel more helpful as a counselor or as a systems navigator? Why?
 - a. What type of client is a counselor most helpful for?
 - b. What type of client is a systems navigator most helpful for?
88. How would you change the role of the counselor to improve your ability to help clients? How about the role of the systems navigator?

Conclusion

89. In your opinion, what additional services (outside of peer counselors/systems navigators) would have been helpful to clients to engage them in HIV care? How about for substance use treatment?
90. How have your views on the best way to help people who inject drugs engage with HIV care changed over time? How about with substance use treatment?

Thank you for sharing your perspective. Before we conclude, is there anything else you would like to share about your role as a provider in this area? And/or anything we should consider as we improve the HPTN 074 program?

[Round 2] Stakeholder Interview Guide: Intervention Participants

Objective: *Identify client- and systems-level barriers and/or facilitators initiation and adherence to HIV care and substance use treatment. Assess the feasibility and acceptability of HPTN 074 intervention to address these barriers and/or facilitators with index participants randomized to the intervention program.*

Introduction

It is nice to see you again, I hope you are well. Thank you for taking the time to talk again.

22. Tell me a little bit about what you have been doing since we last talked (about 1 year ago).
 - a. Probe: Tell me about any changes in your employment status.
 - b. Probe: Tell me about any changes in your marital status.
 - c. Probe: Tell me about any time you may have spent at a hospital.
 - d. Probe: Tell me about any time you may have spent in detention or incarceration.

Barriers and Facilitators to ART Access

For participants who are not yet taking ART or have been on ART less than 2 months:

As you know, we are working to improve access to HIV and substance treatment services for people who inject drugs. Let's begin by identifying the most common challenges and issues for you to access ART and the strategies used to address these issues.

23. Since we last talked (about 1 year ago), what are barriers you have faced to initiate ART?
 - a. Probe: Tell me about barriers that your friends or relatives who are not using drugs face to initiate ART.
 - b. Probe: In your opinion, how do the barriers that non-drug users face differ from the barriers that drug users face?
24. What did ARV doctors advise you to do to overcome these issues?
 - a. Probe: How was this advice helpful?
 - b. Probe: Was there anything that you wanted your ARV doctors to do to help you with these issues? If so, what was it?
25. What did **[name of systems navigator/counselor]** do to help you overcome these issues? (Hint: counseling sessions, sessions with a supporter, phone calls, guidance in clinics, providing access to free examinations)
 - a. Probe: How was this helpful?
 - b. Probe: Was there anything else that you wanted **[name of systems navigator/counselor]** to do to help you with these issues? If so, what was it?
26. Since you started the project, how do you feel that your readiness to initiate ART has changed?
 - a. Probe: Why do you think your readiness to initiate ART has changed?

Barriers and Facilitators to ART Adherence

As you know, we are working to improve access to HIV and substance treatment services for people who inject drugs. Let's begin by identifying the most common challenges and issues for you to adhere to ART and the strategies used to address these issues.

27. Since we last talked (about 1 year ago), what are barriers you have faced to adhere to ART?
- Probe: Tell me about any barriers you faced to get the ART medication regularly.
 - Probe: Tell me about any barriers you faced to take ART on time regularly. (Hint: side effects)
28. What did ARV doctors advise you to do to overcome these issues?
- Probe: How was this advice helpful?
 - Probe: Was there anything else that you wanted your ARV doctors to do to help you with these issues? If so, what was it?
29. What did **[name of systems navigator/counselor]** do to help you overcome these issues?
- Probe: How was this helpful?
 - Probe: Was there anything else that you wanted **[name of systems navigator/counselor]** to do to help you with these issues? If so, what was it?
30. Since you started the project, how do you feel that your ART adherence has changed?
- Probe: Why do you think your ART adherence has changed?

Barriers and Facilitators to Substance Use Treatment

As you know, we are working to improve access to HIV and substance use services for people who inject drugs. Let's begin by identifying the most common challenges and issues for you to access substance use treatment and the strategies used to address these issues.

31. Since we last talked (about 1 year ago), what are barriers you have faced to take substance use treatment (MMT, rehabilitation services, buprenorphine, etc.)?
32. What did doctors at drug treatment centers advise you to do to overcome these issues?
- Probe: How was this advice helpful?
 - Probe: Was there anything else that you wanted your MMT doctors to do to help you with these issues? If so, what was it?
33. What did **[name of systems navigator/counselor]** do to help you overcome these issues?
- Probe: How was this helpful?
 - Probe: Was there anything else that you wanted **[name of systems navigator/counselor]** to do to help you with these issues? If so, what was it?
34. Since you started the project, how do you feel that your readiness to take substance use treatment (MMT, rehabilitation services, buprenorphine, etc.) has changed?
- Probe: Why do you think your readiness to take substance use treatment has changed?

ART and Substance Use Treatment

Now, I am going to ask you a couple questions about the challenges involved with taking ART and substance use treatment at the same time.

35. How do you feel about taking ART and substance use treatment at the same time?
- Probe: What advice did ARV doctors give you to take ART and substance use treatment at the same time?

- b. Probe: What advice did doctors at drug treatment centers give you to take ART and substance use treatment at the same time?
 - c. Probe: What advice did **[name of systems navigator/counselor]** give you to take ART and substance use treatment at the same time?
36. Since you joined the project (about 1 year ago), how do you feel that your readiness to take ART and substance use treatment at the same time has changed?
- a. Probe: Why do you think your readiness to take ART and substance use treatment at the same time has changed?
 - b. Probe: How did your ARV doctors influence your readiness to take ART and substance use treatment at the same time?
 - c. Probe: How did your doctors at drug treatment centers influence your readiness to take ART and substance use treatment at the same time?
 - d. Probe: How did your counselor/navigator influence your readiness to take ART and substance use treatment at the same time?

Evaluating the HPTN 074 Intervention

Thank you for helping me understand the challenges that people who inject drugs face with taking ART. Now I'd like to shift our conversation to discussing strategies to improve this process. I want to remind you that your opinion is very helpful for us to improve these programs. It is just as important for me to understand what is not going well as it is for me to know what is going well. Your responses will be kept private so do not worry about what others would think about your opinion.

37. How did the sessions with your counselor/navigator change over time? (Hint: session topics, family participation)
- a. Probe: How did your relationship with your counselor/navigator change over time?
 - b. Probe: How did the type of support or advice your counselor/navigator gave you change over time?
38. Which session did you feel was most helpful to you? Which session did you feel was least helpful? Why?
- a. Probe: How can the sessions be improved?
39. Some clients requested additional (booster) sessions after attending two counseling sessions. Did you receive any additional (booster) sessions (i.e. about depression, drug treatment, risk reduction, etc.)? Why or why not?
- a. *If yes:* Why were these additional topics interesting to you?
 - i. Which topics were the most helpful? Why?
 - b. *If no:* Why were you uninterested in attending additional (booster) sessions?
40. Tell me about any topics that you wished we had offered during the sessions. Why would those topics be helpful?
41. Walk me through your most recent visit with the counselor/navigator.
- g. Probe: What did you discuss?
 - h. Probe: What advice or strategies did s/he recommend?
 - i. Probe: In what way was the advice helpful?

- j. Probe: Did you have any remaining questions after the visit?
 - k. Probe: Are there any strategies that you have not found helpful? Why not?
 - l. Probe: In what way have these visits addressed the barriers you mentioned earlier?
42. You have spent the last year working with the counselor/navigator. What was the most helpful thing that a counselor/navigator did for you? (Hint: counseling sessions, sessions with a supporter, phone calls, guidance in clinics)
- a. Probe: What was the least helpful thing that a counselor/navigator did for you?
43. **[Name of systems navigator/counselor]** interacted with you in various ways. How would you change the role of **[name of systems navigator/counselor]** to improve their ability to help people who inject drugs?

Conclusion

44. In your opinion, what additional resources or strategies could help reduce some of the barriers you mentioned?
- a. Hint: reorganizing clinic, reducing wait time, reducing stigma in the community

Thank you so much for your thoughts. Is there anything else you want to share about your experience in the ART program?

[Round 2] Stakeholder Interview Guide: Intervention Participants (VIETNAM SITE ONLY)

Objective: *Identify client- and systems-level barriers and/or facilitators initiation and adherence to HIV care and substance use treatment. Assess the feasibility and acceptability of HPTN 074 intervention to address these barriers and/or facilitators with index participants randomized to the intervention program.*

Introduction

It is nice to see you again, I hope you are well. Thank you for taking the time to talk again.

45. Tell me a little bit about what you have been doing since we last talked (about 1 year ago).
- a. Probe: Tell me about any changes in your employment status.
 - b. Probe: Tell me about any changes in your marital status.
 - c. Probe: Tell me about any time you may have spent at a hospital.
 - d. Probe: Tell me about any time you may have spent in detention or incarceration.

Barriers and Facilitators to ART Access

For participants who are not yet taking ART or have been on ART less than 2 months:

As you know, we are working to improve access to HIV and substance treatment services for people who inject drugs. Let's begin by identifying the most common challenges and issues for you to access ART and the strategies used to address these issues.

46. Since we last talked (about 1 year ago), what are barriers you have faced to initiate ART?
- a. Probe: Tell me about barriers that your friends or relatives who are not using drugs face to initiate ART.
 - b. Probe: In your opinion, how do the barriers that non-drug users face differ from the barriers that drug users face?
47. What did ARV doctors advise you to do to overcome these issues?
- a. Probe: How was this advice helpful?
 - b. Probe: Was there anything that you wanted your ARV doctors to do to help you with these issues? If so, what was it?
48. What did **[name of systems navigator/counselor]** do to help you overcome these issues? (Hint: counseling sessions, sessions with a supporter, phone calls, guidance in clinics, providing access to free examinations)
- a. Probe: How was this helpful?
 - b. Probe: Was there anything else that you wanted **[name of systems navigator/counselor]** to do to help you with these issues? If so, what was it?
49. Since you started the project, how do you feel that your readiness to initiate ART has changed?
- a. Probe: Why do you think your readiness to initiate ART has changed?

Barriers and Facilitators to ART Adherence

As you know, we are working to improve access to HIV and substance treatment services for people who inject drugs. Let's begin by identifying the most common challenges and issues for you to adhere to ART and the strategies used to address these issues.

50. Since we last talked (about 1 year ago), what are barriers you have faced to adhere to ART?
- Probe: Tell me about any barriers you faced to get the ART medication regularly.
 - Probe: Tell me about any barriers you faced to take ART on time regularly. (Hint: side effects)
51. What did ARV doctors advise you to do to overcome these issues?
- Probe: How was this advice helpful?
 - Probe: Was there anything else that you wanted your ARV doctors to do to help you with these issues? If so, what was it?
52. What did **[name of systems navigator/counselor]** do to help you overcome these issues?
- Probe: How was this helpful?
 - Probe: Was there anything else that you wanted **[name of systems navigator/counselor]** to do to help you with these issues? If so, what was it?
53. Since you started the project, how do you feel that your ART adherence has changed?
- Probe: Why do you think your ART adherence has changed?

Structural change

ONLY for clients who are NOT taking ART at Thai Nguyen Health Center

In July 2016, the health center was integrated into the hospital. Let's begin by talking about this change in service delivery.

54. How did you first learn that you needed to switch to the hospital to get HIV services?
- Probe: How did you feel when you first learned about this change?
55. When the health center became a part of the hospital, how did things change for you?
- Probe: How do you think your ability to access HIV services changed?
 - Probe: Since you switched to the hospital, what are barriers you have faced to access HIV services?
56. What did ARV doctors advise you to do to overcome these issues?
- Probe: How was this advice helpful?
 - Probe: Was there anything you wanted your ARV doctors to do to help you with these issues? If so, what was it?
57. What did **[name of systems navigator/counselor]** do to help you overcome these issues? (Hint: counseling sessions, sessions with a supporter, phone calls, guidance in clinics, providing access to free examinations)
- Probe: How was this helpful?
 - Probe: Was there anything else that you wanted **[name of systems navigator/counselor]** to do to help you with these issues? If so, what was it?
58. Since you switched to the hospital, how do you feel that your readiness to manage your HIV diagnosis has changed? What about your readiness to manage your substance use issues?

Insurance change

If you are doing the interview in 2017, ask the insurance change questions in past tense as the insurance change will have already been made.

59. In January 2017, you will be required to get health insurance to get HIV services for free. How do you feel about this change?
 - a. Probe: Why do you feel that way?
60. How do you think your access to HIV services will change once health insurance is required? Why?
61. What are barriers you think you will face to access HIV service once health insurance is required?
62. What support will you need to overcome these barriers?

Barriers and Facilitators to Substance Use Treatment

As you know, we are working to improve access to HIV and substance use services for people who inject drugs. Let's begin by identifying the most common challenges and issues for you to access substance use treatment and the strategies used to address these issues.

63. Since we last talked (about 1 year ago), what are barriers you have faced to take substance use treatment (MMT, rehabilitation services, buprenorphine, etc.)?
64. What did doctors at drug treatment centers advise you to do to overcome these issues?
 - a. Probe: How was this advice helpful?
 - b. Probe: Was there anything else that you wanted your MMT doctors to do to help you with these issues? If so, what was it?
65. What did **[name of systems navigator/counselor]** do to help you overcome these issues?
 - a. Probe: How was this helpful?
 - b. Probe: Was there anything else that you wanted **[name of systems navigator/counselor]** to do to help you with these issues? If so, what was it?
66. Since you started the project, how do you feel that your readiness to take substance use treatment (MMT, rehabilitation services, buprenorphine, etc.) has changed?
 - a. Probe: Why do you think your readiness to take substance use treatment has changed?

ART and Substance Use Treatment

Now, I am going to ask you a couple questions about the challenges involved with taking ART and substance use treatment at the same time.

67. How do you feel about taking ART and substance use treatment at the same time?
 - a. Probe: What advice did ARV doctors give you to take ART and substance use treatment at the same time?
 - b. Probe: What advice did doctors at drug treatment centers give you to take ART and substance use treatment at the same time?
 - c. Probe: What advice did **[name of systems navigator/counselor]** give you to take ART and substance use treatment at the same time?

68. Since you joined the project (about 1 year ago), how do you feel that your readiness to take ART and substance use treatment at the same time has changed?
- Probe: Why do you think your readiness to take ART and substance use treatment at the same time has changed?
 - Probe: How did your ARV doctors influence your readiness to take ART and substance use treatment at the same time?
 - Probe: How did your doctors at drug treatment centers influence your readiness to take ART and substance use treatment at the same time?
 - Probe: How did your counselor/navigator influence your readiness to take ART and substance use treatment at the same time?

Evaluating the HPTN 074 Intervention

Thank you for helping me understand the challenges that people who inject drugs face with taking ART. Now I'd like to shift our conversation to discussing strategies to improve this process. I want to remind you that your opinion is very helpful for us to improve these programs. It is just as important for me to understand what is not going well as it is for me to know what is going well. Your responses will be kept private so do not worry about what others would think about your opinion.

69. How did the sessions with your counselor/navigator change over time? (Hint: session topics, family participation)
- Probe: How did your relationship with your counselor/navigator change over time?
 - Probe: How did the type of support or advice your counselor/navigator gave you change over time?
70. Which session did you feel was most helpful to you? Which session did you feel was least helpful? Why?
- Probe: How can the sessions be improved?
71. Some clients requested additional (booster) sessions after attending two counseling sessions. Did you receive any additional (booster) sessions (i.e. about depression, drug treatment, risk reduction, etc.)? Why or why not?
- If yes:* Why were these additional topics interesting to you?
 - Which topics were the most helpful? Why?
 - If no:* Why were you uninterested in attending additional (booster) sessions?
72. Tell me about any topics that you wished we had offered during the sessions. Why would those topics be helpful?
73. Walk me through your most recent visit with the counselor/navigator.
- Probe: What did you discuss?
 - Probe: What advice or strategies did s/he recommend?
 - Probe: In what way was the advice helpful?
 - Probe: Did you have any remaining questions after the visit?
 - Probe: Are there any strategies that you have not found helpful? Why not?
 - Probe: In what way have these visits addressed the barriers you mentioned earlier?

74. You have spent the last year working with the counselor/navigator. What was the most helpful thing that a counselor/navigator did for you? (Hint: counseling sessions, sessions with a supporter, phone calls, guidance in clinics)

a. Probe: What was the least helpful thing that a counselor/navigator did for you?

75. [Name of systems navigator/counselor] interacted with you in various ways. How would you change the role of [name of systems navigator/counselor] to improve their ability to help people who inject drugs?

Conclusion

76. In your opinion, what additional resources or strategies could help reduce some of the barriers you mentioned?

a. Hint: reorganizing clinic, reducing wait time, reducing stigma in the community

Thank you so much for your thoughts. Is there anything else you want to share about your experience in the ART program?

APPENDIX B
Materials Checklist

- Participant Informed Consent Form
- Interview guide
- Digital recorder
- Back-up digital recorder
- Extra batteries for digital recorders
- Pad of paper and a pen
- Additional items to be added, per site

APPENDIX C
Consent to Participate in a Research Study

APPENDIX E
Interview Feedback/Summary Forms

INTERVIEW SUMMARY: COUNSELOR/NAVIGATOR

***Purpose:** To help the research team identify and share intervention successes and challenges in real time. These forms will be shared with other systems navigators/peer counselors within each research site, and relevant themes may be shared across HPTN sites, with the ultimate goal of improving how HPTN 074 intervention address clients' barriers and facilitators.*

| PARTICIPANT INFORMATION | |
|--------------------------------|--------------------------------|
| ID: | Role: |
| Clinic/Location: | Length of time in role: |

| INTERVIEW INFORMATION | |
|------------------------------|--------------|
| Interviewer Name: | Date: |

| SUCCESSFUL STRATEGIES | | |
|---|---|-----------------------------|
| <i>Document strategies counselors/navigators described during the interview as being useful or helpful to HPTN 074 participants. Include strategies for access to ART/MMT services, as well as adherence to either treatment regimen.</i> | | |
| | Description of strategy or recommendation | Why has this proved useful? |
| 1 | | |
| 2 | | |
| 3 | | |
| 4 | | |
| 5 | | |

| AREAS FOR IMPROVEMENT |
|---|
| <i>Document strategies counselors/navigators described during the interview as being least helpful to HPTN 074 participants, and any reason they were not successful or suggestions for future improvement. Include strategies for access to ART/MMT services, as well as adherence to either treatment regimen. This section may also include identifying barriers that are not currently addressed by the HPTN 074 intervention, as</i> |

these will be important to highlight and address in future implementation.

| | Description of strategy or recommendation | Suggestions for improvement |
|---|--|------------------------------------|
| 1 | | |
| 2 | | |
| 3 | | |
| 4 | | |
| 5 | | |

INTERVIEW SUMMARY: CLINIC PERSONNEL

***Purpose:** To help the research team identify and share feedback from providers about the facilitator and barriers to accessing HIV and substance use care in real time. These forms will be shared with systems navigators/peer counselors within each research site, and relevant themes may be shared across HPTN sites, with the ultimate goal of improving how HPTN 074 intervention address clients' barriers and facilitators.*

PARTICIPANT INFORMATION

| | |
|-------------------------|--------------------------------|
| ID: | Role: |
| Clinic/Location: | Length of time in role: |

INTERVIEW INFORMATION

| | |
|--------------------------|--------------|
| Interviewer Name: | Date: |
|--------------------------|--------------|

SUGGESTIONS TO IMPROVE HPTN 074

Document strategies counselors/navigators described during the interview as being useful or helpful to HPTN 074 participants. Include strategies for access to ART/MMT services, as well as adherence to either treatment regimen.

ART Access

| | Identified barrier | Recommendations for addressing this |
|---|--------------------|-------------------------------------|
| 1 | | |
| 2 | | |
| 3 | | |
| 4 | | |
| 5 | | |

ART Adherence

| | | |
|---|--|--|
| 1 | | |
| 2 | | |
| 3 | | |

| | | |
|--------------------------------|--|--|
| 4 | | |
| 5 | | |
| Substance Use Treatment | | |
| 1 | | |
| 2 | | |
| 3 | | |
| 4 | | |
| 5 | | |

INTERVIEW SUMMARY: INTERVENTION PARTICIPANT

***Purpose:** To help the research team identify and share feedback from providers about the facilitator and barriers to accessing HIV and substance use care in real time. These forms will be shared with systems navigators/peer counselors within each research site, and relevant themes may be shared across HPTN sites, with the ultimate goal of improving how HPTN 074 intervention address clients' barriers and facilitators.*

PARTICIPANT INFORMATION

ID:

Clinic/Location:

INTERVIEW INFORMATION

Interviewer Name:

Date:

Brief Summary of Interview

Barriers Identified

Suggestions for Improving HPTN 074 Intervention