HPTN 094
Implementation Science Manual

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1 Implementation Objectives

To evaluate implementation of "one-stop" integrated health services using a mobile unit, supported by peer navigation, across study sites to identify mechanisms at multiple levels to:

1. Guide real-time improvements and refinements in the conduct of the study to ensure primary and secondary outcomes are met with fidelity
2. Examine the quality and process of services delivered in each study arm, particularly as these affect primary and secondary outcomes
3. Develop evidence-based guidance for policymakers on the uptake and implementation of integrated health services using peer navigation and mobile health units in urban US regions to address HIV in PWID
4. Identify factors that enhance or impede the delivery of integrated health services using a mobile unit, supported by peer navigation, on primary and secondary outcomes, including responding to the impact of COVID-19 on service delivery

2 Implementation Evaluation Overview

The purpose of this manual is to provide guidance on the operation of the implementation science component of the HPTN 094 Study, as described in Section 6.6 of the study protocol. This manual describes procedures for all five sites of HPTN 094.

A mixed method, theory-driven (PRISM) approach will be used to collect quantitative and qualitative data to determine factors associated with fidelity of implementation, effectiveness, and dissemination of integrated healthcare delivered in mobile unit, supported by peer navigation. Evaluation will be conducted for each study site and will include three primary sources: documentation of protocol activities, semi-structured in-depth interviews, and ethnographic observations.

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 094 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 Implementation Science PI.

3 Implementation Evaluation Timeline and Process

3.1 Assessments

Implementation evaluation data will be collected over the course of the study during three phases: the pre-implementation phase, implementation phase, and the evaluation phase (to assess the impact implementation factors had on primary and secondary outcomes).

3.2 Feedback, Adaptation, and Documentation

In support of our implementation evaluation objectives, the implementation evaluation team will use Stirman and colleagues (2019) FRAME approach to identify and document real-time adaptations made to the implementation of the intervention at the site and cross-site levels (see **Appendix A**). The FRAME (Framework for Reporting Adaptations and Modifications-Expanded) approach systematically documents key elements related to how and why an adaptation decision was made, the nature of the adaptation, and the adaptation's relationship with fidelity to core elements of the intervention.

During the **pre-implementation phase**, the data will be reviewed once by the implementation evaluation team and used to document the empirically-based selection of target neighborhoods to implement the intervention. Results will be discussed, refined through discussion with site investigators at a cross-site meeting and documented.

During the **implementation phase**, the data will be reviewed monthly by the implementation evaluation team and used to provide site-specific quarterly feedback that will guide real-time improvements to the implementation process. Any changes to how the intervention in either study arm is adapted in response to this feedback will be documented by the implementation evaluation team and re-assessed with site investigators at cross-site meetings.

During the **evaluation phase**, data sources will be evaluated and triangulated to expand on and contextualize how the intervention implementation affected HPTN 094 primary and secondary study outcomes, and provide guidance on how the intervention can be adopted, adapted, and implemented in similar public health jurisdictions.

Implementation Assessment Schedule by Data Source and Study Phase

1. Documentation of Study Protocol Activities	2. Semi-structured In-Depth Interviews	3. Ethnographic Observations
PRE-IMPLEMENTATION		
Routine Meetings (agenda) ☐ Cross-site protocol meetings ☐ Community engagement	--	**Landscape Analysis** ☐ One-time analysis ☐ Update changes in overdose stats every 3-6 months as a standing agenda item.
IMPLEMENTATION		
Routine Meetings (agenda) ☐ Cross-site protocol meetings ☐ Community engagement ☐ Site Protocol and CAB meetings ☐ Provider team calls **Fidelity Checklists** ☐ Clinical Services by site ☐ Peer Navigation by site ☐ QA/QC data by site **Efficacy evaluation process** ☐ Participant screening and enrollment demographics by site	**Qualitative Interview** ☐ 39 one-time interviews per site	**Ecological Assessment** ☐ Brief weekly report, quarterly feedback
EVALUATION		
Routine Meetings (agenda) ☐ Cross-site protocol meetings ☐ Community engagement ☐ Site Protocol and CAB meetings ☐ Provider team calls **Efficacy evaluation process** ☐ Participant screening and enrollment demographics by site ☐ Participant outcome data by site, study arm, select subgroups	--	--

4 Protocol Activities (data source 1)

Data from protocol activities such as routine meetings, fidelity monitoring, and efficacy evaluation procedures will be routinely collected by LOC study staff. Protocol activities will be analyzed by the implementation

evaluation team through documenting the process and outcomes of study-related meetings, capturing participant data, and documenting the conduct of the study.

4.1 Data Collection, Synthesis, and Feedback

Protocol activities data will be collected through the following methods:

4.1.1 Protocol meetings

A standing agenda item related to implementation evaluation will be added to existing community engagement, CAB, protocol site, and cross-site meetings. Responses to these agenda items will be flagged in meeting minutes or transcripts and field notes and submitted to the implementation evaluation team on a monthly basis for review and synthesis.

- Site-level Community Engagement and CAB meetings will be used to collect data on community perceptions toward the intervention, environmental factors such availability and perceived quality/cultural competency of community-based services, how resources are allocated, and policies enforced in neighborhoods where the intervention is implemented, and how the COVID-19 epidemic has affected delivery of community-based services to PWID.
- Cross-site protocol meetings, Site-specific protocol meetings, Provider team calls will be used to collect data on factors that are affecting the delivery of the intervention by study staff (e.g., how to coordinate clinical and peer navigation encounters), participant access (e.g., where to park mobile units to maximize privacy), and adjustments to study infrastructure (e.g., staffing mobile units, refrigeration, internet access).

4.1.2 Study records

Participant records and encounter forms, quality assurance and quality control activities, and standard checklists for assessing fidelity metrics in clinical and peer navigation encounters will be aggregated by study site and implementation neighborhoods, and submitted to the implementation evaluation team on a monthly basis for review and synthesis.

- Participant records and encounter forms will be used to assess who is being *reached* by the intervention, optimize representation of specific subgroups (e.g., PWID of color, women, young adults), and inform the distribution of factors affecting the *effectiveness* of the intervention (i.e., benefits and any unintended negative outcomes) by specific subgroups.
- Quality assurance and quality control (QA/QC) activities, as well as checklists for assessing fidelity to study protocols in clinical and peer navigation encounters will be used to assess the *adoption* and delivery of the intervention in both study arms, help estimates costs associated with *implementation,* and document how adaptations may affect the *effectiveness* of the intervention.

4.1.3 Existing site-specific resources

Sociodemographic data characterizing the opioid and HIV epidemics of each study site and site-specific neighborhoods where the intervention will be implemented will be obtained from past published reports or service records and screening and enrollment records. These data will be used as the comparison (denominator) for determining the representativeness of the interventions' *reach, effectiveness,* and *adoption* across urban communities affected by these co-occurring epidemics in the US mid-Atlantic, South and West.

5 In-depth Interviews (data source 2)

Semi-structured in-depth interviews will identify and contextualize barriers and facilitators to the implementation of the intervention that may influence primary and secondary outcomes. Interviews will be conducted with PWID, intervention providers and staff, and community stakeholders to elicit multi-level factors (i.e., patient, healthcare

delivery, community environment, structural) affecting the intervention delivery, care access, and ability to sustain engagement in integrated care services.

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 analytic methods are described in **Appendix B** of this manual.

5.1 Recruitment Sampling Frame

Thirty-nine interviews will be conducted per study site for a total of 195 interviews. Sections 5.1.1 – 5.1.3 outline the qualitative sampling framework for participants.

Appendix C outlines 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. Qualitative field staff will be responsible for documenting the number and type of individual (PWID, mobile unit providers, community stakeholders) approached for IDI recruitment and the outcome of the recruitment encounter (agreement to participate, declined participation, other [specify]). Recruitment status will be documented during weekly qualitative team meetings by the qualitative PI and submitted to the implementation evaluation team monthly.

Participation of stakeholders, mobile unit staff and clients of intervention services (PWID participants) will be entirely voluntary. If someone chooses not to participate, he/she/they will experience no penalty or loss of benefits. Furthermore, procedures will be undertaken to ensure that supervisors are not informed of a staff member or stakeholder's decision regarding participation. To ensure protection of staff and stakeholder participation or refusal the recruiting and interview staff 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/their 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.

5.1.1 Research Justification for Sample Size

Prior research indicates between 15-20 interviews are needed to reach saturation on a research question within a relatively homogenous study population. In-depth interviews data collection will be stratified across all five study sites and monitored for saturation of responses via twice monthly meetings between the qualitative PI and site-level interviewers. Our in-depth interviews sampling framework was developed to allow us to capture salient themes at the site-level with the capacity of scale across five sites to contextualize implementation experiences – at multiple levels – that could affect the implementation of integrated services on observed outcomes and guide the uptake and implementation of integrated services in other regions in the U.S. to underserved groups.

5.1.2 Interviews with Community Stakeholders

A total of 15 interviews per site (75 total) will be conducted with community stakeholders involved in the delivery of stand-alone brick and mortar services to PWID. We aim for representation of both front-line service providers (50-60%) and management-level staff who can speak to the system-level infrastructure of local service delivery (HIV n=3, MOUD n=3, harm reduction n=3, primary care n=3, public health officials n=3) who are more homogeneous in terms of their service delivery role than PWID accessing services. This sampling frame aims to achieve saturation of response for each service type (across sites) and compare regional variation in experiences serving PWID within the local service landscape between sites. Stakeholders will be identified through landscape analysis of mapping of community assets and gaps during the pre-implementation phase.

5.1.3 Interviews with Mobile Unit Staff

Interviews will be conducted with seven staff, per site, who support integrated health delivered in each mobile health unit (35 total). The sample will include mobile unit providers and staff (clinicians delivering MOUD and ARV treatment n=2, peer navigators n=3, staff involved in recruitment and retention activities n=2) who are more

homogeneous in terms of their service delivery role than PWID accessing services. This sampling frame aims to achieve saturation of response for each personnel type needed to implement integrated care across sites, and compare regional variation in experiences delivering services (as a team) between sites.

5.1.4 Interviews with Clients (PWID)

Ten percent of PWID (n=17) enrolled at each study site will be purposefully sampled (85 total). The goal is to achieve saturation of response related to site-level external environments and to compare regional variation in these experiences between sites for diverse underserved groups. For each site, 17 PWID will be purposefully sampled to explore challenges by gender (25-30% female), race/ethnicity (25-30% non-Hispanic white), and HIV status (25-30% HIV-positive) on recruitment, retention, and delivery of services in both arms (including the impact of COVID-related challenges). Sampling will be conducted such that participants are demographically representative of the local injection communities in terms of age, gender, race, and HIV status. Demographic targets will be identified through landscape analysis of site-specific opioid and HIV epidemics in the pre-implementation phase.

5.2 Interview Guides

Interviews will be conducted using a standard guide (see **Appendix D**) that includes site-specific probes and a combination of community stakeholder, provider, and client-focused queries. Guided by the PRISM framework, interviews will explore factors that (a) facilitate or impede the implementation of the intervention (e.g., perceptions of the intervention, ability to deliver/access the intervention, community environment, policy and system-level factors) and (b) help contextualize factors influencing key implementation outcomes (e.g., reach, effectiveness, adoption). An example of a community stakeholder-centered query is community perceptions and infrastructures that would affect the sustainability and scalability of the intervention. An example of a provider-centered query is staffing and resource requirements to deliver MOUD and HIV/PrEP care in a mobile unit. An example of a client-centered query is willingness to initiate MOUD or HIV/PrEP care in a mobile unit.

5.3 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 E** and should be modified for site-specific needs.

5.3.1 Timeline

In-depth interviews will be conducted approximately 6 months after the study implementation phase. Recruitment may begin up to 1-3 weeks prior to the interviews.

5.3.2 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 094 SSP and in site specific SOPs. Source documentation for interviews may consist of checklists, recruitment logs, and transcripts.

5.4 Data Collection

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

Semi-structured interviews with community stakeholders, mobile unit staff, and intervention participants will be based on a standard interview guide that will be used at all sites. Interview guides may include site-specific probes developed in collaboration with the implementation team. All interviews will be audiotaped and sent to a professional vendor for centralized transcription and translation (if needed). All participant identifiers will be removed from transcripts. Transcripts will be analyzed in two phases: topical and interpretive.

5.4.1 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 a 1, 2, 3, or 4 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.

5.4.2 Recording

Interviews will last approximately one hour. All interviews will be audio recorded and transcribed by qualified personnel. Electronic recordings and transcription 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 backup. 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. 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.

5.4.3 Demographic Data Collection

After reviewing and obtaining informed consent with the participant, interviewers should complete the Participant Demographics form provided in **Appendix F**.

5.4.4 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 G**. Site staff should review these forms at the completion of each round of interviews, summarize key points, and submit this information to the implementation evaluation team and site PI.

Twice a month, post-interview summaries will be reviewed by the implementation team with interviewers across study sites to contextualize site-specific and cross-site emerging themes and refine ways in which interview probes are asked to optimize the data collection process. The goal of post-interview summaries is to provide feedback or lessons learned to the implementation team to improve intervention reach and quality.

Post-interview field summaries should reflect on:

- The intervention's perceived value or shortcomings (e.g., met and unmet needs)
- Factors that make it harder or easier to deliver/access the intervention
- Contextual factors in the community environment that could affect how the intervention is implemented in the mobile unit or accessed by PWID (e.g., community norms, NIMBY-ism, quality of/proximity to existing services, limited privacy for screening/using van services)
- Policy and structural factors that affect the implementation and potential sustainability of the intervention.
- Factors that affect the ability to reach, engage, or retain PWID of diverse backgrounds (e.g., PWID of color, women, young adults)

Summaries will be used to inform rapid thematic analysis for the purpose of informing and documenting real-time adaptations to the intervention implementation. A synthesis of the rapid thematic analysis will be shared during site protocol and cross-site meetings by the Implementation Science PI.

5.4.5 Confidentiality and Privacy

Audio files will be saved on a password-protected, access-limited computer and any physical copies of the file 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.

5.5 Transcription and Translation

All interviews will be audiotaped and sent to a professional vendor for centralized transcription and translation (if needed). If there are specific cases where an internal team member is needed 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 participant's nonverbal cues, such as extended pauses or intonations that may convey contextual meaning 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 go to the clinic with Sean, my boyfriend.	I don't go to the clinic 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). 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 the implementation phase.

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.

5.6 Final Submission of Data

Sites should select one contact person who is responsible for submitting all final interview data, including a copy of the demographic form, translated interview transcript, and post-interview field summary to the Implementation Science 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 documents.

5.7 Rapid Thematic Analysis and Feedback

To guide real-time improvements and refinements in the conduct of the study to ensure primary and secondary outcomes are met with fidelity, transcript summaries will be created by site staff trained in qualitative methods. Summaries will be discussed with the implementation evaluation team across-sites and results entered into a matrix for rapid thematic analysis. Any changes to how the intervention in either study arm is adapted in response

to this analysis will be documented by the implementation evaluation team and re-assessed with site investigators at cross-site meetings.

6 Ethnographic Observations (data source 3)

Ethnographic observations of the surrounding environment and delivery of integrated healthcare and peer navigation will be conducted at each study site. The data will be captured by research assistants trained in conducting ethnographic observations.

Ethnographic data will be collected through the following methods:

Landscape analysis to document objective criteria for selecting potential neighborhood locations for INTEGRA van services and study recruitment in the pre-implementation phase.

Ecological assessments of study sites in the implementation phase to ensure the location of INGEGRA van services and study recruitment occur in the local areas with the greatest need.

Qualitative ethnographic observations at two timepoints during the implementation phase to document contextual factors that affect the delivery of integrated care services in a mobile unit and transition to community-based services.

Time-and-motion studies will be conducted over a two-week period at each site during the qualitative ethnographic observation period to collect data to document the time and staff resources needed to deliver integrated care services in a mobile unit and transition participants to community-based services.

6.1 Landscape Analysis

During the pre-implementation period, each site will complete a one-time formal landscape analysis that will be used to document objective criteria for selecting potential neighborhoods in which intervention services (i.e., INTEGRA study mobile unit) and participant recruitment should occur.

Updates on key epidemiological data with a greater propensity to change over time (i.e. overdose deaths) will be updated every 3-6 months as a cross-site meeting standing agenda item during the implementation phase. This monitoring will help to ensure recruitment sites continue to target priority neighborhoods affected by the opioid and HIV epidemics.

6.1.1 Landscape Analysis Set-Up and Materials

A landscape analysis will be completed by each study site drawing on local data (see section 6.1.2) and resources to contextualize potential intervention neighborhoods and locations within each neighborhood that are optimal for intervention activities.

6.1.1.1 Timeline

Up to 3 months prior to the intervention implementation's projected start date, each study site will initiate the landscape analysis. Study sites will be given 4 weeks to complete the analysis (e.g., 08-JAN-2021 to 08-FEB-2021) so that results are collected at least one month prior to the projected start date. Each site will be given information that states the specific date range for completing the landscape analysis in line with estimated study launch (e.g., 08-MAR-2021).

6.1.1.2 Survey Link

Each study site will first compile the requested data for the landscape analysis (see **Appendix H**) and then enter results into Qualtrics through a secure link provided by the LOC to site investigators.

6.1.2 Documentation Requirements for Landscape Analysis

Study sites are to retain copies of all primary data and resources used to complete their landscape analysis (e.g., pdfs, links to public health surveillance reports, field notes). The landscape analysis survey link will request sites to provide an AMA-style reference list of primary data and resources used to complete the landscape analysis, and dates these data were accessed. For help with AMA formatting, visit https://owl.purdue.edu/owl/research_and_citation/ama_style/index.html

6.1.2.1 Data Sources

Relevant data sources may vary by study site, but in general will include accessing local city and neighborhood-level (i.e., by zip code or U.S. Census block) data on HIV and opioid use surveillance and service utilization data for the most recent year surveillance data are provided, data on opioid-related overdose deaths, drug-related arrests, neighborhood sociodemographic data.

6.1.2.2 Google Maps

Google Maps will be used to document the location of each proposed study recruitment neighborhood (i.e. zip code), and the proximity of potential neighborhoods to one another. Note a neighborhood may be contained within a subsection of a single zip code or inclusive of more than one zip code. Please document which zip code best reflects the HIV, opioid, and sociodemographic data for a given neighborhood.

Please see **Appendix I** for detailed instructions on how to create this map.

For each potential recruitment neighborhood, Google Maps will be used to document (1) the parameters of a given neighborhood as delineated by main intersections (i.e. neighborhood borders), (2) ideal locations within each neighborhood where the study van could be located, (2) estimated travel times between the location where the study van resides overnight to ideal van locations in the neighborhood, (3) the location of relevant resources and services in the neighborhood, and (4) the distance and travel time to and from ideal van location to the nearest service site (estimated using most appropriate mode of travel for the area [i.e., walking, ride share, driving]).

6.1.2.3 Site Staff and Community Stakeholders

The site PI will be responsible for identifying site-specific staff best suited to collect the data and resources, liaise with local stakeholders, and synthesize observations to respond to the landscape analysis survey.

Please see **Appendix J** for guidelines on discussions with community stakeholder to contextualize responses to the landscape analysis survey.

Contextual and historical records from study staff and community stakeholders may be gathered to inform brief summaries that will be used to contextualize ideal locations within potential neighborhoods. Field notes should be taken by study staff and used to document any conversations that may inform or help to contextualize the data reported in the landscape analysis.

6.1.3 Data Collection

Landscape analysis data will be collected locally and documented through responses to questions sent to study sites via Qualtrics survey link. Survey questions can be viewed in **Appendix H** and will ask sites to specifically identify potential neighborhoods for study activities, document the scope of the HIV and opioid epidemics impact on these neighborhoods, and document proximity to study-related resources and services.

6.1.3.1 Identifying Study Site Neighborhoods

Most sites will have several neighborhoods that are known for having well-established injection drug use communities. These communities may overrepresent injection communities that are white, male, and older. To ensure recruitment neighborhoods can reach PWID who are younger or reflective of communities of color with

more pronounced HIV disparities, multiple factors will be documented that support the importance of including specific neighborhoods in our sampling frame.

Potential neighborhoods that extend beyond those with well-established injection communities might include neighborhoods with emerging trends in increased opioid-related overdose or drug-related arrests; neighborhoods with increased trends in HIV diagnoses among women and people of color, and those which community stakeholders believe are home to emerging or less-well known injection communities.

The objective is to systematically document the data for each neighborhood that might reasonably be considered for study recruitment to produce a data driven rational for prioritizing study recruitment sites.

6.1.3.2 Documenting the Scope of the HIV and Opioid Epidemics

Data documenting the scope of each sites' HIV and opioid epidemics should be leveraged from local reliable sources such as the City, County, or State Departments of Public Health, law enforcement records, and recent peer reviewed data sources stemming from research specific to the study site. Recent data generated by national groups such as the Centers for Disease Control and Prevention specific to study sites may also be appropriate.

Similarly, neighborhood-level sociodemographic data should be accessible for all sites from the US Census Bureau or other local/State agencies involved in Health and Human Service Agency-related activities.

6.1.3.3 Proximity to resources and services

Proximity to resources and services will be documented as one-way travel (in total miles and total minutes) using Google Maps. Google Maps was selected as the platform for documenting location and establishing proximity metrics because, (i) it is a universal platform available free of charge to all study sites, (ii) it provides a standardized algorithm to calculate travel distance/time, (iii) allows for multiple locations to be systematically documented on a single map by staff with limited training or knowledge of GIS methods, and (iv) allows maps to be saved and shared with others.

Each site will add all potential recruitment neighborhoods and related data to their map. Each site can save their Google Map to work on and update while developing landscape analysis responses.

See **Appendix I** on how to construct the map and how to include necessary information such as neighborhood boundaries, locations for relevant services or study activities, and travel time (one-way) between specific locations on the map.

6.1.4 Submission and Synthesis of Data

Landscape analysis data will be submitted to the implementation evaluation team and reviewed with site PIs to document the prioritization and selection of recruitment sites. A synthesis of this process will be documented and shared during site protocol and cross-site meetings by the Implementation Science PI.

6.2 Ecological Assessments of Study Sites

Ecological assessments of selected recruitment sites where the study van is parked will be documented weekly throughout the implementation phase to monitor recruitment site needs and productivity.
The objective of these weekly ecological assessments is to document the reach, adoption, and implementation of the INTEGRA intervention within the target population. Aligned with pragmatic applications of the RE-AIM model (Glasgow and Estabrooks, 2018), data will be used to assess:

Reach is typically defined as the "absolute number, proportion, and representativeness of individuals who are willing to participate in a given initiative". Practically speaking, these data will allow us to characterize and

optimize *who* was intended to benefit from the intervention (target community), who actually participates (enrolled) in the study, and who is exposed to the intervention (treated in study van).

Adoption is typically defined as the absolute number, proportion, and representativeness of settings where the intervention could be and is implemented. Practically speaking, these data will characterize *where* the intervention is implemented.

Implementation is typically defined at the setting level and includes assessing the consistency of intervention delivery as intended, adaptations made, and time and costs associated with delivering the intervention. Practically speaking, these data will characterize how consistently the intervention was delivered in each neighborhood at each study site, and support analyses investigating the costs associated with the intervention and how implementation may have affected the observed outcomes of the intervention.

6.2.1 Ecological Assessments Set-Up and Materials

6.2.1.1 Timeline

Ecological assessments of selected recruitment sites where the study van is parked will be documented weekly throughout the implementation phase to monitor recruitment site needs and productivity.

6.2.1.2 Survey Link

At the end of each week, sites will be emailed a Qualtrics survey link to record data on recruitment sites where the study van was parked. Data will be documented by study van location *not* recruitment site, because this is the location at which the intervention (i.e. integrated treatment) is delivered.

6.2.2 Documentation Requirements

For each day of the week, study staff will document:

- Date (mm-dd-yyyy)
- Neighborhood name
- Nearest cross streets
- Zip Code
- Number of study hours at site (active hours following set up, but prior to take down)
- Any notable characteristics of- or changes to- the neighborhood site where the van was located that may have affected participant enrollment or treatment. This includes both barriers and facilitators. Examples can include changes in policy or policing measures, change in reputation in services, neighborhood acceptance of PWID, etc.
- Any notable changes to the study van or study resources (e.g. equipment, staff, etc.) that may have affected how treatment was delivered to participants or accessed by participants.

It may be helpful for sites to keep an electronic log in the study van that gets filled out at the end of each day. This log can then be collected by the field supervisor at each site to facilitate data entry each week. Sites can tailor this process to ensure continuity among staff and for the person who will be responding each week. Examples include the use of an Excel spreadsheet, Google Doc, Google sheet, etc., that will have the date and any observations made that were notable.

6.2.3 Staff

Brief weekly surveys will be completed by the field supervisor at each site or a staff member with similar knowledge regarding the day to day recruitment and retention activities at field sites.

6.2.4 Data Synthesis and Feedback

These data will be cross-referenced with enrollment and study visit data (e.g. number of participants enrolled, number of participants treated on the study van) and participant characteristics (gender, race/ethnicity, age, HIV status) captured for a given study day at each site.

These study day visits will then be examined by neighborhood characteristics (e.g. population size, HIV prevalence, overdose rates by gender and race/ethnicity composition) identified in the landscape analysis. These comparisons will be compiled by the implementation science team quarterly and reported back to study sites.

The comparisons will be used to characterize each site's ability to enroll and treat a diverse target population that is representative of local HIV and opioid-related health disparities. These data can be used to adjust recruitment targets as needed to optimize study reach.

Any changes made to the selection of study sites, in response to these data, will be documented by the implementation science team. Discussions related to the intervention's reach, adoption, and implementation will be standing agenda item on study calls. Responses will be recorded from the study minutes and used to contextualize ecological assessment data.

7 Cost and Cost-Effectiveness Procedures

7.1 Cost analysis

This evaluation is intended to influence the delivery of HIV services the healthcare sector perspective. This cost analysis will include the financial costs for all activities and inputs used to implement the intervention in the study, as well as include an economic component that incorporates costs of resources that may have been either donated or shared with existing government health services that were leveraged in the implementation of this study. Overhead costs and expenses such as building infrastructure, maintenance, and building expenses will also be included in the cost analysis. Activity-based costing will be used to identify the main activities, resources, and specific inputs.

7.1.1 Health care sector costing from existing records (not human subject research)

Expenditure reports will be obtained from project expense reports to cover the following components:

Start-up: This section will include program development costs. These include (but are not limited to) costs necessary to mobilize efforts within the community, interviewing, hiring, and training of staff and advertisements.

Materials and Supplies: This section will include computers and technological supplies, medications, and printing.

Training**:** This section will include project-specific training that will be provided to the team members working on the project at project initialization and whenever a need arises. These costs include rental of venues, light catering for the training events, and printing materials. The *Contact Costs* for research staff salary grade/time is not counted in this section.

Personnel: We plan to estimate health worker costs, which are the product of salaries and time spent delivering the intervention (the latter will be estimated using time-motion studies)**.**

Commodities: We will capture quantities of all drugs, diagnostics, and consumables used in routine healthcare related to the intervention.

Overheads: We will estimate facility overheads by using expenditure reports and allocation formulae developed in previous research studies.

7.1.2 Provider time-motion study

We will do time-motion studies of frontline health workers who will be responsible for delivering HIV care at study sites, specifically comparing time allocations before and after the intervention is implemented. Health workers who will be involved in HIV care will be invited to participate in the study.

The research assistant will observe the time taken to provide services to participants in the time-motion studies. Time-motion data will be collected in two waves:

(1) First observation (HIV care delivered in mobile vans)

(2) Second observation (HIV care delivered in traditional clinics)

The research assistant will collect data on a random day of the month. The same health workers may be observed more than once in the study.

On the appointed day, the research assistant will situate themselves in a discrete location in the mobile van/clinic and observe the activities of the team over their typical workday. The research assistant will use a stopwatch and the survey instrument to record time spent on different activities.

At the completion of the observation, the research assistant will review the data collected on the survey instrument with the team member and will correct or clarify data recorded as needed.

The research assistant will collect data until the heterogeneity in the time taken to complete procedures is captured.

Data analysis plan

The time-motion logs will be analyzed using descriptive statistics to estimate the average amount of time spent (minutes per week) delivering HIV care at mobile clinics as compared to delivering care at traditional clinics.

7.2 Cost-effectiveness analysis

We plan to use the trial data to get de-identified, aggregate health outcome data. One of the outcome measurements of this costing project is the cost-effectiveness.

The cost effectiveness analysis will compare the incremental costs per package of interventions delivered and effectiveness at mobile clinics compared to traditional clinics. The incremental cost effectiveness ratio (ICER) will be measured by the additional costs incurred divided by the change in health outcomes.

$$ICER = \frac{COST_{mobile} - COST_{traditional}}{Effectiveness_{mobile} - Effectiveness_{traditional}}$$

$$ICER = \frac{\Delta\, costs}{\Delta \text{ health outcome}}$$

APPENDIX A: Stirman FRAME Protocol to Document Implementaiton Adaptations

Protocol to Document Implementation Adaptations

Throughout the **implementation phase**, the **Stirman FRAME Protocol** will be used to document and guide real-time improvements and refinements (adaptations) to the implementation of the interventions in both arms to ensure primary and secondary outcomes are met with fidelity (implementation objective 6a). This iterative process will occur in three steps.

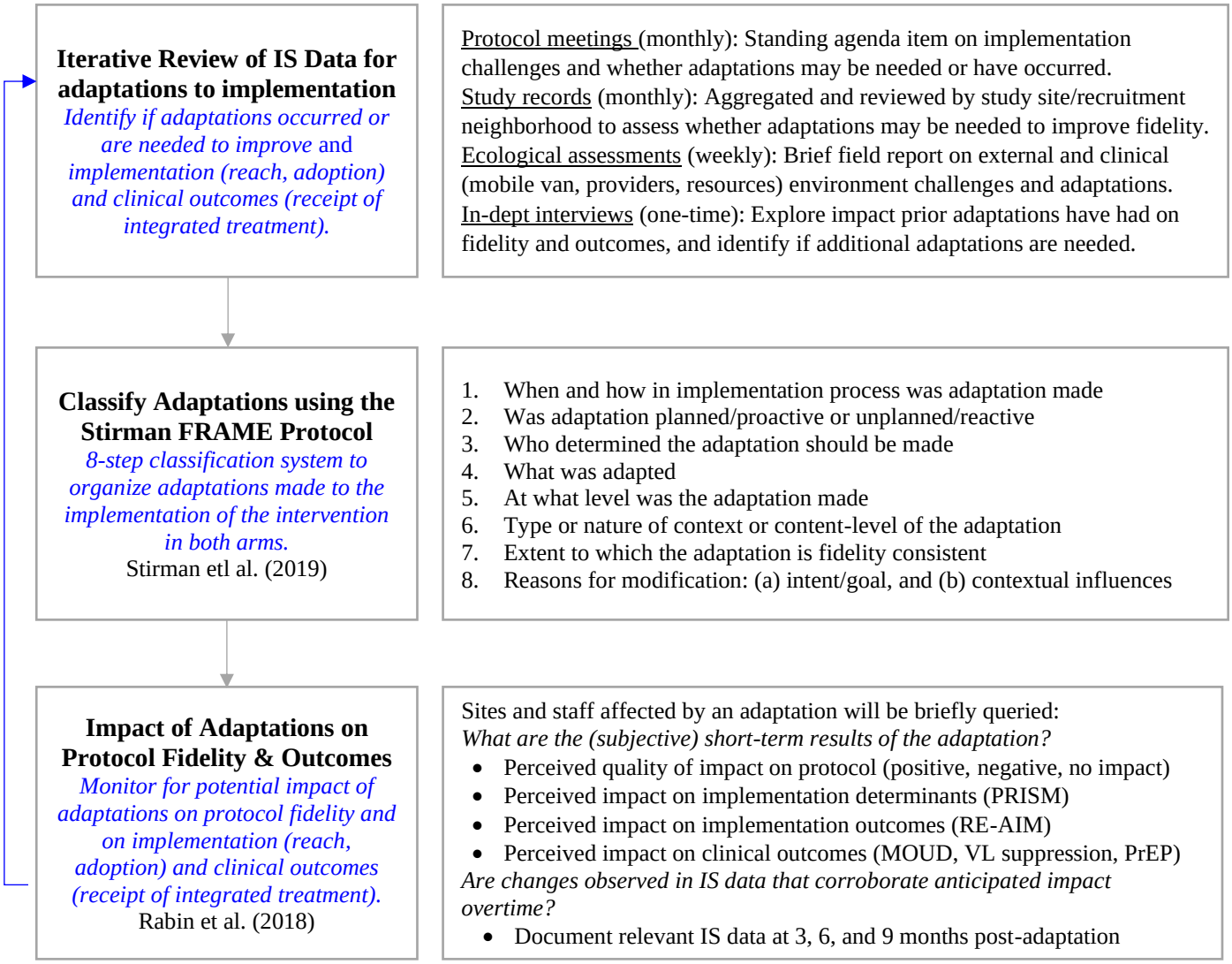

Figure 1. Iterative identification and classification of study protocol adaptations on outcomes of interest

STEP 1: Iterative Review of IS Data for adaptations to implementation.

Members of the IS team will convene monthly to review and synthesize IS data sources across study sites and recruitment neighborhoods (as applicable), to ***identify if adaptations*** to the interventions in either study arm have occurred or are needed in the conduct of the study to ensure primary and secondary study outcomes are met with

fidelity. Following guidance by Rabin and colleagues (2018), this process will also attend implementation outcomes, guided by the RE-AIM Model (reach, effectiveness, adoption, implementation/ ability of staff to deliver intervention successfully, and maintenance) where applicable.

STEP 2: Classify Adaptations using the Stirman FRAME Protocol.

Once an adaptation is identified, members of the IS team will follow up with appropriate study team member (e.g. field coordinator, peer navigators, site PI) to classify and organize the adaptations. The 8 step classification system and code definitions are outlined in Table X. This brief assessment will conclude with an open-ended question to explore the intended impact of the adaptation(s) on protocol fidelity and outcomes (see Step 3).

STEP 3. Assess the impact of adaptations on protocol fidelity and outcomes.

During the classification of an adaptation (Step 2), the appropriate sites and staff affected by an adaptation will be briefly queried (< 10 minutes) on their perceived short-term impact of the adaptation. Following guidance by Rabin and colleagues (2018), we will ask:

- *"We understand that the full impact of this adaptation cannot be determined at this time. Instead we hope you can tell us what you think the short-term impact of this adaption will be on the intervention over the next 3-6 months."*

Responses will be probed to document:

- Perceived *quality of impact* on protocol (positive, negative, no impact)
- Perceived influence on *implementation determinants* (PRISM: Patient/provider perceptions of the intervention in both arms, Receipt/delivery of intervention in both arms, External/community factors on intervention access, System/policy factors on intervention infrastructure/sustainability)
- Perceived impact *on implementation outcomes* (RE-AIM: reach, effectiveness, adoption, implementation/ ability of staff to deliver intervention successfully, and maintenance,)
- Perceived impact on *primary and secondary clinical outcomes* (MOUD, VL suppression, PrEP use)

IS data, relevant to a particular adaptation, will be reviewed again 3-, 6-, and 9- months post adaptation to document the presence (or absence) of observed data to qualitatively corroborate, clarify, or correct the impact of the adaptation on the conduct of the study and ability to achieve primary and secondary study outcomes with fidelity.

Deliverables: Results from this process will be used to (i) develop evidence-based guidance for policy makers and public health officials on the uptake and implementation of integrated health services using peer navigation and mobile health units in urban US regions to address HIV in PWID (implementation objective 6c), and (ii) help to identify factors that enhance or imped the delivery of integrated health services using a mobile unit, supported by peer navigation, on primary and secondary outcomes (implementation objective 6d).

Table 1. Stirman Framework Classification and Coding Protocol

8-Step Classification Structure	Applicable Codes*
1. When and how in implementation process was adaptation made	When: *Pre-implementation/planning/pilot, Implementation, Scale up, Maintenance/sustainment* How: *bottom-up* (e.g., field staff to supervisor), *top-down* (e.g. protocol chair to site-PI)
2. Was adaptation planned/proactive or unplanned/reactive	*planned/proactive* (to prevent anticipated challenges) *unplanned/reactive* (in response to unanticipated challenges)

3. Who determined the adaptation should be made	• Decision Maker: • Participants in the decision process: For example, *Political leaders, program leader, funder, administrator, program manager, intervention developer/purveyor, researcher, treatment/intervention team, individual practitioners* (clinicians or peer navigators), *community members, recipients* (PWID)
4. What was adapted	*Content* (adaptations made to intervention content itself, or that impacts how aspects of the treatment are delivered [intervention procedures, materials, delivery modality]) *Contextual* (adaptations made to the way the overall treatment is delivered to a new setting or population [format, setting, personnel, population]) *Training* (adaptations made to the way staff are trained in the protocol) *Evaluation* (adaptations to the way the intervention is evaluated) *Implementation & scale up activities* (adaptations to the strategies used to implement or spread the intervention)
5. At what level was the adaptation made	For whom/what is the content/training/evaluation/implementation adaption made? *Individual recipient, Target intervention group, Cohort/individuals that share a particular characteristic, Individual practitioner, Clinic/unit level, Hospital/Organization, Network system/community* Contextual adaptations were made to which target? *Format, Setting, Personnel, Population*
6. Type or nature of context or content-level of the adaptation	*Tailoring/tweaking/refining* *Adding/removing/skipping elements* *Shortening/condensing* (pacing/timing) *Lengthening/extending* (pacing/timing) *Substituting* *Reordering of intervention modules or segments* *Spreading* (breaking up session content over multiple sessions) *Integrating parts of the intervention into another framework* *Integrating another treatment into EBP* (not using the whole protocol and integrating other techniques into a general EBP approach) *Repeating elements or modules* *Loosening structure* *Departing from the intervention* ("drift") followed by a return to protocol within the encounter *Drift from protocol without returning*
7. Extent to which the adaptation is fidelity consistent	*Fidelity consistent* (core elements or functions preserved) *Fidelity inconsistent* (core elements or functions changed) *Unknown*
8. Reasons for the adaptation:	Typically the intent/goal of the adaptation will align with implementation outcomes (RE-AIM) and the contextual influences will align with implementation determinants (PRISM).
a. intent/goal of the adaptation	For example, *Increase reach or engagement, Increase retention, Improve feasibility, Improve fit with recipients (PWID), To address cultural factors, Improve effectiveness/outcomes, Reduce cost, Increase satisfaction*
b. contextual influences that influenced the decision	Sociopolitical: *existing laws, mandates, policies, regulations, political climate, funding policies, historical context, societal/cultural norms, funding or resource allocation/availability* Organization/setting: *available resources, competing demands or mandates, time constraints, service structure, location/accessibility, regulatory/compliance, billing constraints, social context, mission, cultural or religious norms*

	Provider (Clinician, Peer Navigator): *race, ethnicity, sexual/gender identity, first/spoken languages, previous training and skills, preferences, clinical judgment, cultural norms, competency, perception of intervention* Recipient (PWID): *race/ethnicity, gender identity, sexual orientation, access to resources, cognitive capacity, physical capacity, literacy and education level, first/spoken languages, legal status, cultural or religious norms, comorbidity/multimorbidity, immigration status, crisis or emergent circumstances, motivation and readiness*
* Codes are italicized	

Wiltsey Stirman, S., Baumann, A.A. & Miller, C.J. (2019) The FRAME: an expanded framework for reporting adaptations and modifications to evidence-based interventions. *Implementation Sci* **14,** 58. https://doi.org/10.1186/s13012-019-0898-y

Rabin BA, McCreight M, Battaglia C, Ayele R, Burke RE, Hess PL, Frank JW and Glasgow RE (2018) Systematic, Multimethod Assessment of Adaptations Across Four Diverse Health Systems Interventions. *Front. Public Health* 6:102. doi: 10.3389/fpubh.2018.00102

APPENDIX B: Analysis of Qualitative In-depth Interviews

Analysis Protocol of Qualitative In-Depth Interviews

Overview. Our qualitative in-depth interview (IDIs) sampling framework was developed to capture salient themes at the site-level with the capacity of scale across five sites to contextualize implementation experiences – at multiple levels - that could affect the implementation of integrated services on observed outcomes and guide the uptake and implementation of integrated services in other regions in the U.S. to underserved groups.

Analysis of the implementation science IDIs will be coordinated through weekly meetings by the implementation science PI with the support of the qualitative PI, to facilitate an iterative process.

Prior to the conduct of these interviews, meetings will ensure that the IS objectives and process are integrated into the training of qualitative field staff and that interview guides are adapted as needed to explore the process and impact of any adaptations made to the intervention protocol in both study arms.

Weekly meetings will continue, with qualitative field staff, as interviews are being collected to facilitate iterative probing and development of emergent implementation science concepts in subsequent interviews. Interviewer field notes will be used to help facilitate these discussions. Emergent concepts will inform the structure of an initial open coding structure for analysis and will be used to monitor for saturation of response.

The qualitative analysis team will first read transcripts multiple times to get familiar with the data, developing memos on important observations, patterns, and contexts. Observations will be discussed in relation to our implementation science objectives at weekly meetings and used to further refine the codebook. Topical analysis will identify common themes emerging to our key research questions attending to patterns and connections that emerge across participant responses. Interpretive analysis will explore the intervention implementation facilitators and barriers from the perspective of the patient (PWID), mobile unit providers delivering the intervention (clinicians, peer navigators, staff), and the community (stakeholders involved in the delivery of stand-alone brick and mortar services to PWID). Across these multi-level experiences, analysis will explore:

- ***Patient-level.*** Responses related to site-level external environments and to compare regional variation in these experiences between sites for diverse underserved groups (i.e., gender, race/ethnicity, HIV status) on recruitment, retention, and delivery of services in both arms (including the impact of COVID-related challenges).
- ***Provider-level.*** Responses related to the services delivery environment for each personnel type, facilitators and challenges to implement integrated care across sites, and compare regional variation in experiences delivering services (as a team) between sites.
- ***Community-level.*** Responses reflecting front-line service providers and management-level staff who can speak to the system-level infrastructure of local service delivery (HIV, MOUD, harm reduction, primary care, public health officials) to compare experiences serving PWID for each service type (across sites) and compare regional variation in experiences serving PWID within the local service landscape between sites.

Unanticipated and emergent themes specific to individual sites or subgroups will be documented and explored by the qualitative analysis team.

APPENDIX C: Methods to Document and Recruit for Qualitative In-depth Interviews

Methods and Criteria for Recruitment of In-depth Interviews

Sampling Framework for recruitment of IDI participants:

PWID	Mobile Unit Providers	Community Stakeholders
n = 17 per site (85 total)	n=7 per site (35 total)	n=15 per site (75 total)
Overall, the total PWID sample per site should aim for: • 25-30% female PWID • 25-30% non-Hispanic white PWID • 70-15% PWID of color (25-30% non-Hispanic Black and 25-30% Latinx)) • 25-30% PWID living with HIV	Each site will interview: • Clinicians n=2 • Peer navigators n=3 • Staff involved in recruitment and retention activities n=2	Overall, stakeholders at each stie should reflect front-line service providers (50-60%) and management-level staff (40-50%) who can speak to the system-level infrastructure of local service delivery. Stakeholders should reflect the following service types: HIV n=3, MOUD n=3, harm reduction n=3, primary care n=3, public health officials n=3
Qualitative field staff should work with the mobile unit staff responsible for recruitment activities to identify potentially eligible PWID and dates of upcoming study visits. Potentially eligible PWID will be approached by recruitment staff and if interested, recruitment staff will coordinate an introduction to the qualitative field staff. Qualitative field staff will be responsible for individual recruitment, ensuring the decision to participate is voluntary and confidential.	Site PIs will work with the qualitative PI to identify all eligible providers and mobile unit staff. The qualitative PI will coordinate with qualitative field staff to recruit eligible providers and mobile unit staff, ensuring the decision to participate is voluntary and confidential.	Specific stakeholders will be identified through the landscape analysis in the pre-implementation phase and through collaborative discussion with site-specific CABS. CAB members or other site staff may introduce qualitative field staff to potential stakeholders. Qualitative field staff will be responsible for individual recruitment, ensuring the decision to participate is voluntary and confidential.

Documenting recruitment efforts. Qualitative field staff will be responsible for documenting the number and type of individual (PWID, mobile unit providers, community stakeholders) approached for IDI recruitment and the outcome of the recruitment encounter (agreement to participate, declined participation, other [specify]). Recruitment status will be documented during weekly qualitative team meetings by the qualitative PI and submitted to the implementation evaluation team monthly.

APPENDIX D: Interview Guides

HPTN 094 Interview Guides

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 thoughts and experiences [*providing/accessing*] healthcare services, medications for opioid dependence, and medications to treat or prevent HIV in this community. We hope to understand barriers and facilitators for clients, particularly people who inject drugs, to get HIV tests and to access and adhere to these medications. Your input will help us improve programs and services for people who inject drugs in the community.

Anything that you say to me will be kept confidential. Our conversation is audio recorded and then transcribed. This means what we discuss will be written out, and 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 ID 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 find the 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

Community Stakeholder Interview Guide

Objective: *This discussion aims to better understand factors that could influence the coordination and future sustainability of mobile units delivering integrated healthcare and peer navigation within the local community and healthcare services landscape.*

Semi-structured Interview:

Please state the date, location (city), participant ID, and interviewer ID at the start of the interview

1. To start, please tell me about your role in the community.

Probe: history/experience serving PWID, how they fit within the local MOUD/HIV service landscape

Probe: what does a typical day look like

2. What are the main barriers and facilitators for PWID to access services in the community?

Probe: healthcare services related to MOUD, HIV, STI, Hepatitis, and harm reduction

Probe: reputation/competency/accessibility of service providers in the community

Probe: community norms/attitudes and enforcement of laws/policies toward PWID in the community

3. How does the delivery of integrated services in a mobile unit, supported by peer navigation, affect the service landscape in the community?

Probe: funding, policies, and infrastructure factors related to siloed vs. integrated service delivery

Probe: perceived benefits/challenges/needs of maintaining integrated service delivery via mobile unit

Probe: perceived benefits/challenges/needs of maintaining peer navigation

4. How has COVID-19 affected PWID and access to services in the community?

Probe: short- and long-term impact of COVID on substance use and HIV related health outcomes

Probe: short- and long-term impact of COVID on staff/providers, funding and other resources

Probe: what was and what else could have been done to support how the community managed COVID-19

5. Site-specific Queries: *** to be determined with site PI ***

Mobile Unit Staff Interview Guide

Objectives: *This discussion aims to better understand factors that affect the delivery and sustainability of INTEGRA study mobile units delivering integrated healthcare and peer navigation in the community, and how this healthcare delivery model fits within the existing service landscape for people who inject drugs.*

Interview:

Please state the date, location (city), participant ID, and interviewer ID at the start of the interview

1. **To start, please tell me about your role in the INTEGRA study.**

Probe: history/experience serving PWID, how their role supports the delivery of MOUD/HIV services

Probe: what does a typical day look like

2. **What are the main barriers and facilitators to engaging PWID in INTEGRA study services?**

Probe: [are we asking "What are the barriers and facilitators to providing"]healthcare services related to MOUD, HIV, STI, Hepatitis, and harm reduction (in both arms) ["both from the van and in the community at large?]

Probe: ability to reach diverse PWID in the study and initiate/maintain them in MOUD/HIV services[both in the van and out of the van?]

Probe: experiences connecting PWID to similar services in the local community (in both arms)

3. **What affects how you deliver INTEGRA study services in the community?**

Probe: staffing, space, and community factors that help or make it harder to deliver services

Probe: perceived benefits/challenges/needs to maintain integrated service delivery via mobile unit

Probe: perceived benefits/challenges/needs to maintain peer navigation

4. **How has COVID-19 affected how you access services in the community?**

Probe: short- and long-term impact of COVID on substance use and HIV related health outcomes

Probe: short- and long-term impact of COVID on staff/providers, funding and other resources

Probe: what else could have been done to support how INTEGRA services managed COVID-19

5. **Site-specific Queries:** *** to be determined with site PI ***

Client Interview Guide

Objective: *This discussion aims to better understand factors that affect access, initiation, and adherence to substance use and HIV services among people who inject drugs, including experiences with the INTEGRA study mobile units integrated healthcare and peer navigation services in the community.*

Interview:

Please state the date, location (city), participant ID, and interviewer ID at the start of the interview

1. **To start, please tell me about your experiences in this community as someone who injects drugs**

Probe: history injecting drugs, experiences accessing/using local MOUD/HIV services

Probe: what does a typical day look like

2. **What are the main barriers and facilitators to accessing services in the community before this study?**

Probe: healthcare services related to MOUD, HIV, STI, Hepatitis, and harm reduction

Probe: reputation/competency/willingness to use service providers in the community

Probe: community norms/attitudes and enforcement of laws/policies that affect service access

3. **What are your experiences with using INTEGRA study services?**

Probe: use/declined services related to MOUD, HIV, STI, Hepatitis, and harm reduction, peer navigation

Probe: what makes it harder/easier to access INTEGRA study services compared to existing services

Probe: what do you like/dislike about using healthcare and peer navigation services in a mobile unit

Probe: benefits/challenges/needs to start services in a mobile unit then transition to existing services

4. **How has COVID-19 affected how you deliver INTEGRA study services in the community?**

Probe: short- and long-term impact of COVID on substance use and HIV related health outcomes

Probe: short- and long-term impact of COVID on access to healthcare services and other resources

Probe: what else could have been done to support your access and use of services during COVID-19

5. **Site-specific Queries:** *** to be determined with site PI ***

APPENDIX E: Interview Materials Checklist

Materials Checklist

1. Participant Informed Consent Form (2 copies per interview)
2. Interview guide
3. Participant demographic coversheet
4. Digital recorder
5. Back-up digital recorder
6. Extra batteries for digital recorders
7. Pad of paper and a pen
8. Water for participants
9. ** Additional items to be added, per site **
10. ** Additional items to be added for COVID-19 precautions **

APPENDIX F: Interview Participant Demographic Cover Sheet

Participant Demographic Cover Sheet

Data Collection

PID: _____ Date of Interview: _____ Interviewer ID:_____

Participant Demographics

1. Gender (circle one):

   Cisgender man Cisgender woman Transgender man Transgender woman Nonbinary

1. Age: ____ years

2. Education (select one): _____ 1-5 years (Primary schooling)

   _____ 6-9 years (Secondary schooling)

   _____ 10-12 years (High schooling)

   _____ 13-16 years (University/College)

   _____ 17-23 years (Higher education, Master/Doctor/PhD)

Role and Context

4. City, Recruitment Neighborhood or Clinic _____

5. Services Provided or Received *(Mark all that apply)*

   ____ MOUD ____ART ____ PrEP ____ Navigation ____Other, Specify _____

6. Role (Consumer, Provider, Other - Specify): _____

7. Years in that role: _____ years

APPENDIX G: Interview Field Summary Forms

Interview Field Summary Forms

Purpose: *To help the research team identify and share intervention successes and challenges in real time. These forms will be shared with the implementation evaluation team and site PI, and relevant themes may be shared across HPTN 094 sites, with the ultimate goal of improving the implementation and process of the HPTN094 intervention.*

INTERVIEW INFORMATION

Date of summary: _____ Date of Interview: _____

Participant ID: _____ Interviewer ID: _____

Participant role (Consumer, Provider, Other - Specify): _____

Interview location (city, recruitment neighborhood): _____

SUCCESSFUL STRATEGIES *Briefly document factors helping providers deliver/PWID access substance use and HIV related services in the local community. Include factors related to how stakeholders/providers/clients view:*	**BRIEF SUMMARY** *Put n/a if prompt not applicable, do not leave blank*
• *INTEGRA study services (mobile integrated healthcare, peer navigation)*	
• *INTEGRA staff, mobile unit space/resources, van location, community interactions*	
• *Community attitudes/norms toward PWID and INTEGRA, substance use, and HIV services*	
• *Proximity to and reputation of existing substance use and HIV service providers*	
• *Enforcement of laws/policies, available funding/resources on service access*	
• *Differences in perceptions/use of services by service type or sociodemographic subgroups*	
• *Other observations*	
AREAS FOR IMPROVEMENT	**BRIEF SUMMARY**

Briefly document factors impeding how providers deliver/PWID access substance use and HIV related services in the local community. Include factors related to how stakeholders/providers/clients view:	*Put n/a if prompt not applicable, do not leave blank*
• *INTEGRA study services (mobile integrated healthcare, peer navigation)*	
• *INTEGRA staff, mobile unit space/resources, van location, community interactions*	
• *Community attitudes/norms toward PWID and INTEGRA, substance use, and HIV services*	
• *Proximity to and reputation of existing substance use and HIV service providers*	
• *Enforcement of laws/policies, available funding/resources on service access*	
• *Differences in perceptions/use of services by service type or sociodemographic subgroups*	
• *Other observations*	

APPENDIX H: Landscape Analysis Survey

Landscape Analysis: Survey

Objective: to document objective criteria for selecting potential sites for INTEGRA mobile unit services and recruitment.

Instructions: Please review the HPTN Implementation Science Manual, Section 6. 1 Landscape Analysis to help you compile your responses prior to entering the data in the Qualtrics link provided to your site. You will be asked to complete at least one landscape analysis prior to site implementation.

BEGIN SURVEY:

1. **Study Site:**
[select from menu of 5 study sites]

2. **Date completed**:
MM/DD/YYY _____

3. **How many neighborhoods were considered as potential study site locations in your landscape analysis?**
Number of neighborhoods:_____

4. **Number**
Auto populate number of fields based on response to Q3:

Neighborhood Name	Zip Code(s)	Number of potential van locations in neighborhood
1.		
2.		
3.		
n…		

5. **Can more than one neighborhood share the same van location as a recruitment site?**
( ) No
( ) Yes → If yes, then specify which neighborhoods from Q4 list

INSTRUCTIONS: Please use Google Maps to generate the following information prior to completing this section of the survey.

6. **Please generate and upload a map that documents each of the proposed neighborhoods (i.e. zip codes) that contain potential recruitment sites in your city.** Please label each neighborhood in the map using the name you gave it in Q3.

    a. Please paste a link to your map below

b. Please document the proximity (in total miles, and total minutes travel time) of each neighborhood to the location where the study van will be stored overnight

Neighborhood Name	Total driving distance in miles (one way)	Total driving time in minutes (one way)
1.		
2.		
3.		
n…		

NEIGHBORHOOD-SPECIFIC SURVEY RESPONES

Instructions: Next, we will ask you specific questions for each of the neighborhoods you have identified as containing potential recruitment sites. These questions will help us to characterize the scope of the HIV and opioid epidemics in potential settings where the van could be located. If you are unable to use neighborhood (i.e., zip code) – specific data for any of your responses, please provide an explanation of how the data are aggregated and should be interpreted in the comments section for each study site.

***Note** the following questions (e.g. Q7-18) will be repeated for each neighborhood listed in Q4.*

Please see **Appendix J** for guidelines on discussions with community stakeholder to contextualize responses to the landscape analysis survey.

NEIGHBORHOOD 1: [populate neighborhood name]

7. Neighborhood population size:
   _____ people

8. In this neighborhood, what proportion (i.e. %) of the population in this neighborhood is:
   a. Latino or Hispanic _____
   b. Non-Hispanic Black or African American _____
   c. Non-Hispanic white _____
   d. Living at or below the federal poverty level _____

9. Neighborhood-level HIV prevalence _____,month and year [MM-YYYY] reported _____

10. Neighborhood-level HIV incidence _____, month and year [MM-YYYY] reported _____

11. Overdose deaths per 100,000 people, _____, month and year [MM-YYYY] reported _____

12. Drug-related arrests per 100,000 people _____, month and year [MM-YYYY] reported _____

13. NEIGHBORHOOD 1: Summary of this neighborhood's overall potential for helping the site reach the target population relative to other potential neighborhoods

14. NEIGHBORHOOD 1: Summary of typical attitudes towards PWID and services for PWID in this neighborhood

15. NEIGHBORHOOD 1: Summary of laws and policies, how they are enforced/implemented, and other structural factors that affect HIV prevention, harm reduction, and MOUD delivery in this neighborhood

16. NEIGHBORHOOD 1: Summary of COVID-19's impact on the HIV/opioid epidemics and related services in this neighborhood.

17. NEGHBORHOOD 1: Summary of how any permissions or community buy-in was obtained to identify areas to park the study van within this neighborhood

18. NEIGHBORHOOD 1: Other Comments (including clarification on data sources):

INSTRUCTIONS: Please use Google Maps to generate the following information for this neighborhood prior to completing this section of the survey.

Please ensure the Google Map link you provided in Q6a documents responses to Q19 and Q20 specific to this neighborhood.

Please see **Appendix I** for instructions on how to generate this map for your site

Please generate and upload a link to your study site map that documents:

19. For NEIGHBORHOOD 1, please document:

    a. Boundaries (north, east, south, west) of the neighborhood on the map that sets boundaries at major intersections, cross streets, or other notable land marks.

    b. Document location(s) within the neighborhood potential van locations by dropping a pin and labeling the pins in sequential order as, VAN Site 1, Van Site 2, etc. Make sure the total number of potential van sites documented match your response in Q3.

20. For NEIGHBORHOOD 1, please document location(s) within or closest to the neighborhood where the following resources and services can be accessed:

    a. Emergency rooms – Drop a pin and label in sequential order "ER #"

    b. Non-emergency, primary care clinics – Drop a pin and label in sequential order "Primary Care #"

    c. HIV care (where ART can be accessed) – Drop a pin and label in sequential order "ART care #"

    d. HIV care (where PrEP can be accessed) – Drop a pin and label in sequential order "PrEP care #"

    e. MOUD care (where buprenorphine or methadone can be accessed) – Drop a pin and label in sequential order "MOUD care #"

    f. Syringe service programs (where new syringes can be accessed including pharmacies) – Drop a pin and label in sequential order "SSP services #"

    g. Overdose prevention distribution (where naloxone can be accessed) – Drop a pin and label in sequential order "Narcan #"

    h. Jails and prisons (including immigration detention centers) – Drop a pin and label in sequential order "Jail #"

21. NEIGHBORHOOD 1: Review the map with stakeholders, and summarize the local service agencies or providers with reputations for delivering culturally competent care to PWID in this neighborhood.

22. NEIGHBORHOOD 1: Review the map with stakeholders, and summarize how the local service agencies have been impacted by COVID-19

SURVEY END:

23. Based on the data and community stakeholder feedback you have provided; rank order the recruitment neighborhoods from Q3 from best (lowest value =1) to worst (highest value) for each of the following implementation domains:

    a. Availability of brick and mortar HIV services

    b. Potential to deliver culturally competent HIV services to PWID

    c. Availability of brick and mortar MOUD services

    d. Potential to deliver culturally competent MOUD services to PWID

    e. HIV and MOUD services that are co-located or within close proximity to each other

    f. Potential to reach underrepresented PWID (i.e. PWID who are younger, women, racial/ethnic minorities)

    g. Enforcement of laws/policies that may assist PWID in accessing services

24. Please upload your site-specific reference list of primary data and resources that were used to complete the landscape analysis. Please use the template provided below, format citations in AMA citation style, and include any links to these data sources and dates these data were accessed. Please upload a copy of this reference list and retain a local copy of all data and resources used in this landscape analysis.

AMA Citation of data source	Date Accessed	Link to data source

APPENDIX I: Landscape Analysis Map Instructions

Landscape Analysis: Map Instructions

How to Create a Map for HPTN 094 Landscape Analysis

Getting Started

1. Before starting, create a site-specific Gmail account that you can use to save the maps you create to. Please share this log-in information with the site-PI so that the map can be accessed and edited as needed
2. Once you have logged in to your site-specific Gmail account, go to maps.google.com
3. Click on the information bar on the left (looks like three parallel lines) and go to "Your Places" on the menu
4. In "Your Places" click on "MAPS"
5. At the bottom, click "CREATE MAP"
6. Label this map as HPTN 094-"your city. An **example map** has been created, and can be accessed through the link at the bottom of this document. In this example, the map is labeled HPTN 094-San Diego.

Adding Neighborhoods

7. Click "Add layer" and label this Neighborhood 1 – "Neighborhood name", using the neighborhood name you used in your landscape analysis. **Each neighborhood will be a new layer.** In the San Diego example map provided in the link below, we have labeled our neighborhoods with their local names, respectively: Neighborhood 1 – Gaslamp, Neighborhood 2 – North Park, and Neighborhood 3 – South Bay
8. Refer to **Table 1**: Color Coding for Map (below) to correctly color code each required part of the map.
9. **To create boundary:** Click on the "Draw a Line" icon. Then, click "add line or shape." This will allow you to draw a square/shape around the boundary of the neighborhood that you are working on. Once you have completed the boundary, label it as "Neighborhood 1 Boundary." Complete this for each neighborhood.
    a. The boundary will give the information on how large your neighborhood is and how many miles it encompasses.
    b. Guidance on how to define a neighborhood's boundaries should be informed by each sites' local HIV, overdose, and drug arrest data ***and*** input from local community stakeholders.

Documenting Locations and Resources

10. **To create Van Sites:** Click the pin icon near the search bar. Find the place that you want to have your van and drop the pin. Label this pin as Van Site 1. Do this for the other van sites that you suggested and label them accordingly (Van Site 2, Van Site 3, etc.).
    a. The process of identifying potential van sites within a neighborhood should also be informed via additional input from local community stakeholders (see **Appendix J**).

11. **To add resources to map:** It will be simplest to find the services and to save them to your map. To do this, find the place you are looking for and when the pin comes up, click it. A square will pop up showing the information of the place and at the bottom you will see "+ Add to map." Click this and it will add to the map you are working on.

    a. The process of identifying resources should also be informed via additional input from local community stakeholders (see **Appendix J**).

12. **Label the resources:** Once the resources have been added to the map, press the edit button, which looks like a pencil, and label it (e.g., MOUD #1, Jail #1).

    a. Some resources may provide more than one service. In this case, label all the services within it, while numbering each one and labeling what number it is. For example, a resource may be MOUD #1 and HIV ART #2 if an HIV ART service for that neighborhood was already documented.

Calculating Travel Times

13. **To obtain travel distances and times via directions:** Click one of the places that you have added to your map. Click "add directions" and this will create another layer. You will be able to add whichever destination you have saved to your maps.

    For example, if you are starting where the van is parked, you can type in Van Site 1 and it will pop up with all the places you have labeled as Van Site 1 and show you which neighborhood it belongs to. Click which site you want to go to and then the directions will be created. You can add destinations on to this to calculate additional directions (travel distances and times) as needed.

Sharing and Editing Maps

14. **To share your map:** Click the "+Share" button and it will provide a link that you can copy and paste to email. You can also share it through the drive and put in an email address.

15. **To make map editable by others:** Click the "+Share" button and then click on "Drive sharing." In the box that is titled "Get link" click "Change." You will see "Anyone with the link" and to the right there is a drop-down menu to pick "Editor" or "Viewer." Click on "Editor" to enable others with the link to be able to edit the map.

Link to example map for San Diego, CA:
https://www.google.com/maps/d/edit?mid=11CvnGMFx2Js0AevCR7DWHnnVH1_yGfr3&usp=sharing

Table 1: Color Coding for Map

Resource/Service/Location	Color	Color Code in Google Maps
Parking Location (home base)	Blue (default color)	RGB (2, 136, 209)
Van Sites (field locations)	Yellow	RGB (255, 234, 0)
Emergency Rooms/Jails/Prisons	Red	RGB (230, 81, 0)
Brick and Mortar Services: ***Non-emergency, primary care clinics/HIV care (ART and PrEP)/MOUD/Syringe Service Programs/Overdose Prevention Distribution***	Green	RGB (15, 157, 88)

Neighborhood Boundary	Black (default color)	RGB (0, 0, 0)

APPENDIX J: Landscape Analysis Conversations with Community Stakeholders

Landscape Analysis: Conversations with Community Stakeholders

Instructions: As you work to develop your Landscape Analysis Map and Survey responses for submission to the implementation science evaluation team, it will be helpful to interact with, and receive guidance from, local community stakeholders (including community advisory boards).

Below we provide some guidance on this process, but recognize that individual sites may already have more formal communication structures in place for liaising with community stakeholders.

Getting Started

1. Before meeting with local community stakeholders, it may be best to gather your local epidemiological data to identify (a) what neighborhoods are most likely affected by the HIV and opioid epidemics, including areas that may reflect 'emerging areas' where newer injection communities might be forming, and (b) generate an initial draft your Google Maps of these potential neighborhoods (with preliminary boundaries) that can be reviewed and revised in collaboration with stakeholders.
2. It may also be helpful to have an idea of what services and resources are closest to each potential neighborhood (see section 6).

Conversations on Neighborhood Selection

3. Share your Google Map of potential neighborhoods you are considering for study recruitment and service delivery. Discuss with stakeholders how well positioned each area is to help your team reach the target population or to provide services to the target population and why.
4. Explore whether there are any areas you may have overlooked that were not well represented by local epidemiological data.
    a. This could include areas where overdose rates are hovering just under the radar, places where overdoses are going unreported/underreported.
    b. This could also include places outside well-known injection communities where PWID or PWLH congregate more often for a sense of community or safety.
5. Comparing neighborhoods, ask community stakeholders to reflect on what areas might have:
    a. Better reach into the target population, have poorer access to stand-alone HIV, MOUD, Harm Reduction services.
    b. Areas where there may be more social conflict or harassment from the community or law enforcement that could make recruitment or delivering services more challenging.
6. Explore environmental contexts and social norms that might affect recruitment and delivery of services in each neighborhood:
    a. What areas within each neighborhood would be good to recruit participants or deliver services, and what areas would be less suitable?

b. How are community members and local businesses likely to react to the study/study van being located in the neighborhood, and who are important opinion leaders site staff should try to engage with?

Conversations to Define Neighborhood Boundaries and Van Sites

7. Explore with community stakeholders what cross-streets, intersections, or other 'markers' would best define the boundaries for a given neighborhood and adjust your Google Map boundaries as needed.

8. Within each neighborhood, explore areas that would be good for locating the HPTN 094 study team for recruitment, including areas where the mobile unit can be parked and accessed by PWID.

    a. Explore the proximity of these potential van sites and their proximity to other organizations such as schools, churches, hospitals/urgent care, police precincts or immigration enforcement that could affect community support or study recruitment.

Conversations Exploring Neighborhood Proximity of Services and Resources

9. Share with community stakeholders the kinds of services this study will be linking PWID to through peer navigation (in both study arms). This includes MOUD care, HIV prevention and treatment services (i.e. PrEP care, ART), harm reduction services (including syringe service programs and overdose prevention programs).

    a. Share what services you have located so far, and explore if there are any you are missing or need to revise.

    b. Related to cultural competency for serving PWID, explore what kind of reputation local HIV/MOUD/Harm Reduction services providers in the area might have among PWID? Among their fellow service providers?

    c. Are some services more accepted (or avoided) by certain groups (e.g. women, people of color, young adults) than others? What about these services set them apart?

10. Explore the proximity of potential neighborhoods to other services and organizations that can affect the health and safety of PWID. This includes locations of local hospitals/emergency rooms, primary care clinics where PWID can access services, and law/immigration enforcement offices and detention sites.

    a. Share which of these services/organizations you have located so far, and explore if there are any you are missing or need to revise.

    b. Related to cultural competency for serving PWID, explore what kind of reputation these local services/organizations the area might have among PWID? Among their fellow service providers?

    c. Are some services/organizations more accepted (or avoided) by certain groups (e.g. women, people of color, young adults) than others? What about these services set them apart?

Conversations Documenting the Impact of COVID-19 on the Local Services Landscape

11. Explore how COVID-19 has affected the local service landscape with community stakeholders.

    a. Discus how COVID-19 has affected the local HIV and opioid epidemics. Have specific neighborhoods been more impacted than others? (Such as increased overdoses, decreased access in care, less participation in care)

    b. How has COVID-19 affected access to or use of HIV, MOUD, and Harm Reduction services among PWID? Has COVID-19 affected the real or perceived need for these services among PWID?

    c. Has COVID-19 affected local infrastructure for delivering HIV, MOUD, and Harm Reduction services (e.g. staffing needs, funding resources, impacted the implementation of HIV and MOUD/substance use care?

    d. What other health and social impacts has COVID-19 had on PWID and local service agencies? Explore potential for both unintended positive and negative effects (e.g., increased access to telehealth or failure to recognize front line harm reduction staff as essential workers).