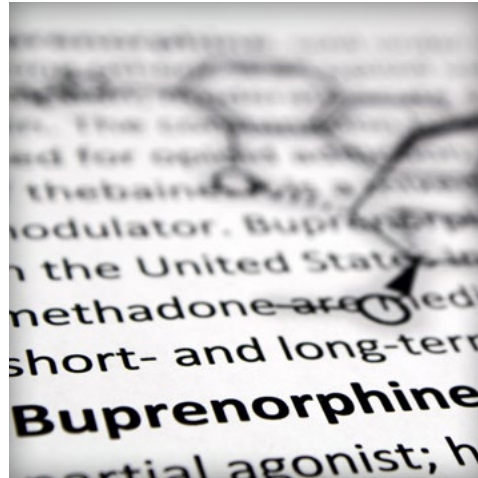
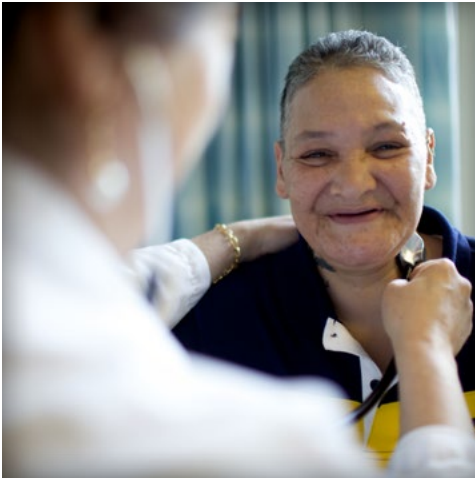
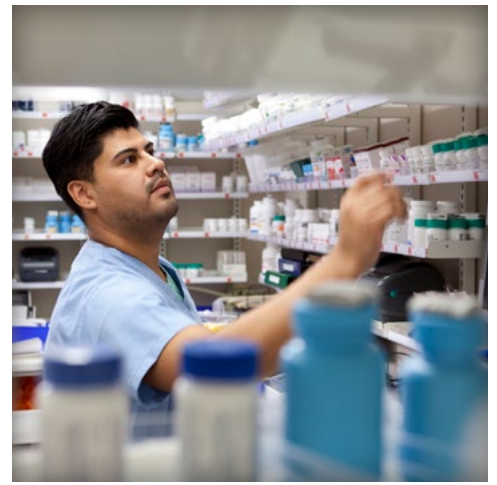


EVALUATION PROTOCOLS



Integrating Buprenorphine Treatment for Opioid Use Disorder in HIV Primary Care

DISSEMINATION OF
**EVIDENCE-
INFORMED.**
INTERVENTIONS



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This report was supported by the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services (HHS) as part of an award totaling \$500,000 with no percentage financed with non-governmental sources. The contents of this document are those of the authors and do not necessarily represent the official views of nor an endorsement, by HRSA, HHS or the U.S. government.

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Background

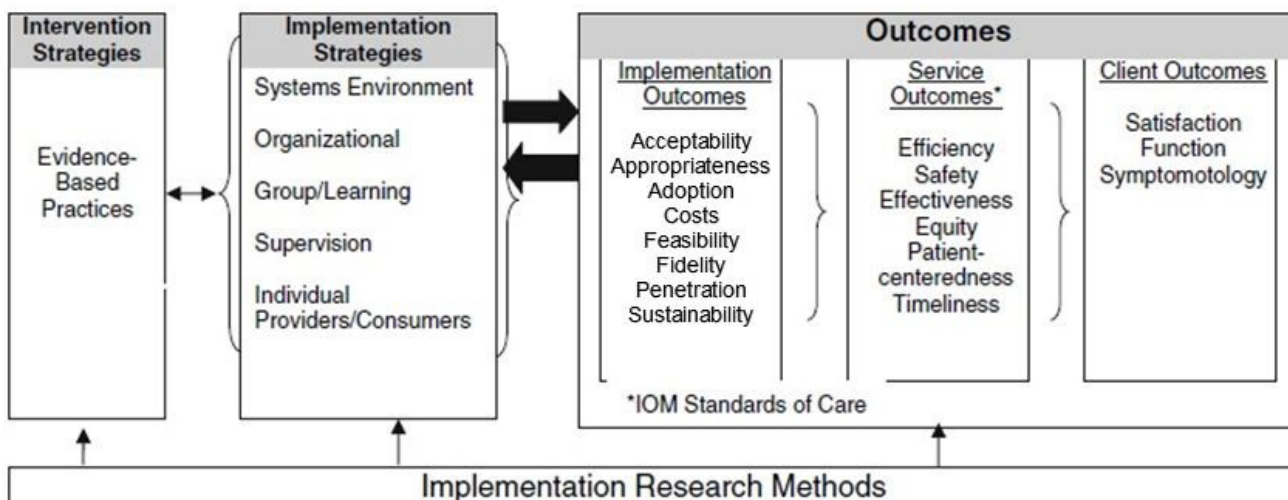
In 2015, the U.S. Department of Health and Human Services, Health Resources and Services Administration, HIV/AIDS Bureau, Special Projects of National Significance (HRSA SPNS) funded the Dissemination of Evidence-Informed Interventions (DEII) initiative to study the implementation of four interventions that had previously demonstrated effectiveness in improving linkage to and retention in HIV primary care. DEII established an Implementation Technical Assistance Team (or ITAC, directed by AIDS United) and a Dissemination and Evaluation Center (or DEC, directed by Boston University and Abt Associates). The ITAC funded 12 sites to replicate the four previously implemented interventions. Detailed information about the DEII intervention can be found on Target HIV (<https://targethiv.org/deii>).



This document serves as a compendium of data collection tools for the multi-site implementation and outcome evaluation. Implementation and outcome data was used to inform the development and production of four evidence-informed **Care And Treatment Interventions (CATIs)** that are replicable, capable of producing optimal HIV Care Continuum outcomes, and easily adaptable to the changing healthcare environment.

DEII Evaluation Design

The DEII DEC evaluated the implementation of the Integrating Buprenorphine Treatment for Opioid Use Disorder in HIV Primary Care intervention. As part of this evaluation, the DEC examined implementation, service, and patient-level outcomes. Implementation outcomes (further discussed below) are related to implementation barriers and facilitators, ability to be faithful to the proposed implementation model and activities, feasibility of implementation, and long-term integration of intervention activities into the standard of care. Service outcomes are related to the way in which services are provided to each client (i.e., appropriate and timely care to each patient). Patient-level outcomes are related to improvements in client health and client satisfaction. The Proctor Model of Implementation Research (Proctor et al., 2009)¹ is uniquely designed to measure both implementation and patient outcomes in a systematic way.



The Proctor Model, visually depicted above, posits that changes in outcomes are dependent not only on the evidence-based interventions implemented but on the strategies used to implement those interventions. The model provides ways to assess the intervention (evidence-based practice), different types of implementation strategies, and three levels

¹ Proctor, E. K., Landsverk, J., Aarons, G., Chambers, D., Glisson, C., & Mittman, B. (2009). Implementation research in mental health services: An emerging science with conceptual, methodological, and training challenges. *Administration and Policy in Mental Health and Mental Health Services Research*, 36(1), 1-17. doi: 10.1007/s10488-008-0197-4

of outcomes (implementation, service, and client). The implementation outcomes will measure the process of the particular strategies used to adopt the evidence-based practice, the service outcomes examine the impact of on patient care and safety outcomes, and the client outcomes assess outcomes specific to the client experience. Appropriate outcome measures used in each category (implementation, service, and client) depend upon the specific evidence-based practice (in this case, the intervention model) and local context.

Implementation Domain Definitions and Evaluation Questions

- 1) **Acceptability** –The perception among stakeholders (e.g. consumers, providers, managers, policy makers) that an intervention is agreeable.
 - a. To what degree are site providers, staff, and leadership willing and able to take on the full terms of the intervention?
- 2) **Appropriateness** – The perceived fit or relevance of the intervention in a particular setting or for a particular target audience (provider or consumer) or issue.
 - a. To what degree does the provider think the intervention is the appropriate intervention for the target population?
- 3) **Adoption** – The intention, initial decision, or action to try to employ a new intervention.
 - a. To what degree are providers and staff willing to implement the intervention by following the protocol outlined in the implementation plan?
- 4) **Cost** – The incremental cost of the delivery strategy (e.g. how the services are delivered in a particular setting). The total cost of the implementation would also include the cost of the intervention itself.
 - a. What does it cost to implement the intervention?
- 5) **Feasibility** – The extent to which an intervention can be carried out in a particular setting or organization.
 - a. What are the barriers and facilitators to effective implementation of the intervention?
- 6) **Fidelity** – The degree to which an intervention was implemented as it was designed in an original protocol, plan, or policy.
 - a. To what degree is the intervention being implemented as outlined in the implementation plan?
- 7) **Integration** – (For the purposes of this multi-site evaluation, the DEC has agreed to combine the domains of penetration and sustainability into one encompassing domain of integration.) Focusing on the degree to which an intervention is integrated and institutionalized in a service setting
 - a. To what degree do sites integrate the intervention into their other ongoing efforts to improve outcomes along the HIV Care Continuum?

Service Domain Definitions and Evaluation Questions

- 1) **Efficiency** – Avoiding waste, including waste of equipment, supplies, ideas, and energy, duplication of services, duplication of staff efforts
 - a. Does the intervention avoid duplication and alleviate burden?
- 2) **Safety** – Avoiding injuries to patients from the care that is intended to help them. Patient and provider safety (i.e. mental health safety)
 - a. What are the policies and procedures in place to protect patient and staff safety?
- 3) **Effectiveness** – Providing services based on scientific knowledge to all who could benefit, and refraining from providing services to those no likely to benefit
 - a. Does the site provide the intervention to the appropriate target audience?
- 4) **Equity** – Providing care that does not vary in quality because of personal characteristics such as gender, ethnicity, geographic location, and socioeconomic status
 - a. Does the site provide the intervention to all members of the target audience in the same way?
- 5) **Patient-centeredness** – Providing care that is respectful of and responsive to individual patient preferences, needs, and values, and ensuring that patient values guide all clinical decisions.
 - a. Do patients experience care in accordance with their needs and preferences?
- 6) **Timeliness** – Reducing waits and sometimes harmful delays for both those who receive and those who give care.

- a. Can patients access the intervention in a timely way; Is the intervention effective in getting patients into care and/or community-based services?

Client Domain Definitions and Evaluation Questions

- 1) **Satisfaction** – Extent to which patients were satisfied with the intervention
 - a. Were the clients satisfied with the intervention?
- 2) **Functioning** – Client quality of life and reduction of barriers
 - a. Does the intervention improve physical and mental health function?
- 3) **Symptoms** – Clinical data, linkage and retention as measured by patient appointments and gaps in care, viral load
 - a. Does the intervention lead to improvements in: linkage to and retention in HIV medical care, ART among persons in HIV medical care, viral load suppression among persons in HIV medical care, substance use or mental health service utilization.

The multisite evaluation protocol was approved by the Boston University Charles River Campus Institutional Review Board. The 12 participating demonstration sites across the four interventions also obtained local IRB approval to implement specific components of the multisite evaluation including the documentation of interventionist longitudinal outcomes survey and medical abstraction.

For the DEII initiative, all participants for each phase of the evaluation were recruited via convenience or purposeful sampling techniques. A pre-post study design was used to collect client outcome data. The DEII initiative did **not** include experimental interventions, and there were no control or comparison groups. All data (qualitative & quantitative) were originally submitted to the Boston University Biostatistics and Epidemiology Data Analytic Center and stored on secure, password protected servers. Qualitative data were transcribed and stored on a secured server for analysis.

Integrating Buprenorphine Treatment for Opioid Use Disorder in HIV Primary Care Eligibility Criteria

Persons 18 years or older who are living with HIV and opioid use disorder (as determined by DSM-V criteria):

Potential participants must:

- be eligible for primary care at the intervention site
- desire pharmacotherapy for their opioid use disorder
- be able and willing to comply with buprenorphine treatment program policies

Site and Initiative Staff Involved in Data Collection

Primary Prescriber: Buprenorphine prescribers are responsible for entering their activities into the patient medical record (later used for medical chart abstraction).

Clinical Coordinator: The Clinical Coordinator is responsible for initially introducing the evaluation, providing a warm handoff of the participant to the data manager, working with the data manager to conduct outreach for follow-up evaluation activities, and collecting data through the encounter form. More details on the role of the Clinical Coordinator are provided in the implementation manual (<https://targethiv.org/deii>).

Data Manager: The Data Manager is a team member who does not provide intervention treatment services. This person needs to have a background in data collection, management, and IRB applications, and have training in human subject research.

DEC team: The DEC was responsible for administering many of the implementation science tools during the DEII study. For future evaluation efforts, the DEC recommends identifying a team that is not responsible for or engaged in intervention implementation efforts to administer these tools (for example, a team addressing continuous quality improvement (CQI) within the clinic system).

Data Sources for Implementation Evaluation

Data Source	Brief Description	Relationship to Proctor Model Domains	Frequency of data collection	Collection method for DEII	Recommendations for future evaluations
Organizational Readiness to Change Assessment - ORCA	The scales were designed to assess organizational readiness to change in preparation for testing interventions designed to implement evidence-based changes in clinical practice. The scales are intended for diagnostic use, to identify needs or conditions that can be targeted by implementation activities or resources, and to provide a prognosis of the success of the change effort at the organizational level. (Helfrich, Li, Sharp, Sales 2009). The ORCA was administered to: Intervention staff, clinic team members, clinic leadership, and staff that interact with the target population (front desk staff, scheduling staff, nurses, counselors, case managers, etc.)	Implementation outcomes: acceptability, adoption, appropriateness, integration	One time pre-implementation.	The ORCA was completed online and submitted to the DEC through web-based data portal	Assign data collection responsibility to Data Manager or CQI team To best measure change over time and to make sure that intervention staff are on-boarded to the organization prior to administration, the ORCA should be completed up to 30 days prior to implementation kick-off, and then at a second time point for comparison (at least 1 year post full implementation). Alternatively, a pre-program assessment of strengths and opportunities could be implemented to assess readiness.
Initial-site visit report	Conducted with project staff and site leaders prior to implementation to determine training and technical assistance needs, staff readiness, willingness, and self-efficacy related to implementation.	Implementation outcomes: acceptability, adoption, appropriateness	One time during initial site visit.	Intervention team members completed the form and submitted it to the DEC. Typed notes were stored on a secure server and transferred to a	Assign data collection responsibility to Data Manager or CQI team Rename activity "Kick-off Meeting" and hold meeting

Data Source	Brief Description	Relationship to Proctor Model Domains	Frequency of data collection	Collection method for DEII	Recommendations for future evaluations
	<p>During the kick-off, intervention team members can review the following:</p> <ul style="list-style-type: none"> • MOU's (current and in process) • Staffing plan and job postings/announcements for vacant budgeted positions • Referral forms (Internal and External) • National HIV/AIDS and the Ending the Epidemic Strategies • Implementation Training Materials and any immediate training and TA needs • Internal opportunities for staff development and training • Existing and needed systems for data collection, and anticipated challenges with data collection and analysis 			<p>qualitative coding software (e.g. NVivo) for analysis.</p>	<p>prior to implementation. Suggested "Kick-off Meeting" data collection tool provided in appendix</p>
Encounter form	<p>Used to record each encounter with each individual client. The encounter form tracks the kind of interaction the interventionist had with the client (in person, through phone call etc.), the services provided to the client during the interaction, and how long the interaction lasted.</p>	<p>Implementation outcomes: feasibility, fidelity</p>	<p>The participant encounter form should be completed anytime the Peer conducts an activity with a participant either in person or on behalf of the participant. Only one participant</p>	<p>Clinical Coordinators completed the encounter form through a web-based data portal.</p>	<p>In the absence of a web-based data portal, Interventionists collect data through an online survey tool or Excel spreadsheet stored on a secure server. If possible, a form should be integrated into the clinics EMR</p>

Data Source	Brief Description	Relationship to Proctor Model Domains	Frequency of data collection	Collection method for DEII	Recommendations for future evaluations
			encounter form should be submitted per participant per day of services provided.		and staff can document activities in the EMR to share with other team members.
Monthly report form	Used gather general information about implementation process and issues, staffing, budgetary and evaluation progress. Forms track progress on project implementation; changes in staffing, key program elements, partners and resources; progress on multi-site evaluation (data collection, IRB updates, data entry, etc.); and integration throughout the organization (impact on programs and staff) outside of the intervention team members. Contextual tracking (policies, funding announcements, political climate, etc.) will be included in this monthly form.	Implementation outcomes: feasibility, fidelity, integration Service outcomes: Efficiency, safety	Monthly	Intervention team members completed the form and submitted it to the DEC. Typed notes were stored on a secure server and transferred to a qualitative coding software (e.g. NVivo) for analysis.	Assign and integrate as part of clinic's data collection responsibility to Data Manager or continuous quality improvement (CQI) team
Key informant qualitative interviews	Conducted with project staff and key partners to determine barriers and facilitators to implementation of the protocol; perceived efficacy in implementation; clinical, programmatic, and systemic outcomes; and progress towards long term integration of the intervention at the site. Key informant interviews happen at multiple levels of the intervention team and organizational	Implementation outcomes: feasibility, fidelity, integration Service outcomes: efficiency, safety, effectiveness, equity, patient-	1 time point in the final year of DEII funding.	The DEC team recorded the interviews over a conference line and then had the interviews transcribed for analysis. All audio-recordings of the semi-structured interviews were transcribed for analysis. The .mp3 files of recorded interviews were sent to a central, HIPAA compliant transcription agency. Word	Assign data collection responsibility to Data Manager or CQI team Select key informants that represent a diversity of opinions and experiences in implementation based on role (e.g., leadership, direct service provision,

Data Source	Brief Description	Relationship to Proctor Model Domains	Frequency of data collection	Collection method for DEII	Recommendations for future evaluations
	chart at the clinic (including key leadership and program staff)	centeredness, timeliness		files were developed from each audio file. No names of clients were recorded on the audio files. All proper names of persons, agencies, and locations were removed from the transcripts and substituted with codes to protect and ensure privacy and confidentiality of participants. After transcription audio recordings were destroyed once qualitative coding and analysis is complete.	administration) or tenure within the organization or implementation team. Conduct interviews on an annual basis to assess change over time.
Site visit report	The site visit report form will record staff group and individual feedback regarding implementation process, barriers, facilitators and situational inputs and variations impacting implementation. The DEC will also collect information on contextual factors related to integration, partnerships (client linkage to community resources, community resource capacity to meet the needs of clients in the intervention), and funding. Site visit report forms will also record any training or technical assistance needs identified by the DEC or by the site staff members.	Implementation outcomes: feasibility, fidelity, integration Service outcome: efficiency, safety	1 form was completed for each annual site visit (3 site visits total).	Intervention team members completed the form and submitted it to the DEC. Typed notes were stored on a secure server and transferred to a qualitative coding software (e.g. NVivo) for analysis.	Assign data collection responsibility to Data Manager or CQI team. This data collection form could be used to structure an annual intervention team meeting or to complete an annual progress report.
Fidelity monitoring checklist	Through fidelity monitoring, the DEC will be able to determine what it takes to implement consistently with a high level of quality, across varying	Implementation outcome: Fidelity	Patient IDs are generated prior to the start of the month. All in-	Prior to the start of the month, 30% of the participant IDs were randomly selected. The Clinical Coordinators used an audio	Assign data collection responsibility to Data Manager or CQI team.

Data Source	Brief Description	Relationship to Proctor Model Domains	Frequency of data collection	Collection method for DEII	Recommendations for future evaluations
	<p>implementation sites and their subsequent local contexts (Glasgow, Lichtenstein, & Marcus, 2003). Fidelity monitoring will provide insight to unintended program outcomes (attributed to a Type III error or flaw in the intervention program theory). This monitoring takes place throughout the implementation.</p> <p>Each intervention has core elements that must be implemented in a consistent way across the intervention cohort. Each element will be monitored by the DEC throughout implementation to measure adherence to the intervention plan.</p> <p>Random samples of audio recordings will be used by the DEC to monitor for fidelity. A checklist developed by the DEC will be used to evaluate fidelity of the content of the recording.</p>		<p>person interactions with patients whose IDs were selected are recorded throughout the month. Interventionists have 72 hours after the interaction to upload audio recordings to the site's secure files. The two data staff have one month to review and complete Fidelity Checklists for the 10% of patient ID audio recordings selected. On a quarterly basis, they meet with other program staff to discuss intervention fidelity.</p>	<p>device to record all Peer-patient interactions for the patient IDs selected for the month. The following month, 10% of patient IDs that were selected to be recorded are randomly selected to be reviewed.</p> <p>Two data staff meet to listened to all of the peer-interventionist interaction recordings and independently completed the intervention Fidelity Checklist for each recording. Afterward, the staff met to discuss their findings. The data staff meet with program management and leadership staff to discuss fidelity to the peer intervention and any deviation from the model. Recordings were be destroyed within 12 months of being uploaded to files.</p>	
Cost analysis worksheet	Worksheet to track overall intervention costs, labor and programmatic costs, cost per client served, cost per client retained	Implementation outcome: implementation cost	Annually	Site financial and administrative personnel submitted cost worksheet to ITAC with monthly invoicing.	Only include programmatic costs; no evaluation costs. Separate start up from recurrent

Data Source	Brief Description	Relationship to Proctor Model Domains	Frequency of data collection	Collection method for DEII	Recommendations for future evaluations
					implementation costs.
Baseline client survey	Socio-demographics, risk and needs variables, barriers to care, stigma, violence and trauma, use of services including health care, support services, mental health and substance use, services, adherence to treatment outcomes, quality of life	Client outcomes: Satisfaction, function,	1 survey per client within 7 days of enrollment.	Ideally, the screening, baseline, and follow-up interviews should be conducted by the data manager because they are the least likely to have any direct involvement in the client's care, that is not always possible. Data Managers entered data directly into the web-based online portal. Data Managers brought paper copies in the event of technical difficulties and later entered that data into the portal.	Identify a backup person with the next least likelihood of direct involvement with client care who is not one of the interventionists. Consider all of the ways in which a person could interact with patient care. A case manager who is not involved in the intervention could consent participants, however that case manager could have some decision making power over the client's care, which could be viewed as coercive.
Follow-up client survey	Risk and needs variables, barriers to care, violence and trauma, use of services including health care, support services, mental health and substance use, services, mediators such as relationship with providers, quality of life, and satisfaction with care	Client outcomes: Satisfaction, function	At 6, 12 and 18 months	Data Managers entered data directly into the web-based online portal. Data Managers brought paper copies in the event of technical difficulties and later entered that data into the portal.	Site staff partnered with data managers to locate clients or schedule follow-up surveys on the same day that the client was scheduled to meet with the Clinical Coordinator.

Data Source	Brief Description	Relationship to Proctor Model Domains	Frequency of data collection	Collection method for DEII	Recommendations for future evaluations
Medical chart abstraction	Based data elements outlined in the RSR: core medical services including outpatient ambulatory medical care, CD4 counts and dates, viral load counts and dates, mental health services, medical case management, prescribed HART; support services including case management, referral for health care and supportive services, and substance use services.	Implementation outcomes: timeliness Client outcomes: function, symptomatology	The Medical Chart Abstraction is conducted three times for each participant once at 6 months post enrollment, once at 12 months post enrollment, and once at 18 months post enrollment	Data Managers completed a TeleForm that was later uploaded to the Boston University Biostatistics and Epidemiology Data Analytic Center.	Site staff batched the medical chart abstractions, dedicating one day to tackle multiple charts rather than completing them throughout the month.
Qualitative client interviews	Interviews with patients about their experience in the intervention	Client outcomes: Satisfaction, function, symptomatology	1 time point in the final year of DEII funding.	Data managers conducted and recorded interviews that were then uploaded to a secure data portal. Audio-recordings of the semi-structured interviews were transcribed for analysis. The .mp3 files of recorded interviews were sent to a central, HIPAA compliant transcription agency. Word files were developed from each audio file. No names of clients were recorded on the audio files. All proper names of persons, agencies, and locations were removed from the transcripts and substituted with codes to protect and ensure privacy and confidentiality of participants. After transcription audio recordings were destroyed	Depending on internal resources and staffing, these interviews could be conducted on an annual basis with different participants each year, or be replaced with focus groups.

Data Source	Brief Description	Relationship to Proctor Model Domains	Frequency of data collection	Collection method for DEII	Recommendations for future evaluations
				once qualitative coding and analysis is complete.	

Preparing for Evaluation

- Translate tools as appropriate into the regional dialect of a given language, provide a certificate of translation to submit to the IRB to verify the translation.
- Determine data management and storage protocols

The Data Manager is responsible for securely storing study documents in appropriate locations. It is recommended that **separate** storage locations be provided for the following documents.

Master ID list:

- This document provides a key linking participants' names and study ID numbers. This list should be securely stored apart from all other study documents and should never be shared with anyone outside of the evaluation study.
- If kept as an electronic file:
 - DO save this file to a single, unique location on either a secure server or encrypted computer requiring user access authorization.
 - DO use a password to lock this file from viewing.
 - DO **NOT** copy this file to any other location.
- If kept as a physical file:
 - DO keep this list locked in a secure place at all times.
 - DO keep this list separate from any collected data with identifiable information.
 - DO **NOT** make copies of this list.
 - DO **NOT** let anyone borrow this list.

Individual participant files:

- Each evaluation study participant should have a separate file (one per participant) that is securely stored apart from other participant files. Documents kept in this file include:
 - Signed informed consent forms
 - Signed HIPAA authorization forms (as needed)
 - Signed waivers for receipt of compensation (if applicable)
 - **Note:** If you are required by your IRB or system to keep a master list of incentives or reimbursements, this should **NOT** be kept here.
 - **Note:** Documents with a participant's name and those with their study ID should not be stored together, so data collection forms should **NOT** be stored here.
- DO keep these files locked in a secure place at all times or use a secure signature such as Docusign.

Blank data collection forms & other study documents to keep extra hard copies of:

- Participant baseline and follow-up questionnaires
- Participant encounter forms
- Eligibility & enrollment forms
- Informed consent forms
- HIPAA authorization forms
- Waiver for receipt of compensation

Master list of incentives/reimbursements (if required):

If you are required by your IRB or system to keep a master list of incentives or reimbursements, this should be kept separate from the Master ID list and other study documents containing participant information.

- Determine data cleaning process/protocols
- Collect human subjects training certificates from any staff involved in data collection activities
- Determine if IRB approval is needed.
 - Depending on how a site plans on using the data (for example to publish in peer-reviewed literature or to conduct a general quality improvement project), the site may need to obtain IRB approval before enrolling participants and collecting data. Consult with your local IRB for more information.
- Obtain necessary Data Use Agreements
 - Data Use Agreements (DUAs) are contractual documents used for the transfer of nonpublic data that is subject to some restriction on its use. DUAs serve to outline the terms and conditions of the transfer. Specifically, DUAs address important issues such as limitations on use of the data, obligations to safeguard the data, liability for harm arising from the use of the data, publication, and privacy rights that are associated with transfers of confidential or protected data. The understanding established by a DUA can help avoid later issues by clearly setting forth the expectations of the parties (provider and recipient). A site may need one if you are partnering with an external organization to collect, manage, or analyze data.
- Obtain financial incentives for participation in the patient surveys and interviews
 - This compensation **cannot be a monetary reward** (i.e. cash, checks, etc.). Incentives will also follow guidelines for use of Ryan White HIV/AIDS Program Funds (RWHAP), which prohibit cash payments to intended recipients of services. This prohibition includes cash incentives and cash intended as payment for RWHAP services. Where direct provision of the service is not possible or effective, store gift cards, vouchers, coupons, or tickets that can be exchanged for a specific service or commodity (e.g., food or transportation) must be used. Store gift cards that can be redeemed at one merchant or an affiliated group of merchants for specific goods or services that further the goals and objectives of the RWHAP are also allowable as incentives for eligible program participants. Voucher and store gift card programs should also be administered in a manner which assures that they cannot be exchanged for cash or used for anything other than the allowable goods or services, and that systems are in place to account for disbursed vouchers and store gift cards. Note: General-use prepaid cards are considered “cash equivalent” and are therefore unallowable. Such cards generally bear the logo of a payment network, such as Visa, MasterCard, or American Express, and are accepted by any merchant that accepts those credit or debit cards as payment. Gift cards that are cobranded with the logo of a payment network and the logo of a merchant or affiliated group of merchants are general-use prepaid cards, not store gift cards, and therefore are also unallowable.
 - The provision of compensation be documented, and the participant should sign the ***Waiver-for-receipt of compensation*** to acknowledge receipt of the compensation and that it will not be used for alcohol, firearms, or tobacco products. The documentation of the compensation should be kept with all study records in a locked, password protected file (if electronic) and stored with the copies of the participant’s consent form.

Evaluation Activity Checklist

Prior to implementation start up

- Administer the Organizational Readiness to Change Assessment (ORCA)
- Complete initial site visit report
- Complete monthly monitoring form

During project implementation start up

Ongoing (dependent on participant enrollment, participant interactions, and transition to the standard of care):

- Screen clients for eligibility to participate in evaluation
- Consent clients into the evaluation
- Conduct baseline interview
- Complete the encounter forms
- Collect audio recordings of selected participant and intervention staff interactions

Monthly:

- Complete monthly monitoring form

During implementation

Ongoing (dependent on participant enrollment, interactions, and transition to the standard of care):

- Screen client for eligibility to participate in evaluation
- Consent participant into the evaluation
- Conduct baseline interview
- Conduct follow-up interview
- Complete the encounter forms
- Collect audio recordings of selected participant and intervention staff interaction
- Complete medical chart abstraction (6, 12 & 18 months after enrollment)

Monthly:

- Conduct data cleaning activities (e.g. data audits)
- Complete monthly monitoring form

At least once in a project life:

- Conduct key informant interviews or focus groups (depending on staff and budget)
- Conduct patient qualitative interviews

Appendix A: Organizational Readiness to Change Assessment

This tool was based on the validated instrument: Helfrich, C. D., Li, Y.-F., Sharp, N. D. & Sales, A. E. (2009). Organizational readiness to change assessment (ORCA): Development of an instrument based on the Promoting Action on Research in Health Services (PARIHS) framework. *Implementation Science*, 4: 38. doi: 10.1186/1748-5908-4-38.

What is your role at the clinic/agency?

Intervention Staff

- | | | |
|--|--|---|
| <input type="checkbox"/> Enhanced Patient Navigator | <input type="checkbox"/> Peer | <input type="checkbox"/> Clinical Coordinator |
| <input type="checkbox"/> Transitional Care Coordinator | <input type="checkbox"/> Community Case Manager | <input type="checkbox"/> Data Manager |
| <input type="checkbox"/> Project Manager | <input type="checkbox"/> Administrative Supervisor | <input type="checkbox"/> Clinical Supervisor |

Clinical Staff

- | | | |
|---|---|---|
| <input type="checkbox"/> Prescribing Provider | <input type="checkbox"/> Clinician (RN, NP, PA) | <input type="checkbox"/> Medical Assistant |
| <input type="checkbox"/> Pharmacist | <input type="checkbox"/> Nutritionist | <input type="checkbox"/> Behavioral Health Provider |

Clinic Leadership

- | | | |
|---|--|---|
| <input type="checkbox"/> Medical Director | <input type="checkbox"/> Clinic Director | <input type="checkbox"/> Executive Director |
|---|--|---|

Other Clinic Staff

- | | | |
|---|---|--|
| <input type="checkbox"/> Case Manager/Patient Navigator | <input type="checkbox"/> Scheduling Staff | <input type="checkbox"/> Billing staff |
| <input type="checkbox"/> Social Worker | <input type="checkbox"/> Benefits Counselor | <input type="checkbox"/> Other (specify) |

For each of the following statements, please rate the strength of your agreement with the statement, from 1 (strongly disagree) to 5 (strongly agree).

EVIDENCE ASSESSMENT

Q1. The proposed intervention:

	Strongly Disagree	Disagree	Neither Agree or Disagree	Agree	Strongly Agree	Don't know/not applicable
a) Is supported by evidence from past HIV interventions	1	2	3	4	5	99
b) Is supported by evidence from other health care systems	1	2	3	4	5	99
c) Should be effective, based on current scientific knowledge	1	2	3	4	5	99

Q2. The proposed intervention:

	Strongly Disagree	Disagree	Neither Agree or Disagree	Agree	Strongly Agree	Don't know/not applicable

a) Is supported by clinical experience with Ryan White patients	1	2	3	4	5	99
b) Is supported by clinical experience with patients in other health care systems	1	2	3	4	5	99
c) Conforms to the opinions of clinical experts in this setting	1	2	3	4	5	99

Q3. The proposed intervention:

	Strongly Disagree	Disagree	Neither Agree or Disagree	Agree	Strongly Agree	Don't know/not applicable
a) Will be well-accepted by patients similar to those who come to this clinic	1	2	3	4	5	99
b) Are consistent with clinical practices that have been accepted by patients similar to those who come to this clinic	1	2	3	4	5	99
c) Take into consideration the needs and preferences of patients similar to those who come to this clinic	1	2	3	4	5	99
d) Appear to have more advantages than disadvantages for patients similar to those who come to this clinic	1	2	3	4	5	99

CONTEXT ASSESSMENT

For each of the following statements, please rate the strength of your agreement with the statement, from 1 (strongly disagree) to 5 (strongly agree).

Q4. Senior leadership/clinical management in your organization:

	Strongly Disagree	Disagree	Neither Agree or Disagree	Agree	Strongly Agree	Don't know/not applicable
a) Reward clinical innovation and creativity to improve patient care	1	2	3	4	5	99
b) Solicit opinions of clinical staff regarding decisions about patient care	1	2	3	4	5	99
c) Seek ways to improve patient education and increase patient participation in treatment	1	2	3	4	5	99

Q5. Staff members in your organization:

	Strongly Disagree	Disagree	Neither Agree or Disagree	Agree	Strongly Agree	Don't know/not applicable
a) Have a sense of personal responsibility for improving patient care and outcomes	1	2	3	4	5	99
b) Cooperate to maintain and improve effectiveness of patient care	1	2	3	4	5	99
c) Are willing to innovate and/or experiment to improve clinical procedures	1	2	3	4	5	99
d) Are receptive to change in clinical processes	1	2	3	4	5	99

Q6. Senior leadership/clinical management in your organization:

	Strongly Disagree	Disagree	Neither Agree or Disagree	Agree	Strongly Agree	Don't know/not applicable
a) Provide effective management for continuous	1	2	3	4	5	99

improvement of patient care						
b) Clearly define areas of responsibility and authority for clinical managers and staff	1	2	3	4	5	99
c) Promote team building to solve clinical care problems	1	2	3	4	5	99
d) Promote communication among clinical services and units	1	2	3	4	5	99

Q7. Senior leadership/clinical management in your organization:

	Strongly Disagree	Disagree	Neither Agree or Disagree	Agree	Strongly Agree	Don't know/not applicable
a) Provide staff with information on performance measures and guidelines	1	2	3	4	5	99
b) Establish clear goals for patient care processes and outcomes	1	2	3	4	5	99
c) Provide staff members with feedback/data on effects of clinical decisions	1	2	3	4	5	99
d) Hold staff members accountable for achieving results	1	2	3	4	5	99

Q8. Opinion leaders in your organization:

	Strongly Disagree	Disagree	Neither Agree or Disagree	Agree	Strongly Agree	Don't know/not applicable
a) Believe that the current practice patterns can be improved	1	2	3	4	5	99
b) Encourage and support changes in practice	1	2	3	4	5	99

patterns to improve patient care						
c) Are willing to try new clinical protocols	1	2	3	4	5	99
d) Work cooperatively with senior leadership/clinical management to make appropriate changes	1	2	3	4	5	99

Q9. In general in my organization, when there is agreement that change needs to happen:

	Strongly Disagree	Disagree	Neither Agree or Disagree	Agree	Strongly Agree	Don't know/not applicable
a) We have the necessary support in terms of budget or financial resources	1	2	3	4	5	99
b) We have the necessary support in terms of training	1	2	3	4	5	99
c) We have the necessary support in terms of facilities	1	2	3	4	5	99
d) We have the necessary support in terms of staffing	1	2	3	4	5	99

FACILITATION ASSESSMENT

For each of the following statements, please rate the strength of your agreement with the statement, from 1 (strongly disagree) to 5 (strongly agree).

Q10. Senior leadership/clinical management will:

	Strongly Disagree	Disagree	Neither Agree or Disagree	Agree	Strongly Agree	Don't know/not applicable
a) Propose a project that is appropriate and feasible	1	2	3	4	5	99
b) Provide clear goals for improvement in patient care	1	2	3	4	5	99
c) Establish a project schedule and deliverables	1	2	3	4	5	99

d) Designate a clinical champion for the project	1	2	3	4	5	99
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Q11. The project clinical champion:

	Strongly Disagree	Disagree	Neither Agree or Disagree	Agree	Strongly Agree	Don't know/not applicable
a) Accepts responsibility for the success of this project	1	2	3	4	5	99
b) Has the authority to carry out the implementation	1	2	3	4	5	99
c) Is considered a clinical opinion leader	1	2	3	4	5	99
d) Works well with the intervention team and providers	1	2	3	4	5	99

Q12. Senior leadership/clinical management/staff opinion leaders:

	Strongly Disagree	Disagree	Neither Agree or Disagree	Agree	Strongly Agree	Don't know/not applicable
a) Agree on the goals for this intervention	1	2	3	4	5	99
b) Will be informed and involved in the intervention	1	2	3	4	5	99
c) Agree on adequate resources to accomplish the intervention	1	2	3	4	5	99
d) Set a high priority on the success of the intervention	1	2	3	4	5	99

Q13. The implementation team members and existing staff:

	Strongly Disagree	Disagree	Neither Agree or Disagree	Agree	Strongly Agree	Don't know/not applicable
a) Share responsibility for the success of this project	1	2	3	4	5	99

b) Have clearly defined roles and responsibilities	1	2	3	4	5	99
c) Can accomplish intervention tasks within their regular workload	1	2	3	4	5	99
d) Have staff support and other resources required for the project	1	2	3	4	5	99

Q14. The implementation plan for this intervention:

	Strongly Disagree	Disagree	Neither Agree or Disagree	Agree	Strongly Agree	Don't know/not applicable
a) Identifies specific roles and responsibilities	1	2	3	4	5	99
b) Clearly describes tasks and timelines	1	2	3	4	5	99
c) Includes appropriate provider/patient education	1	2	3	4	5	99
d) Acknowledges staff input and opinions	1	2	3	4	5	99

Q15. Communication will be maintained through:

	Strongly Disagree	Disagree	Neither Agree or Disagree	Agree	Strongly Agree	Don't know/not applicable
a) Regular project meetings with the project champion and team members	1	2	3	4	5	99
b) Involvement of staff in project planning and implementation	1	2	3	4	5	99
c) Regular feedback to clinical management on progress of project activities and resources needs	1	2	3	4	5	99
d) Regular feedback to clinicians on	1	2	3	4	5	99

effects of practice changes on patient care/outcomes						
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Q16. Progress of the project will be measured by:

	Strongly Disagree	Disagree	Neither Agree or Disagree	Agree	Strongly Agree	Don't know/not applicable
a) Collecting feedback from patients regarding proposed/ implemented changes	1	2	3	4	5	99
b) Collecting feedback from staff regarding proposed/ implemented changes	1	2	3	4	5	99
c) Developing and distributing regular performance measures to clinical staff	1	2	3	4	5	99
d) Providing a forum for presentation/ discussion of results and implications for continued improvements	1	2	3	4	5	99

Q17. The following are available to make the selected plan work:

	Strongly Disagree	Disagree	Neither Agree or Disagree	Agree	Strongly Agree	Don't know/not applicable
a) Staff incentives	1	2	3	4	5	99
b) Equipment and materials	1	2	3	4	5	99
c) Patient awareness/need	1	2	3	4	5	99
d) Provider buy-in	1	2	3	4	5	99
e) Intervention team	1	2	3	4	5	99
f) Evaluation protocol	1	2	3	4	5	99

Q18. Plans for evaluation and improvement of this intervention include:

	Strongly Disagree	Disagree	Neither Agree or Disagree	Agree	Strongly Agree	Don't know/not applicable
a) Periodic outcome measurement	1	2	3	4	5	99
b) Staff participation/satisfaction survey	1	2	3	4	5	99
c) Patient satisfaction survey	1	2	3	4	5	99
d) Dissemination plan for performance measures	1	2	3	4	5	99
e) Review of results by clinical leadership	1	2	3	4	5	99

Additional questions:

1. From your perspective, what are the potential barriers for implementing this intervention at your site?
2. From your perspective, what are the characteristics of your site or factors unique to your site that will facilitate a successful intervention?
3. Is there anything you'd like to share regarding your agency, its organizational culture, the community in which you work, or other contextual factors that would impact the implementation?

Appendix B: Initial Site-Visit Report

Staffing Plan

- Are there existing staff who will work on the initiative? Who are they?
- Are you hiring new staff?
 - Which positions?
 - What is your timeline for hiring?
 - What are the personnel protocols that impact hiring for these positions?
 - What is your on-boarding process for new staff?

Roles & Responsibilities

- What are your strategies and challenges accommodating the responsibilities of the following positions?
 - Clinical Care Coordinators
- What is the level of senior management and leadership “buy-in”?

Systems Coordination Strategies

- Who is part of the health care team?
 - How does the team function; case conferencing, daily huddles?
- How will the interventionist be integrated into the team?
 - What are the current and/or anticipated challenges in integrating the interventionists into the health care team?
 - What have been the successes/accomplishments in relationship to integrating the interventionist to date?
 - What are the intra-team communications protocols?

Intervention Knowledge and Implementation

- National HIV/AIDS Strategy (NHAS) and Ending the Epidemic (EHE)
 - What elements of the NHAS and EHE will this intervention address?
- Intervention Target Population
 - What is your strategy to identify eligible patients in the target population?
 - Any changes post the submission of your proposal?
- Intervention tools
 - Do you have experience with the following tools; acuity scales, care plans, case study templates?

Intervention Collaboration & Networking

- What behavioral health care services are provided at your organization?
 - What modalities of services are offered?
 - Which disciplines provide mental health services?
 - What tools do you use for substance abuse screening?
 - How do you do crisis management?

Intervention Collaboration & Networking (continued)

- Who are the other service providers in the catchment area (housing assistance/case management, employment services, substance use treatment, psychosocial support, etc.)? Describe your current level of collaboration with these providers.
 - Where do PLWHA go for primary care in the area?
 - How do you share information with your community collaborators?
 - MOU's
 - Releases of information protocols
 - When are releases signed at intake? as needed?
 - Shared data systems
 - Referral processes

Staff Development

- What is the level of staff knowledge in the areas of:
 - Referral processes – internal/external
 - Boundaries
 - Confidentiality/HIPPA

Data Management & Collection

- General overview of data systems
 - Who is the data manager?
 - How will they work with the interventionist and other program staff?
 - Are there any anticipated training needs on the data collection side?
 - Does the data manager have any questions on the multi-site data collection forms?
 - What experience do you have with data collection via tablet computer? Do your organization's policies/protocols support data collection via remote devices? Where/ will data be located?
 - Will there be multiple staff that who will be collecting and entering data?
 - What data are currently collected and entered into EMR, other medical records, housing records, other support services, RW databases?
 - Who is responsible for supervising these staff members?
 - How is data collection reviewed for quality?

IRB

- What is the application type and process?
- Do you have boilerplate language for IRB protocol?
- Are there any anticipated challenges or current concerns with regards to seeking IRB approval?
- Have data collection staff received necessary certifications (e.g. human subjects, IRB approval, etc.)?
- What is the expected sample size for baseline and follow-up over time? How will this be different from the number of patients you anticipate providing services too?
- Do you anticipate any possible barriers to data collection, if yes what are the possible barriers?

Web-site data entry

- Have you done direct electronic data capture before?
 - If yes, what hardware did you use (e.g., laptop, iPad)
 - If yes, what software did you use (if known)
 - Do you have internet access in the areas in which you intend to collect data?
 - Do you currently have hardware you would like to use for electronic data capture, if not what do you plan to purchase for this study?

Enrollment Strategies

- Have you developed a strategy (or updated an existing strategy) to meet the enrollment target? Please tell us more about that strategy.
- Please provide a briefing on your current/historical provision of services to your target population.
- Has anything changed post your proposal submission that impacts your enrollment strategies?

Team Integration

- How will you integrate Clinical Coordinators into your healthcare team?
 - How will their role be defined for the team?
 - Is this role a new role on the team or in your organization?
 - What are the established or new communication protocols that will support their integration?
 - What are some of the anticipated challenges that will impact full integration of the Clinical Coordinators?

- Is your administrative and/or clinical support staff in place?
 - How will these staff members support the Clinical Coordinators?
 - Are there any changes that need to be made in terms of their schedule, workload, training?
What are some of the anticipated challenges and do you have plans to overcome these anticipated challenges?

Appendix C: Monthly Reporting Tool

1. Program update: work plan, terms and conditions related to program activities, implementation, etc.
 - a. Have there been any major changes within your clinic or community that could influence your implementation or evaluation (changes in funding, community events or news stories, opening new clinic locations, local or national policies that impact your work with your patients)
 - b. To what degree is the intervention being implemented as designed in the adapted intervention and implementation plan?
 - i. At this stage in the project, how is the intervention being implemented?
 - ii. Challenges/barriers? Solutions?
 - iii. How many participants have you enrolled in the intervention?
 1. Are you on track to meet your enrollment goals?
 2. Are there any additional or alternative enrollment strategies that should be explored?
 - c. How has this intervention been integrated into the care services provided at your site?
 - d. How does it complement or conflict with other programs at the clinic?
2. Have you used this intervention to make changes to other clinic service or programs or to apply for funding for other programming?
3. Do you have any financial updates: budgets, carryover requests, new grants awarded, anything that would impact a cost analysis.
4. Do you have any staffing updates (including new contractors, new staff members, major administrative changes in the organization, integration of intervention team members into the clinical team)
 - a. Has your staff participated in any trainings (offered either by your clinic/organization, a community partner, national partners, etc.)?
 - i. Training topic:
 - ii. Training modality (in person, online):
 - iii. Notes:
 - b. Do staff feel as though they are getting sufficient supervision or support from staff at the organization?
 - c. Does the intervention avoid duplication and alleviate staff burden (“right-sizing” – equitable redistribution of work)?
5. Evaluation updates
 - a. Are there any barriers or challenges to implementing the evaluation activities?
 - b. How are patients/clients responding to the evaluation activities?
 - c. Are there any barriers or challenges to locating patients/clients for follow-up activities?
6. Additional comments:

Appendix D: Screening and Eligibility Form

Eligibility and enrollment form for DEII **Buprenorphine** initiative

Instructions: Please answer the following questions regarding the client's eligibility for the DEII Buprenorphine initiative. This form should be completed for any client referred to the DEII Buprenorphine initiative.

1. Is the person 18 years or older? No Yes
2. Is this person HIV-positive? No Yes

BUPRENORPHINE

Client must respond "yes" to all of the following questions to be eligible:

1. Is the client diagnosed with an opioid use disorder as determined by DSM-5 criteria? No Yes
2. Does the client want pharmacotherapy for the opioid use disorder? No Yes
3. Is the client currently receiving primary care at the intervention site? No Yes
 - 3a. If the client is not currently receiving primary care at the intervention site, are they eligible for primary care at the intervention site? No Yes

How many times did the interventionist attempt to reach this client, prior to the time where the interventionist was able to connect with the client and explain the intervention activities to the client? _____

INFORMED CONSENT

10. Did the subject sign the consent form?	<input type="radio"/> No <input type="radio"/> Yes
10a. Date consent form signed (mm/dd/yyyy)	____/____/____
11. Did the subject sign the audio recording consent form?	<input type="radio"/> No <input type="radio"/> Yes
11a. Date audio consent form signed (mm/dd/yyyy)	____/____/____

If NOT CONSENTED, specify reason(s): (choose all that apply)	
Client's reasons:	Discretion of study staff:
<input type="checkbox"/> Timing	<input type="checkbox"/> Too tired
<input type="checkbox"/> Not interested/Client didn't want to wait	<input type="checkbox"/> Too ill, physical health problem
<input type="checkbox"/> Personal problems	<input type="checkbox"/> Too ill, mental health problem
<input type="checkbox"/> Questions too personal	<input type="checkbox"/> Inappropriate behavior
<input type="checkbox"/> Too ill	<input type="checkbox"/> Not comprehending questions
<input type="checkbox"/> Unknown	<input type="checkbox"/> Incomprehensible responses
<input type="checkbox"/> Other (specify): _____	<input type="checkbox"/> Too high/inebriated
	<input type="checkbox"/> Other (specify): _____

OUTCOME

Ineligible / Eligible: **Participant ID #:** _____

IMPORTANT: The Participant ID will be used on all study instruments. Write it down and store in secure locked/password protected file with the participant's contact information and/or your local Client ID.

Appendix E: Evaluation FAQ Handout for Study Participants

1. Is it mandatory that patients in the interventions also be part of the evaluation?
All patients should be informed and asked to enroll in the evaluation, however, participation is completely voluntary. Patients can decline and still receive the intervention services. There will be a form you will be asked to complete about why the patient declined. These data will be collected and used only in the aggregate.
2. Will my answers to surveys be kept private?
Yes, all answers will be kept private and confidential. After conducting the patient survey interviews, site staff will never have access to individual responses with identifiers.
3. Who can see my answers?
Identify staff who will be able to see the responses (data manager, CQI team). Your Clinical Coordinator and your doctor will not be able to see these responses.
4. How long will the interview take?
The time for this interview varies, but it generally takes about [XX] minutes. Of course, each person may take a little more or less time, depending on that individual's pace.
5. Why should some participate in the evaluation?
We understand that your time is valuable. Your participation in the survey can help efforts to bring needed medical care and health promotion services to your community. The only way that we can improve services for people with HIV is to ask them about their experience with programs like this one, and ask them for their opinions about how we can improve. One of our goals is to learn lessons about the best ways to provide care and improve outcomes for people with HIV. In order to improve this program and build programs that meet the needs of people with HIV, we'd appreciate you telling us about your experience living with HIV and experience in this program.
6. Can a friend take one of my surveys if I decide to quit?
Because of strict scientific research methods, you cannot be replaced by anyone else for this study.
7. What if "I'm too busy," "I'm not feeling very well," "This is a bad time"?
I understand. We need to learn about the experiences of busy people like you. Our results would be incomplete if we only included respondents who could immediately make the time to talk with us. We can make an appointment for me to visit again, at a time that would be better for you. I can come back in the morning, afternoon, or evening on the best day for you. We can start now and finish when you have more time. Let's start and see how far we can get. We may be able to finish it.
8. Are we offering compensation for completing the surveys?
Yes. We are offering a thank-you gift [describe compensation] to those who complete the interview. Explain the amount your agency is offering
9. Can patients get the results of the study?
Summary reports will be available from [name your health organization] at [timepoint]. Here is the name of the person to call to obtain a copy: [Data Manager at your site].

Appendix F: Audio Recording Checklist

Topics covered in the intervention	Examples	Yes	No	Comments
Role clarification: The interventionist explained the role of the prescribing provider and the clinical coordinator as compared to the other clinic team members.	My role is to support you through all phases of this intervention to ensure that your treatment is successful... The provider's primary role is to prescribe buprenorphine and to ensure that all phases of treatment (from induction, stabilization to maintenance) go smoothly and that you have optimal treatment outcomes...			
Communication strategy: The interventionist explained how the clinical coordinator and patient will communicate with each other throughout the intervention (including modes of communication and frequency).				
Intervention activities: The interventionist explained the intervention activities including the goals of the intervention and the timeline of the intervention.	The buprenorphine interventions primary role is to provide you with office based treatment for your opioid use disorder. Your treatment will include regular visits with your doctor, with myself, the clinical coordinator, random UDS, and ongoing treatment planning			
Intervention phases: The interventionist explain the phases of the intervention, and what the patient can expect during treatment. This explanation includes talking about the overall treatment plan, and the life-cycle of treatment (the general timeline, how a patient moves from one phase to the next, what they can expect from each phase).	<ul style="list-style-type: none"> • The buprenorphine intervention is set up in four phases. Phase 1 is Selecting and Assessing Patients. This phase is to determine if buprenorphine is the right fit for your treatment needs. Phase 2 is Induction. This is when you present in withdrawal and the prescribing provider starts you on your initial dose of Suboxone. Phase 3 is focused on Stabilization. You and your prescriber will work closely together to ensure you are on the right dose of Suboxone. Phase 4 is the Maintenance phase. You will meet regularly with both your prescriber and myself, as determined by your treatment plan, so we can work together to ensure the best treatment outcomes for you. • Treatment with buprenorphine at this clinic will include the following: <ul style="list-style-type: none"> • Assistance preparing for induction • Regularly scheduled visits with prescriber and clinical coordinator • Random UDS • Routine labs and monitoring 			

	<ul style="list-style-type: none"> • Monitoring for correct dose/dose adjustments as needed for Suboxone. • Ongoing treatment planning • Support and community referrals • Risk reduction/harm reduction discussion if still using substances • Ongoing assessment of stages of change • Collaboration with community providers you are engaged with • Assistance with ensuring you have ongoing access to buprenorphine via insurance or other resources. • Tapering planning (as needed) 			
<p>Motivational interviewing techniques: The interventionist: Collaborated with the patient to create a treatment plan Responded appropriately and professionally to patient questions and concerns Acknowledged patient concerns about treatment Supported patient decision making Offered non-judgmental responses to patient questions Verbally summarizes what the patient says to clarify and acknowledge the patient's thoughts and concerns</p>	<p>Let's talk about what your goals are for treatment here at this clinic...?</p> <p>Let's talk about what treatment goals you might have using community resources like mental health counseling, AA meetings, or....?</p> <p>Let's review where you are at in the stages of change with the substance(s) you use....</p> <p>What treatment experiences have you had in the past? What worked for you, what didn't?</p> <p>Are there other treatment resources we can explore together?</p> <p>Who can you share your treatment plan with for additional support?</p> <p>Here's what I heard you say, tell me if I missed anything?</p> <p>It sounds like you...</p> <p>You're wondering if....</p> <p>I hear what you are saying.</p> <p>Let's review what we have covered so far.</p> <p>What questions or concerns do you have about buprenorphine treatment process...?</p> <p>I am hearing you say that you are concerned about....how can we help you?</p> <p>It is common to feel concerned that the Suboxone won't work, that is why we work closely with you during the induction and stabilization phase</p> <p>We are here to support you and your goals.</p> <p>It sounds like you have made the right decision for yourself...</p> <p>We are here to support you through all phases of this processes and understand that this is your decision to make.</p>			

	<p>That's a great question...</p> <p>Let's see if I can help to answer some questions you might have about...</p> <p>I understand...</p> <p>I am glad you asked...</p> <p>It is your decision to choose when you are ready to start or stop treatment...</p>			
<p>Educational materials: The interventionist provided patient education on buprenorphine, treatment, substance use, and/or HIV.</p>	<p>We have some materials that help explain what to expect for (home based vs office) induction...</p> <p>Feel free to share this information with friends and family, it might help answer their questions</p> <p>Is there any other information you might need that we have not already covered?</p>			
<p>Discussed ongoing use: The interventionist discussed the patient's ongoing substance use and risk of substance use.</p>	<p>We understand that relapse is part of the treatment process, would you like to talk about this some more...?</p> <p>You told me that you were not ready to quit using ____, would you like to explore ways that we can minimize your risk while using ____?</p> <p>Would you like to talk about the coping skills you are using now</p> <p>It sounds like you are doing great not using____, would you like to talk some more about your relapse prevention plan?</p> <p>Would you like to spend some time talking about how you feel during the early phase of recovery?</p> <p>It sounds like you are concerned about relapse, let's talk about ways you might be able to prevent that...</p>			
<p>Adherence support: The interventionist provided patient with support in adhering to HIV medications and treatment, and/or buprenorphine treatment. HIV treatment adherence support includes encouraging patients to go to their doctor's appointments, scheduling doctor's appointments, checking in to see if the patient is taking their medication as prescribed.</p>	<p>What do you know about HIV?</p> <p>Where did you get this information?</p> <p>Let's talk about how taking medications help with being in good health</p> <p>What did you and your doctor agree on about adhering to meds and medical appointments?</p> <p>Let's review how taking meds and lab results can show that you are virally undetectable</p> <p>What particular questions do you have about HIV?</p>			
<p>Provide referrals: The interventionist demonstrated understanding of community resources and providers</p>	<p>There are a number of resources available for situations like...</p> <p>Here's the next step for accessing these services...</p> <p>I can make some referrals and your case manager is responsible to do those other referrals</p>			

The interventionist made appropriate referrals The interventionist demonstrated understanding of when to refer a client to the case manager	This is outside of how I can help/ work. Let's connect with your case manager or others on the team for further assistance.			
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General Comments/Feedback

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Appendix G: Sample Audio Recording FAQ Handout for Study Participants

1. Why do you want to record my conversations?

- a. The audio recordings will be reviewed to make sure that we are providing services that address patient needs and will help us to identify opportunities to strengthen the way we provide services to you. The recordings will be used to learn more about the services you may need, and will help me to improve at my job.

2. Who will listen to the recording?

- a. There will be up to 3 people who will review your recordings. These 3 people have human subjects training and are ethically bound to not disclose any of the information that they hear on the recording.

3. I don't want people to know my HIV status.

- a. The audio recordings are confidential. The people who are reviewing them will not know your name or any other identifying information about you. They will not be able to link your name to your recording.

4. How long will they have the recording?

- a. All recordings will be completely destroyed and deleted from any systems 12 months after they have been uploaded into the secure, password protected site at [local site]. [local site] will keep them for a maximum of 12 months but they may delete them earlier than that.

5. Do I have to be recorded?

- a. You do **NOT** have to consent to be recorded in order to participate in the evaluation (the baseline and follow-up) or to receive intervention services. Even if you do consent to participate in audio recording, you can always choose not to be recorded for one session, or part of a session. If you do not consent to be audio recorded, it will not affect the social services or medical care that you receive.

6. When will I be recorded?

- a. Each month, we receive a random sample of patient ID numbers to record over the course of a month. Your number may be on our list for one month or may never be on our list – again, it is a randomly generated list. Once we get that list, your Clinical Coordinator will let you know that they would like to record their interactions with you during that month. The number of times that you are recorded will depend on the number of times that you meet over the course of the month.

7. How do the recordings work? What will happen when I am recorded?

- a. Your Clinical Coordinator will use a handheld audio recorder to record your in-person conversations. The Clinical Coordinator will ask for your permission again before each and every session where they plan on recording, and you can always decline to have that conversation recorded. They will then upload that file to a secure online computer system to share the file with Boston University, who will review the audio file.

Appendix H and I: Participant Questionnaire (Baseline and Follow-Up)

Baseline Survey

Participant ID:

Staff ID:

Site ID:

Form Date:

Interviewer Script: Thank you for agreeing to participate in this study. We are going to cover many topics, including your health, your needs, and your experiences with HIV health care. Some of these questions may be about things you've already discussed with other people at [NAME OF ORGANIZATION]. We are asking you again because this interview is part of a national study that includes people living with HIV from different parts of the country. The data we collect in this survey will not be shared with anyone providing services.

Everything I ask you in this interview is confidential. We would like you to feel comfortable, and be as honest and open as possible. None of your answers will be linked to your name, so please be candid. We hope this study will help us to improve care for people living with HIV.

If a question makes you feel uncomfortable, or brings up feelings or situations you want to talk about, we can refer you to someone you can speak with. Also, if there are any questions you don't feel comfortable answering, you don't have to answer them.

This interview will take less than 1 hour. If at any time you would like to take a break, please let me know. After each question I will read you response options to choose from. As I go through the questions, let me know if there is anything that is unclear. Are you ready to begin?

Interviewer note: DO NOT READ the response option "Refused" to the participant. Only mark this response if a person chooses to skip a question.

SECTION I: DEMOGRAPHICS & BACKGROUND CHARACTERISTICS

1. What is your date or year of birth? (mm/dd/yyyy) ___/___/_____

- Refused
- Don't know

2. Currently, which do you consider yourself to be? [Interviewer: Read responses.]

- Male
- Female
- Transgender
- Gender Non-conforming
- Other (specify): _____
- Refused

3. Are you of Hispanic, Latino/a, or Spanish origin? This is a person of Cuban, Dominican, Mexican, Puerto Rican, South or Central American, or other Spanish culture or origin, regardless of race.

- Yes
- No
- Refused

4. Please answer “Yes” or “No” for each group. Are you: *[Check all that apply]*

- a. American Indian or Alaskan Native. This is a person having origins in any of the original people of North and South America (including Central America), and who maintains tribal affiliations or community attachment.
 - Yes
 - i. Please specify the tribe: _____
 - No
- b. Asian. This is a person having origins in any of the original peoples of the Far East, Southeast Asia, or the Indian subcontinent including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Island, Thailand, and Vietnam.
 - Yes
 - No
- c. Black or African American. This is a person having origins in any of the black racial groups of Africa or the Caribbean.
 - Yes
 - No
- d. Native Hawaiian or other Pacific Islander. This is a person having origins in any of the original peoples of Hawaii, Guan, Samoa, or other Pacific Islands.
 - Yes
 - No
- e. White. This is a person having origins in any of the peoples of Europe, the Middle East, or North Africa.
 - Yes
 - No

5. What language do you speak most of the time, with friends and family? *[One response only.]*

- English
- Spanish
- Haitian Creole
- Other (specify): _____
- Refused

6. What country were you born in?

- 1 of the 50 states in the USA
- Puerto Rico
- US territories (other than Puerto Rico)
- Other (specify): _____
- Refused

7. What is the highest level of education that you’ve completed? *[One response only]*

- No formal education
- Less than high school
- High school diploma or GED received
- Some college or post-high school study
- College graduate (4-year college or university)
- Post-college/graduate
- Don't know
- Refused

8. Including yourself, how many people live in your household? *[One response only]*

- One
- Two
- Three
- Four
- Five or More
- Refused

9. How many children under the age of 18 live in your house? *[One response only]*

- None
- One
- Two
- Three
- Four or more
- Refused

10. During the past 12 months, how many times did you run out of money for basic necessities like housing or food?

[One response only]

- Never
- Daily
- Weekly
- Monthly
- Other (specify): _____
- Refused

11. How many times have you been incarcerated in a correctional facility (jail or prison) in the past 5 years?

_____ # times

12. What kind(s) of health insurance do you have? *[Check all that apply]*

- Medicaid
- Medicare
- A health plan through my state marketplace
- Private insurance through my employer or a family member's employer
- Other private insurance
- Tricare

- Veterans Administration
- Other (specify): _____
- Don't know
- Refused
- None

SECTION II: HOUSING

13. Where do you live now? *[One response only]*

- My own home/apartment (that I own or rent)
- Someone else's home/apartment (that someone else owns or rents)
- Residential or transitional housing
- Treatment program
- Shelter
- The streets/in a car/in a park/on the beach
- Jail
- Other (specify): _____

14. In the past 12 months, was there ever a time in which you had no place to stay, even if it was for just one night?

(Interviewer: After reading "In the past 12 months", include a time reference such as "since last spring...")

- Yes
- No
- Refused

SECTION III: HIV & ADHERENCE

Interviewer Script: These next questions are about your HIV status and taking HIV medications.

15. When did you first test positive for HIV? (mm/dd/yyyy) ___ / ___ / _____

Enter "01" for unknown MONTH; enter "01" for unknown DAY.

- Don't know
- Refused

15a. Were you perinatally infected?

- Yes
- No
- Refused

16. Are you currently taking any HIV medication? *[Show the HIV medication chart]*

- Yes
- No
- Don't know
- Refused

SECTION IV: CASE MANAGEMENT & COMPETING SERVICE NEEDS

17. Do you have an HIV case manager at this clinic? By case manager, we mean an individual who helps you get medical care and/or social services at this clinic. Interviewer: The interventionist is NOT considered a case manager.

- Yes
- No
- Don't know
- Refused

Interviewer Script: Now we are going to ask you about services you may have needed in the last 6 months. First we will ask if you needed the service and then if you got that service. [Interviewer Instructions: for each service (a, b, c....below) ask question #18 first; Check one response only.]

	18. Did you need this service at any time over the last 6 months?		19. Were you able to get this service in the last 6 months?	
	No	Yes	No	Yes
a) Housing assistance (e.g. permanent, temporary, emergency shelter, residential treatment facilities)				
b) Transportation assistance				
c) Assistance in applying for benefits (SSI, SSD, insurance, etc.)				
d) Assistance getting substance use treatment and/or mental health treatment/counseling				
e) Medication assistance (paying for medication, help with prescriptions)				
f) Assistance getting medical care				
g) Did you need any other assistance with services over the past 6 months? Please specify _____				

SECTION V: SUBSTANCE USE²

20. In the past 12 months, how often have you used any tobacco product?

- Daily or almost daily
- Weekly
- Monthly
- Less than Monthly
- Never ->Skip to Q21
- Refused

² Q20-23 from Wu et al., 2016

a. In the past 3 months, did you smoke a cigarette containing tobacco?

- Yes
- No

b. In the past 3 months, did you usually smoke more than 10 cigarettes each day?

- Yes
- No

c. In the past 3 months did you usually smoke within 30 minutes after waking?

- Yes
- No

21. In the past 12 months, how often have you had 5 or more drinks (men)/4 or more drinks (women) containing alcohol in one day?

- Daily or almost daily
- Weekly
- Monthly
- Less than Monthly
- Never ->Skip to Q22
- Refused

a. In the past 3 months, did you have a drink containing alcohol?

- Yes
- No

b. In the past 3 months, did you have 5 or more drinks containing alcohol in a day?

- Yes
- No

c. In the past 3 months have you tried and failed to control, cut down, or stop drinking?

- Yes
- No

d. In the past 3 months, has anyone expressed concern about your drinking?

- Yes
- No

22. In the past 12 months, how often have you used any drugs including marijuana, cocaine or crack, heroin, methamphetamine (crystal meth), hallucinogens, ecstasy/MDMA?

- Daily or almost daily
- Weekly
- Monthly
- Less than Monthly
- Never -> Skip to Q23

Refused

a. In the past 3 months did you use marijuana (hash, weed)?

Yes

No

b. In the past 3 months, have you had a strong desire or urge to use marijuana at least once a week or more often?

Yes

No

c. In the past 3 months has anyone expressed concern about your use of marijuana?

Yes

No

d. In the past 3 months did you use cocaine, crack, or methamphetamine (crystal meth)?

Yes

No

e. In the past 3 months, did you use cocaine, crack, or methamphetamine (crystal meth) at least once a week or more often?

Yes

No

f. In the past 3 months has anyone expressed concern about your use of cocaine, crack, or methamphetamine (crystal meth)?

Yes

No

g. In the past 3 months did you use heroin?

Yes

No

h. In the past 3 months, have you tried and failed to control, cut down, or stop using an opiate pain reliever?

Yes

No

i. In the past 3 months has anyone expressed concern about your use of heroin?

Yes

No

23. In the past 12 months, how often have you used any prescription medications just for the feeling, more than prescribed or that were not prescribed for you?

Daily or almost daily

- Weekly
- Monthly
- Less than Monthly
- Never → Skip to Q24
- Refused

a. In the past 3 months, did you use a prescription opiate pain reliever (for example, Percocet, Vicodin), not as prescribed or that was not prescribed for you?

- Yes
- No

b. In the past 3 months, have you tried and failed to control, cut down, or stop using an opiate pain reliever?

- Yes
- No

c. In the past 3 months has anyone expressed concern about your use of an opiate pain reliever?

- Yes
- No

d. In the past 3 months did you use a medication for anxiety or sleep (for example Xanax, Ativan, or Klonopin) not as prescribed or that was not prescribed to you?

- Yes
- No

e. In the past 3 months, have you had a strong desire or urge to use medications for anxiety or sleep at least once a week or more often?

- Yes
- No

f. In the past 3 months has anyone expressed concern about your use of medication for anxiety or sleep?

- Yes
- No

g. In the past 3 months, did you use a medication for ADHD (for example, Adderall, Ritalin) not as prescribed or that was not prescribed for you?

- Yes
- No

h. In the past 3 months, did you use a medication for ADHD (for example, Adderall, Ritalin) at least once a week or more often?

- Yes
- No

- i. In the past 3 months has anyone expressed concern about your use of medication for ADHD (for example, Adderall or Ritalin)?
- Yes
- No
- j. In the past 3 months, did you use any other illegal or recreational drug (for example, ecstasy, molly, GHB, poppers, LSD, mushrooms, special K, bath salts, synthetic marijuana ('spice'), whip its, etc.)?
- Yes
- No
- k. In the past 3 months, what were the other drugs you used? (fill in response)

24. An (opioid/heroin) overdose is when someone turns blue, has little or no breathing, or passes out and can't be woken up without help, after using opioids. Have you ever had an opioid overdose?

- Yes
- No
- Refused

25. In the past three months, have you participated in any substance use treatment?

- Yes
- No
- Refused

25a. If "yes", which treatments? [Check all that apply]

- Detox
- Inpatient treatment (hospital)
- Residential treatment
- Outpatient treatment
- Counseling
- 12-Step program
- Other treatment for opioid addiction (Methadone, Buprenorphine, Naltrexone)
- Other (Specify): _____

SECTION VI: EXPOSURE TO VIOLENCE/VICTIMIZATION

Interviewer script: The next questions are about abuse and interpersonal violence. Let me know if you would like to stop at any point. As a study interviewer, I am not permitted to discuss any specific incidents of abuse with you, but there is someone on hand who can talk with you if you would like to do so.

26. Have you ever been in a situation in which you were seriously injured, or have you ever been in a situation in which you feared you might be seriously injured or killed?

- Yes
- No
- Refused

27. Before age 18, were you ever physically punished or beaten by a parent, caretaker, or teacher so that: you were very frightened; you thought you would be injured; or you received bruises, cuts, welts, lumps, or other injuries?

- Yes
- No
- Refused

28. Not including punishments or beatings you reported in question 27, have you ever been attacked, beaten, or mugged by anyone, including friends, family members, or strangers?

- Yes
- No
- Refused

29. Has anyone ever made or pressured you into having some type of unwanted sexual contact? Note: by sexual contact we mean any contact between someone else and your private parts or between you and someone else's private parts?

- Yes
- No
- Refused

30. Has a close family member or friend died violently, for example, in a serious car crash, mugging, or attack?

- Yes
- No
- Refused

31. Have you ever witnessed a situation in which someone was seriously injured or killed, or have you ever witnessed a situation in which you feared someone would be seriously injured or killed?

- Yes
- No
- Refused

SECTION VI: HEALTH-RELATED QUALITY OF LIFE³

32. Overall, how would you rate your health during the past 4 weeks?

- Excellent
- Very Good
- Good
- Fair
- Poor
- Very Poor

33. During the past 4 weeks, how much did physical health problems limit your usual physical activities (such as walking or climbing stairs)?

- Not at all

³ SF-8™ Health Survey © 1999, 2001 by QualityMetric Incorporated. All Rights Reserved.

- Very little
- Somewhat
- Quite a lot
- Could not do physical activities

34. During the past 4 weeks, how much difficulty did you have doing your daily work, both at home and away from home, because of your physical health?

- None at all
- A little bit
- Some
- Quite a lot
- Could not do daily work

35. How much bodily pain have you had during the past 4 weeks?

- None
- Very mild
- Mild
- Moderate
- Severe
- Very Severe

36. During the past 4 weeks, how much energy did you have?

- Very much
- Quite a lot
- Some
- A little
- None

37. During the past 4 weeks, how much did your physical health or emotional problems limit your usual social activities with family or friends?

- Not at all
- Very little
- Somewhat
- Quite a lot
- Could not do social activities

38. During the past 4 weeks, how much have you been bothered by emotional problems (such as feeling anxious, depressed or irritable)?

- Not at all
- Slightly
- Moderately
- Quite a lot
- Extremely

39. During the past 4 weeks, how much did personal or emotional problems keep you from doing your usual work, school, or other daily activities?

- Not at all
- Very little
- Somewhat
- Quite a lot
- Could not do daily activities

SECTION VII: Additional information

Is there anything else you would like you would like to share with us about you or your experiences living with HIV?
Open ended response option.

Follow-Up Survey

Intervention	Points where the follow-up survey will be administered to clients enrolled in this intervention			
	3 months post enrollment	6 months post enrollment	12 months post enrollment	18 months post enrollment
Integrating Buprenorphine Treatment into HIV primary care		X	X	X

Participant ID:

Staff ID:

Site ID:

Form Date:

Interviewer Script: Thank you for continuing to participate in this study. Today we are going to cover many topics, including your health, your needs, and your experiences with HIV health care. Some of these questions may be about things you've already discussed with other people at [NAME OF ORGANIZATION]. We are asking you again because this interview is part of a national study that includes people living with HIV from different parts of the country. The data we collect in this survey will not be shared with anyone providing services.

Everything I ask you in this interview is confidential. We would like you to feel comfortable, and be as honest and open as possible. None of your answers will be linked to your name, so please be candid. We hope this study will help us to improve care for people living with HIV.

If a question makes you feel uncomfortable, or brings up feelings or situations you want to talk about, we can refer you to someone you can speak with. Also, if there are any questions you don't feel comfortable answering, you don't have to answer them.

This interview will take less than 1 hour. If at any time you would like to take a break, please let me know. After each question I will read you response options to choose from. As I go through the questions, let me know if there is anything that is unclear. Are you ready to begin?

Interviewer note: DO NOT READ the response option "Refused" to the participant. Only mark this response if a person chooses to skip a question.

SECTION I: DEMOGRAPHICS & BACKGROUND CHARACTERISTICS

1. Including yourself, how many people live in your household? [One response only]

- One
- Two
- Three
- Four

- Five or more
- Refused

2. How many children under the age of 18 live in your house? [One response only]

- None
- One
- Two
- Three
- Four or more
- Refused

3. During the past 6 months, how many times did you run out of money for basic necessities like housing or food? [One response only]

- Never
- Daily
- Weekly
- Monthly
- Other (specify): _____
- Refused

4. How many times have you been incarcerated in a correctional facility (jail or prison) in the past 6 months for even just one night? _____ # times

5. What kind(s) of health insurance do you have? [Check all that apply]

- Medicaid
- Medicare
- A health plan through my state marketplace
- Private insurance through my employer or a family member's employer
- Other private insurance
- Tricare

- Veterans Administration
- Other (specify): _____
- Don't know
- Refused
- None

SECTION II: HOUSING

6. Where do you live now? *[One response only]*

- My own home/apartment (that I own or rent)
- Someone else's home/apartment (that someone else owns or rents)
- Residential or transitional housing
- Treatment program
- Shelter
- The streets/in a car/in a park/on the beach
- Jail
- Other (specify): _____

7. In the past 6 months, was there ever a time in which you had no place to stay, even if it was for just one night?
(Interviewer: After reading "In the past 3/6 months", include a time reference such as "since last spring...")

- Yes
- No
- Refused

SECTION III: HIV ADHERENCE

Interviewer Script: These next questions are taking HIV medications.

8. Are you currently taking any HIV medication? *[Show the HIV medication chart]*

- Yes
- No
- Don't know
- Refused

SECTION IV: CASE MANAGEMENT & COMPETING SERVICE NEEDS

9. Do you have an HIV case manager at this clinic? By case manager, we mean an individual who helps you get medical care and/or social services at this clinic. *Interviewer: The interventionist is NOT considered a case manager.*

- Yes
- No
- Don't know
- Refused

Interviewer Script: Now we are going to ask you about services you may have needed in the last 6 months. First we will ask if you needed the service and then if you got that service. **[Interviewer Instructions:** for each service (a, b, c....below) ask question #10 first; Check one response only.]

	10. Did you need this service at any time over the last 6 months?		11. Were you able to get this service in the last 6 months?	
	No	Yes	No	Yes
a) Housing assistance (e.g. permanent, temporary, emergency shelter, residential treatment facilities)				
b) Transportation assistance				
c) Assistance in applying for benefits (SSI, SSD, insurance, etc.)				
d) Assistance getting substance use treatment and/or mental health treatment/counseling				
e) Medication assistance (paying for medication, help with prescriptions)				
f) Assistance getting medical care				
g) Did you need any other assistance with services over the past 6 months? Please specify _____				

SECTION V: SUBSTANCE USE⁴

13. In the past 6 months, how often have you used any tobacco product?

- Daily or almost daily
- Weekly
- Monthly
- Less than Monthly
- Never-> Skip to Q14
- Refused-> Skip to Q14

a. In the past 3 months, did you smoke a cigarette containing tobacco?

- Yes
- No

b. In the past 3 months, did you usually smoke more than 10 cigarettes each day?

- Yes
- No

c. In the past 3 months did you usually smoke within 30 minutes after waking?

- Yes
- No

14. In the past 6 months, how often have you had 5 or more drinks (men)/4 or more drinks (women) containing alcohol in one day?

- Daily or almost daily
- Weekly
- Monthly
- Less than Monthly
- Never-> Skip to Q15
- Refused-> Skip to Q15

a. In the past 3 months, did you have a drink containing alcohol?

- Yes
- No

b. In the past 3 months, did you have 5 or more drinks containing alcohol in a day?

- Yes
- No

c. In the past 3 months have you tried and failed to control, cut down, or stop drinking?

- Yes
- No

d. In the past 3 months, has anyone expressed concern about your drinking?

⁴ TAPS Scale from Wu et al., 2016

- Yes
- No

15. In the past 6 months, how often have you used any drugs including marijuana, cocaine or crack, heroin, methamphetamine (crystal meth), hallucinogens, ecstasy/MDMA?

- Daily or almost daily
- Weekly
- Monthly
- Less than Monthly
- Never-> Skip to Q16
- Refused -> Skip to Q16

a. In the past 3 months did you use marijuana (hash, weed)?

- Yes
- No

b. In the past 3 months, have you had a strong desire or urge to use marijuana at least once a week or more often?

- Yes
- No

c. In the past 3 months has anyone expressed concern about your use of marijuana?

- Yes
- No

d. In the past 3 months did you use cocaine, crack, or methamphetamine (crystal meth)?

- Yes
- No

e. In the past 3 months, did you use cocaine, crack, or methamphetamine (crystal meth) at least once a week or more often?

- Yes
- No

f. In the past 3 months has anyone expressed concern about your use of cocaine, crack, or methamphetamine (crystal meth)?

- Yes
- No

g. In the past 3 months did you use heroin?

- Yes
- No

h. In the past 3 months, have you tried and failed to control, cut down, or stop using an opiate pain reliever?

- Yes
- No

i. In the past 3 months has anyone expressed concern about your use of heroin?

- Yes
- No

16. In the past 6 months, how often have you used any prescription medications just for the feeling, more than prescribed or that were not prescribed for you?

- Daily or almost daily
- Weekly
- Monthly
- Less than Monthly
- Never -> Skip to Q17
- Refused -> Skip to Q17

a. In the past 3 months, did you use a prescription opiate pain reliever (for example, Percocet, Vicodin), not as prescribed or that was not prescribed for you?

- Yes
- No

b. In the past 3 months, have you tried and failed to control, cut down, or stop using an opiate pain reliever?

- Yes
- No

c. In the past 3 months has anyone expressed concern about your use of an opiate pain reliever?

- Yes
- No

d. In the past 3 months did you use a medication for anxiety or sleep (for example Xanax, Ativan, or Klonopin) not as prescribed or that was not prescribed to you?

- Yes
- No

e. In the past 3 months, have you had a strong desire or urge to use medications for anxiety or sleep at least once a week or more often?

- Yes
- No

f. In the past 3 months has anyone expressed concern about your use of medication for anxiety or sleep?

- Yes
- No

- g. In the past 3 months, did you use a medication for ADHD (for example, Adderall, Ritalin) not as prescribed or that was not prescribed for you?**
- Yes
 No
- h. In the past 3 months, did you use a medication for ADHD (for example, Adderall, Ritalin) at least once a week or more often?**
- Yes
 No
- i. In the past 3 months has anyone expressed concern about your use of medication for ADHD (for example, Adderall or Ritalin)?**
- Yes
 No
- j. In the past 3 months, did you use any other illegal or recreational drug (for example, ecstasy, molly, GHB, poppers, LSD, mushrooms, special K, bath salts, synthetic marijuana ('spice'), whip its, etc.)?**
- Yes
 No
- k. In the past 3 months, what we the other drugs you used? (fill in response)**

17. An (opioid/heroin) overdose is when someone turns blue, has little or no breathing, or passes out and can't be woken up without help, after using opioids. Have you had an opioid overdose in the past 6 months?

- Yes
 No
 Refused

18. In the past 6 months, have you received Narcan to have on hand to use if needed?

- Yes
 No
 Refused

SECTION VI: HEALTH-RELATED QUALITY OF LIFE⁵

19. Overall, how would you rate your health during the past 4 weeks?

- Excellent
 Very Good
 Good
 Fair

⁵ SF-8™ Health Survey © 1999, 2001 by QualityMetric Incorporated. All Rights Reserved.

- Poor
- Very Poor

20. During the past 4 weeks, how much did physical health problems limit your usual physical activities (such as walking or climbing stairs)?

- Not at all
- Very little
- Somewhat
- Quite a lot
- Could not do physical activities

21. During the past 4 weeks, how much difficulty did you have doing your daily work, both at home and away from home, because of your physical health?

- None at all
- A little bit
- Some
- Quite a lot
- Could not do daily work

22. How much bodily pain have you had during the past 4 weeks?

- None
- Very mild
- Mild
- Moderate
- Severe
- Very Severe

23. During the past 4 weeks, how much energy did you have?

- Very much
- Quite a lot

- Some
- A little
- None

24. During the past 4 weeks, how much did your physical health or emotional problems limit your usual social activities with family or friends?

- Not at all
- Very little
- Somewhat
- Quite a lot
- Could not do social activities

25. During the past 4 weeks, how much have you been bothered by emotional problems (such as feeling anxious, depressed or irritable)?

- Not at all
- Slightly
- Moderately
- Quite a lot
- Extremely

26. During the past 4 weeks, how much did personal or emotional problems keep you from doing your usual work, school, or other daily activities?

- Not at all
- Very little
- Somewhat
- Quite a lot
- Could not do daily activities

SECTION VII: PATIENT FEEDBACK

Interviewer script: Please rate your experience with the clinic/health care provider that you interacted with most frequently in the past 6 months.

**27. At this clinic, who is the person you have interacted with most frequently in the past 6 months? _____
(name of interventionist)**

How good was that person at:	Poor	Fair	Good	Very Good	Excellent	N/A
28. Making you feel at ease (introducing him/herself, explaining his/her position, being friendly and warm towards you, treating you with respect, not being cold and abrupt)						
29. Letting you tell your “story” (giving you time to fully describe your condition in your own words, not interrupting, rushing, or diverting you)						
30. Really listening (paying close attention to what you were saying, not looking at the notes or computer as you were talking)						
31. Being interested in you as a whole person (asking/knowing relevant details about your life and your situation, not treating you as “just a number”)						
32. Fully understanding your concerns (communicating that he/she had accurately understood your concerns, not overlooking or dismissing anything)						
33. Showing care and compassion (seeming genuinely concerned, connecting with you on a human level, not being indifferent or “detached”)						
34. Being optimistic (having a positive approach and a positive attitude, being honest but not negative about your problems)						
35. Explaining things clearly (fully answering your questions, explaining clearly, giving you adequate information, not being vague)						
36. Helping you to take control (exploring with you what you can do to improve yourself, encouraging rather than “lecturing” you)						
37. Making a plan of action with you (discussing the options, involving you in the decisions as much as you want to be involved, not ignoring your views)						

38. When I think about my care at this clinic, these words come to mind (check all that apply): Interviewer: read the words below and check those that the participant agrees with. Then ask the participant if there are any additional words s/he would like to add.

Excellent	Rushed
Adequate	Impersonal
Terrible	Cold
OK	Warm
Poor	Dignified
Busy	Respectful
Personal	Humiliating
Caring	Scary
Friendly	Understanding
Safe	Other (write in)
N/A	Other 2 (write in)

39. In the past 6 months, were you treated with courtesy and respect at this clinic?

- Never
- Rarely
- Sometimes
- Usually
- Always

(If answer is “never” or “rarely”, continue to question 40. If answer is “sometimes”, “usually”, or “always”, skip to 41)

40. If you answered “never” or “rarely”, please help us understand why by checking any off the reasons why you feel you may not have been treated with respect and courtesy.

	Yes	No	N/A
My race			
My age			
My gender/sex			
My sexual orientation			
My drug use			
My immigration status			
My difficulty speaking English			
Other:			

For each of the following statements, please rate your level of agreement or disagreement with your experiences at this clinic:

	Completely Agree	Somewhat Agree	Not sure	Somewhat Disagree	Completely Disagree	N/A
41. Appointments for HIV care fit with your schedule						

42. Waiting time at the clinic is not too long						
43. You have enough time with your HIV doctor						
44. You have enough time with your nurse						
45. You have enough time with other clinic staff						
46. The quality of HIV care is good						
47. Support services offered or provided meet your needs						
48. The clinic is helping you with your mental health needs						
49. The clinic is helping you with your substance use issues						

50. I would recommend this clinic to other HIV-positive patients with similar needs:

- Yes
- Maybe/Not sure
- No

SECTION VII: CURRENT DRUG USE

In the past 6 months, how have the following reduced or stopped your drug use?

	Not at all	Very little	Some what	Quite a lot	Completely	N/A
51. Taking buprenorphine						
52. Visits with the nurse						
53. Visits with the doctor						
54. Visits with the coordinator						
55. Visits with a substance use counselor						
56. Group counseling and/or support groups						

57. Support services offered or provided						
--	--	--	--	--	--	--

58. Do you think your dose of buprenorphine is:

- Too much
- Just right
- Too little
- I'm not taking buprenorphine right now

59. How do you feel about the number of take home doses you get?

- I don't have take home doses
- Too few
- Just right
- Too many
- I'm not taking buprenorphine right now

SECTION IX: ADDITIONAL FEEDBACK

60. What else you would like to share with us about you or your experiences living with HIV in the past few months?

Appendix J: Administering the Patient Baseline and Follow-Up Surveys

Section by Section Guidance for the Participant Questionnaire

Participant Interview Administration: Beginning the Interview

Data Manager Script:

Thank you for agreeing to participate in this evaluation. We are going to cover many topics, including your health, your needs, and your experiences with HIV health care. Some of these questions may be about things you've already discussed with other people at [NAME OF ORGANIZATION]. We hope this study will help us to improve care for people with HIV. The data we collect in this survey will not be shared with anyone providing services.

Everything I ask you in this interview is confidential. We would like you to feel comfortable, and be as honest and open as possible. None of your answers will be linked to your name, so please be candid.

If a question makes you feel uncomfortable, or brings up feelings or situations you want to talk about, we can refer you to someone you can speak with. Also, if there are any questions you don't feel comfortable answering, you don't have to answer them.

This interview will take less than 1 hour. If at any time you would like to take a break, please let me know. After each question, I will read you response options to choose from. As I go through the questions, let me know if there is anything that is unclear. Are you ready to begin?

Baseline Questionnaire

Section I: Demographic & Background Characteristics

Q1. *Date or Year of Birth.* Enter the two-digit month, the two-digit day and the four-digit year for the participant's date of birth (MM-DD-YYYY).

Q2. *Current Gender Identity.* Ask the participant to choose one of the response options for current gender identity.

Q3. *Hispanic, Latino/a, or Spanish origin.* Ask if the participant considers herself to be of Hispanic, Latino/a or Spanish origin.

Q4 a-e. *Racial/Ethnic Background.* Ask the participant to answer "yes" or "no" to each of categories listed.

Q5. *Language.* Ask the participant which language she speaks the majority of the time with family and friends. If the participant responds that they are bilingual, ask if there is one language they prefer; or if they continue to say bilingual mark "Other" record bilingual and the respective languages.

Q6. *Birth Country.* Ask the participant what country they were born in.

Q7. *Education.* Ask the participant what the highest level of education is that they have completed.

- "Some college" refers to having completed some (but not all) of a four-year college or university program
- "College graduate" refers to completion of a four-year college or university program.

Q8. *Household.* Ask the participant to describe their household by telling you how many adults and dependents (children, elderly, or individuals living with disabilities that are legally dependents) they live with.

Q9. *Children.* Ask the participant to describe how many children under the age of 18 they live with.

Q10. *Basic Necessities.* Ask the participant to choose the one response option that they feel most accurately describes how frequently they have run out of basic necessities in the past six months.

Q11. *Incarceration*. Ask the participant how many times they have been in jail or prison in the past five years, even if it was just for one night. If response is none or never enter "0".

Q12. *Insurance*. Record the kind of health insurance the participant has and make sure to check all that apply. If the participant mentions a local Medicaid plan i.e. MEDI-CAL, please check "Medicaid". If you are unsure if the insurance falls into a specific category, just mark "Other" and fill in the name of the insurance mentioned by the participant. These can be recoded at a later time. ****Ryan White is NOT considered an insurance****

Section II: Housing

Q13. *Live Now*. Ask the participant where they live right now. Record one response.

Q14. *Locations of Stay*. Ask the participant if in the past 12 months there was a time (even for just one night) where they had no place to stay.

Section III: HIV & Adherence

Q15. *Date of HIV Diagnosis*. Enter month, day, and year for when the participant first tested positive for HIV (MM-DD-YYYY). If the participant cannot recall the month enter "01," if the participant cannot recall the day enter "01." If the participant cannot recall the exact year, prompt by asking if they recall approximately how old they were and/or if they can recall other life events that took place around the same time.

FAQ: What if someone doesn't know the exact date of their diagnosis, and they only know their year of diagnosis?
Answer: Enter January 1 as the date, and then enter the year that the patient reports.

Q15a. *Perinatal Infection*. Ask the participant if they were infected perinatally (infected at birth).

Q16. *Currently Taking HIV Medications*. Ask the participant if they are presently taking HIV medication.

Section IV: Case Management & Competing Service Needs

Q17. *Case Manager*. Ask participant if they have a case manager at this clinic that helps with medical OR social services—including HIV health care and housing services (****This is NOT the intervention staff, i.e. the Clinical Coordinator**).

Q18-19. *Service Needs*. Ask the participant whether they have needed each of the listed services (Q18a-g) in the past 6 months. For each of these items that the participant responds "Yes", ask the follow-up question that appears (Q19a-g), i.e. if the participant was able to receive the service needed. Follow this process for each of the listed services (Q19a-g).

BREAK: Ask the participant if they would like to take a break. The participant can use this opportunity to use the restroom, have a snack, or drink some water. If they feel comfortable continuing, proceed to the following section.

Section V: Substance Use

Q20-Q23. *Substance Use History*. Ask the participant if they have used the substances identified in each question. Record the answer "daily or almost daily", "weekly", "monthly", "less than monthly", or "never". If the participant does not want to answer the question, mark "refused".

Q24. *Overdose history*. Ask the participant if they have experienced an opioid overdose.

Q25-25a. *Substance Use Treatment*. Ask the participant if they have participated in any substance use treatment in the 3 months. If the participant answers "yes", ask the participant what kind of treatment. Ask the participant to listen to all of the options and record all of the responses that are applicable for the type of substance use treatments. Ask the

participant if there are any other substance use treatments that they participated in, mark “other” and record the response.

Section VI: Exposure to Violence/Victimization

Before starting the section, read the following statement to the participant: The next questions are about abuse and interpersonal violence. Let me know if you would like to stop at any point. As a study interviewer, I am not permitted to discuss any specific incidents of abuse with you, but there is someone on hand who can talk with you if you would like to do so.

Q25-31. *Exposure to Violence/Victimization.* Read each question as written, and ask the participant if they have ever been experienced that situation. Record the answer “yes” or “no”. If the participant does not want to answer the question, mark “refused”.

Section VI: Health-Related Quality of Life

Q32. *Self-Perceived General Health.* Ask the participant how they would rate their general health during the past 4 weeks. Read the question and response options exactly as written.

Q33-36. *Health-Related Limitations to Daily Activities.* Ask how the participant’s health is limiting their daily activities during the past 4 weeks. Read each question and its corresponding response options exactly as written.

Q37-39. *Emotional Well-Being.* Ask about the participant’s energy level, how the participant’s physical and/or emotional health is limiting their daily activities, and the impact of her personal or emotional problems during the past 4 weeks. Read each question and its corresponding response options exactly as written.

Section VII: Additional Information

Q40. *Any other information.* Ask the participant if they would like to share anything else about their experience living with HIV. Record the response as accurately and completely as possible.

Follow-up Questionnaire

Section I: Demographic & Background Characteristics

Q1. *Household.* Ask the participant to describe their household by telling you how many adults and dependents (children, elderly, or individuals living with disabilities that are legally dependents) they live with.

Q2. *Children.* Ask the participant to describe how many children under the age of 18 they live with.

Q3. *Basic Necessities.* Ask the participant to choose the one response option that they feel most accurately describes how frequently they have run out of basic necessities in the past 3 months.

Q4. *Incarceration.* Ask the participant how many times they have been in incarcerated in the past 6 months, even if it was just for one night. If response is none or never enter “0”. If the participant reports that they have been in jail or prison, mark the number of times.

Q5. *Insurance.* Record the kind of health insurance the participant has and make sure to check all that apply. If the participant mentions a local Medicaid plan i.e. MEDI-CAL, please check "Medicaid". If you are unsure if the insurance falls into a specific category, just mark "Other" and fill in the name of the insurance mentioned by the participant. These can be recoded at a later time. **Ryan White is NOT considered an insurance**

Section II: Housing

Q6. *Live Now.* Ask the participant where they live right now. Record one response.

Q7. *Locations of Stay.* Ask the participant if in the past 3 months there was a time (even for just one night) where they had no place to stay.

Section III: HIV & Adherence

Q8. *Currently Taking HIV Medications.* Ask the participant if they are presently taking HIV medication.

Section IV: Case Management & Competing Service Needs

Q9. *Case Manager.* Ask participant if they have a case manager at this clinic that helps with medical OR social services—including HIV health care and housing services (****This is NOT the intervention staff, i.e. the Clinical Coordinator.**)

Q10-11. *Service Needs.* Ask the participant whether they have needed each of the listed services (Q10a-g) in the past 3 months. For each of these items that the participant responds "Yes", ask the follow-up question that appears (Q11a-g), i.e. if the participant was able to receive the service needed. Follow this process for each of the listed services (Q11a-g).

BREAK: Ask the participant if they would like to take a break. The participant can use this opportunity to use the restroom, have a snack, or drink some water. If they feel comfortable continuing, proceed to the following section.

Section V: Substance Use

Q12-15. *Substance Use History.* Ask the participant if they have used the substances identified in each question in the past 3 months. Record the answer "daily or almost daily", "weekly", "monthly", "less than monthly", or "never". If the participant does not want to answer the question, mark "refused".

Q16. *Overdose History.* Ask the participant if they have experienced an opioid overdose.

Q17. *Substance Use Treatment.* Ask the participant if they have participated in any substance use treatment in the past 3 months. If the participant answers "yes", ask the participant what kind of treatment. Ask the participant to listen to all of the options and record all of the responses that are applicable for the type of substance use treatments. Ask the participant if there are any other substance use treatments that they have participated in, mark "other" and record the response.

Section VI: Health-Related Quality of Life

Q18. *Self-Perceived General Health.* Ask the participant how they would rate their general health during the past 4 weeks. Read the question and response options exactly as written.

Q19-22. *Health-Related Limitations to Daily Activities.* Ask how the participant's health is limiting their daily activities during the past 4 weeks. Read each question and its corresponding response options exactly as written.

Q23-25. *Emotional Well-Being.* Ask about the participant's energy level, how the participant's physical and/or emotional health is limiting their daily activities, and the impact of their personal or emotional problems during the past 4 weeks. Read each question and its corresponding response options exactly as written.

Section VII: Patient Feedback

Q26. *Identify Interventionist.* Ask the participant for the name of the interventionist that the participant has interacted with most frequently over the past three months.

Q27-36. *Interventionist Feedback.* Based on the response to Q31, ask the participant to rate the interventionist identified in Q31 using response options of "poor", "fair", "good", "very good", or "excellent". If interventionist did not provide the service identified in Q32-41, mark "n/a".

Q37. *Care at the Clinic*. Ask the participant to identify all of the words that come to mind when thinking about their care at the clinic. Read the participant the words in the list provided on the survey, and then ask if they would like to identify additional words. Mark those additional words in the “other” write in boxes.

Q38-39. *Courtesy and Respect*. Ask the participant if she was treated with respect at the clinic. If answer is “never” or “rarely”, continue to question 44. If answer is “sometimes”, “usually”, or “always”, skip to 45. For Q44, ask the participant to identify the reasons why they felt as though they were not treated with respect and courtesy by reading the response options listed. If a participant feels as though they were not treated with respect and courtesy for reasons that were not listed on the survey, write in the participant’s response in “Other”.

Q40-48. *Clinic Experiences*. For each question listed, ask the participant for their level of agreement with the experiences at the clinic over 3 months. If the participant did not experience one of the experiences listed, mark “n/a”.

Q49. *Recommending the Clinic*. Ask the participant if they would recommend the clinic to other patients living with HIV with similar needs.

Section VIII: Current Drug Use

Q50-56. *Impact of Support Systems*. Ask the participant about the impact of the listed support systems in reducing or stopping their drug use.

Q57-58. *Buprenorphine Feedback*. Ask the participant about their dose of buprenorphine.

Section IX: Additional Feedback

Q55. *Additional Feedback*. Ask the participant if they would like to share anything else about their experiences living with HIV.

Appendix K: Medical Chart Abstraction Form

Baseline Chart Review

Today's Date (mm/dd/yyyy): ____/____/____ Staff ID ____

Participant ID _____ Site ID _____

Date of study enrollment (date of signed study consent form): (mm/dd/yyyy): ____/____/____

Chart Review Period 6 months 12 months 18 months

Participant's HIV/AIDS Diagnosis Dates:

HIV diagnosis date:

1.0a	Date (mm/dd/yyyy) ____/____/____ <input type="checkbox"/> Patient report <input type="checkbox"/> Lab test

1.0b Was this patient perinatally infected? Yes No Unknown

AIDS diagnosis date:

1.0c	Date (mm/dd/yyyy) ____/____/____ <input type="checkbox"/> N/A
------	--

Date of LAST HIV primary care visit PRIOR to enrollment:

2.0	Date (mm/dd/yyyy) ____/____/____ <input type="checkbox"/> N/A
-----	--

Participant is newly diagnosed.

Participant is not newly diagnosed but is new to this clinic.

Hepatitis C Diagnosis:

3.0 Is the patient currently positive for Hepatitis C? Y/N/Unknown

3.1 If yes, is your clinic currently treating the patient for Hepatitis C? Y/N/Unknown

CD4 Lab Values and Dates After Enrollment:

Please list the participant's CD4 lab dates and values starting with the first date following study enrollment.

	Date of CD4 Lab Test		CD4 Lab Values		
4.0a	Date (mm/dd/yyyy) ____/____/____	3.0b	_____/mm ³ <input type="checkbox"/> Data pending <input type="checkbox"/> QNS	3.0c	_____%
4.1a	Date (mm/dd/yyyy) ____/____/____	3.1b	_____/mm ³ <input type="checkbox"/> Data pending <input type="checkbox"/> QNS	3.1c	_____%
4.2a	Date (mm/dd/yyyy) ____/____/____	3.2b	_____/mm ³ <input type="checkbox"/> Data pending <input type="checkbox"/> QNS	3.2c	_____%
4.3a	Date (mm/dd/yyyy) ____/____/____	3.3b	_____/mm ³ <input type="checkbox"/> Data pending <input type="checkbox"/> QNS	3.3c	_____%

No CD4 lab data was collected or recorded in the chart during this time period

***QNS = Quantity Not Sufficient**

Viral Load Lab Values and Dates After Enrollment:

Please list the participant's viral load lab dates and values starting with the first date following study enrollment.

	Date of Viral Load Lab Test		Viral Load Lab Values
5.0a	Date (mm/dd/yyyy) ____/____/____	4.0b	_____/copies/mL <input type="checkbox"/> Data pending <input type="checkbox"/> QNS <input type="checkbox"/> Undetectable
5.1a	Date (mm/dd/yyyy) ____/____/____	4.1b	_____/copies/mL <input type="checkbox"/> Data pending <input type="checkbox"/> QNS <input type="checkbox"/> Undetectable
5.2a	Date (mm/dd/yyyy) ____/____/____	4.2b	_____/copies/mL <input type="checkbox"/> Data pending <input type="checkbox"/> QNS <input type="checkbox"/> Undetectable
5.3a	Date (mm/dd/yyyy) ____/____/____	4.3b	_____/copies/mL <input type="checkbox"/> Data pending <input type="checkbox"/> QNS <input type="checkbox"/> Undetectable

No viral load lab data was collected or recorded in the chart during this time period

HIV Primary Care Medical Visits and Dates After Enrollment: For each 3-month period listed below, please document the dates of each HIV primary care medical visit at this clinic. A primary care medical visit is defined as a visit with a prescribing provider (MD, DO, PA, or NP) who is monitoring the patient's HIV lab values and HIV care. This does not

include nursing visits, specialists, or hospital ER or inpatient visits. Data should be collected from electronic or paper charts.

	Primary Care Medical Visits		Primary Care Medical Visits
	Months 1 - 3 _____		Months 4 - 6 _____
6.0a	Date (mm/dd/yyyy) ____/____/____	6.0b	Date (mm/dd/yyyy) ____/____/____
6.1a	Date (mm/dd/yyyy) ____/____/____	6.1b	Date (mm/dd/yyyy) ____/____/____
6.2a	Date (mm/dd/yyyy) ____/____/____	6.2b	Date (mm/dd/yyyy) ____/____/____
6.3a	Date (mm/dd/yyyy) ____/____/____	6.3b	Date (mm/dd/yyyy) ____/____/____
6.4a	Date (mm/dd/yyyy) ____/____/____	6.4b	Date (mm/dd/yyyy) ____/____/____
	No primary care visits were recorded in the chart during this time period <input type="checkbox"/>		No primary care visits were recorded in the chart during this time period <input type="checkbox"/>

HIV Health Care Visits: For each 3-month period listed below, please document the total number of HIV health care visits for each provider. An HIV health care visit is defined as a visit with a non-prescribing provider who is providing supportive medical care, nursing, counseling, education, or management. Data should be collected from electronic or paper charts. For jail interventions: Use this section to record visits that occurred while the participant was NOT IN JAIL.

	Health Care Visits		Health Care Visits
	Months 1 - 3 _____		Months 4 - 6 _____

7.0a	Nurse # of visits _____ <input type="checkbox"/> No visits recorded in this period	7.0b	Nurse # of visits _____ <input type="checkbox"/> No visits recorded in this period
7.1a	Medical Case Manager # of visits _____ <input type="checkbox"/> No visits recorded in this period	7.1b	Medical Case Manager # of visits _____ <input type="checkbox"/> No visits recorded in this period
7.2a	Pharmacist # of visits _____ <input type="checkbox"/> No visits recorded in this period	7.2b	Pharmacist # of visits _____ <input type="checkbox"/> No visits recorded in this period
7.3a	Social Worker # of visits _____ <input type="checkbox"/> No visits recorded in this period	7.3b	Social Worker # of visits _____ <input type="checkbox"/> No visits recorded in this period
7.4a	Mental Health Counselor # of visits _____ <input type="checkbox"/> No visits recorded in this period	7.4b	Mental Health Counselor # of visits _____ <input type="checkbox"/> No visits recorded in this period
7.5a	Substance Abuse Counselor # of visits _____ <input type="checkbox"/> No visits recorded in this period	7.5b	Substance Abuse Counselor # of visits _____ <input type="checkbox"/> No visits recorded in this period
7.6a	Psychiatrist # of visits _____ <input type="checkbox"/> No visits recorded in this period	7.6b	Psychiatrist # of visits _____ <input type="checkbox"/> No visits recorded in this period
7.7a	Other (please specify) _____ # of visits _____ <input type="checkbox"/> No visits recorded in this period	7.7b	Other (please specify) _____ # of visits _____ <input type="checkbox"/> No visits recorded in this period

HIV Antiretroviral Therapy

8.0a	Has this person been prescribed antiretroviral therapy at any time in the past 12 months? (Note: this includes new and existing/refill prescriptions)	<input type="checkbox"/> Yes <input type="checkbox"/> No	8.0b	Date (mm/dd/yyyy) of prescription ____/____/_____ (Please enter the most recent date of prescription) How many refills? _____
------	---	---	------	--

Mental Health and Substance Use Disorders:

9. Has the participant ever been diagnosed with mental health condition(s)?
 Yes No No medical records available prior to study enrollment

9a. If yes, what conditions? (Check all that apply)

- Depression Anxiety Bi-Polar Psychosis
 Other, specify: _____

10. Has the participant ever been diagnosed with a substance use disorder?
 Yes No No medical records available prior to study enrollment

10a. If yes, what substances? (Check all that apply)

- Alcohol Crack/Cocaine Opioids Marijuana Methamphetamine
 Benzodiazepine Nicotine Other, specify: _____

Internal Referrals: *This section refers to participant referrals to services that are housed in your agency and would be recorded in the participant's chart.*

11. Since enrolling in this study, was the participant referred for mental health services **within** your agency?
 Yes No N/A If yes, how many visits did the participant attend? _____

12. Since enrolling in this study, was the participant referred for substance abuse treatment services (including residential treatment) **within** your agency?
 Yes No N/A

If yes, how many visits did the participant attend? _____ (outpatient services only)

- Check here if the substance abuse treatment was residential treatment

External Referrals: *This section refers to participant referrals to services that are housed outside of your agency and would be recorded in the participant chart.*

13. Since enrolling in this study, was the participant referred for mental health services **outside of** your agency?
 Yes No N/A

If yes, how many visits did the participant attend? _____

Not recorded in the chart

14. Since enrolling in this study, was the participant referred for substance abuse treatment services (including residential treatment) **outside of** your agency?
 Yes No N/A

If yes, how many visits did the participant attend? _____ (outpatient services only)

Not recorded in the chart

Check here if the substance abuse treatment was residential treatment

15. Name of data sources

- CareWare or other Ryan White data management system
- Electronic Health Record (type): _____
- Other (please describe): _____

Urine Toxicology Test and Dates:

Please list the participant's urine toxicology dates and results starting with the first date following study enrollment.

	Date of Urine Toxicology Test		Results
B1.a	Date (mm/dd/yyyy) ____/____/____	Opiate: Cocaine: Benzodiazepine: Amphetamine: Cannabinoid: Oxycodone: Buprenorphine: Methadone:	<input type="checkbox"/> positive <input type="checkbox"/> negative <input type="checkbox"/> N/A <input type="checkbox"/> confirmed <input type="checkbox"/> positive <input type="checkbox"/> negative <input type="checkbox"/> N/A <input type="checkbox"/> confirmed <input type="checkbox"/> positive <input type="checkbox"/> negative <input type="checkbox"/> N/A <input type="checkbox"/> confirmed <input type="checkbox"/> positive <input type="checkbox"/> negative <input type="checkbox"/> N/A <input type="checkbox"/> confirmed <input type="checkbox"/> positive <input type="checkbox"/> negative <input type="checkbox"/> N/A <input type="checkbox"/> confirmed <input type="checkbox"/> positive <input type="checkbox"/> negative <input type="checkbox"/> N/A <input type="checkbox"/> confirmed <input type="checkbox"/> positive <input type="checkbox"/> negative <input type="checkbox"/> N/A <input type="checkbox"/> confirmed
B1.b	Date (mm/dd/yyyy) ____/____/____	Opiate: Cocaine: Benzodiazepine: Amphetamine: Cannabinoid: Oxycodone: Buprenorphine: Methadone:	<input type="checkbox"/> positive <input type="checkbox"/> negative <input type="checkbox"/> N/A <input type="checkbox"/> confirmed <input type="checkbox"/> positive <input type="checkbox"/> negative <input type="checkbox"/> N/A <input type="checkbox"/> confirmed <input type="checkbox"/> positive <input type="checkbox"/> negative <input type="checkbox"/> N/A <input type="checkbox"/> confirmed <input type="checkbox"/> positive <input type="checkbox"/> negative <input type="checkbox"/> N/A <input type="checkbox"/> confirmed <input type="checkbox"/> positive <input type="checkbox"/> negative <input type="checkbox"/> N/A <input type="checkbox"/> confirmed <input type="checkbox"/> positive <input type="checkbox"/> negative <input type="checkbox"/> N/A <input type="checkbox"/> confirmed <input type="checkbox"/> positive <input type="checkbox"/> negative <input type="checkbox"/> N/A <input type="checkbox"/> confirmed <input type="checkbox"/> positive <input type="checkbox"/> negative <input type="checkbox"/> N/A <input type="checkbox"/> confirmed
B1.c	Date (mm/dd/yyyy) ____/____/____	Opiate: Cocaine: Benzodiazepine: Amphetamine: Cannabinoid: Oxycodone: Buprenorphine: Methadone:	<input type="checkbox"/> positive <input type="checkbox"/> negative <input type="checkbox"/> N/A <input type="checkbox"/> confirmed <input type="checkbox"/> positive <input type="checkbox"/> negative <input type="checkbox"/> N/A <input type="checkbox"/> confirmed <input type="checkbox"/> positive <input type="checkbox"/> negative <input type="checkbox"/> N/A <input type="checkbox"/> confirmed <input type="checkbox"/> positive <input type="checkbox"/> negative <input type="checkbox"/> N/A <input type="checkbox"/> confirmed <input type="checkbox"/> positive <input type="checkbox"/> negative <input type="checkbox"/> N/A <input type="checkbox"/> confirmed <input type="checkbox"/> positive <input type="checkbox"/> negative <input type="checkbox"/> N/A <input type="checkbox"/> confirmed <input type="checkbox"/> positive <input type="checkbox"/> negative <input type="checkbox"/> N/A <input type="checkbox"/> confirmed <input type="checkbox"/> positive <input type="checkbox"/> negative <input type="checkbox"/> N/A <input type="checkbox"/> confirmed
B1.d	Date (mm/dd/yyyy) ____/____/____	Opiate: Cocaine: Benzodiazepine: Amphetamine: Cannabinoid: Oxycodone: Buprenorphine: Methadone:	<input type="checkbox"/> positive <input type="checkbox"/> negative <input type="checkbox"/> N/A <input type="checkbox"/> confirmed <input type="checkbox"/> positive <input type="checkbox"/> negative <input type="checkbox"/> N/A <input type="checkbox"/> confirmed <input type="checkbox"/> positive <input type="checkbox"/> negative <input type="checkbox"/> N/A <input type="checkbox"/> confirmed <input type="checkbox"/> positive <input type="checkbox"/> negative <input type="checkbox"/> N/A <input type="checkbox"/> confirmed <input type="checkbox"/> positive <input type="checkbox"/> negative <input type="checkbox"/> N/A <input type="checkbox"/> confirmed <input type="checkbox"/> positive <input type="checkbox"/> negative <input type="checkbox"/> N/A <input type="checkbox"/> confirmed <input type="checkbox"/> positive <input type="checkbox"/> negative <input type="checkbox"/> N/A <input type="checkbox"/> confirmed <input type="checkbox"/> positive <input type="checkbox"/> negative <input type="checkbox"/> N/A <input type="checkbox"/> confirmed
B1.e	Date (mm/dd/yyyy) ____/____/____	Opiate: Cocaine: Benzodiazepine: Amphetamine:	<input type="checkbox"/> positive <input type="checkbox"/> negative <input type="checkbox"/> N/A <input type="checkbox"/> confirmed <input type="checkbox"/> positive <input type="checkbox"/> negative <input type="checkbox"/> N/A <input type="checkbox"/> confirmed <input type="checkbox"/> positive <input type="checkbox"/> negative <input type="checkbox"/> N/A <input type="checkbox"/> confirmed <input type="checkbox"/> positive <input type="checkbox"/> negative <input type="checkbox"/> N/A <input type="checkbox"/> confirmed

		Cannabinoid:	<input type="checkbox"/> positive	<input type="checkbox"/> negative	<input type="checkbox"/> N/A	<input type="checkbox"/> confirmed
		Oxycodone:	<input type="checkbox"/> positive	<input type="checkbox"/> negative	<input type="checkbox"/> N/A	<input type="checkbox"/> confirmed
		Buprenorphine:	<input type="checkbox"/> positive	<input type="checkbox"/> negative	<input type="checkbox"/> N/A	<input type="checkbox"/> confirmed
		Methadone:	<input type="checkbox"/> positive	<input type="checkbox"/> negative	<input type="checkbox"/> N/A	<input type="checkbox"/> confirmed
B1.f	Date (mm/dd/yyyy) ____/____/____	Opiate:	<input type="checkbox"/> positive	<input type="checkbox"/> negative	<input type="checkbox"/> N/A	<input type="checkbox"/> confirmed
		Cocaine:	<input type="checkbox"/> positive	<input type="checkbox"/> negative	<input type="checkbox"/> N/A	<input type="checkbox"/> confirmed
		Benzodiazepine:	<input type="checkbox"/> positive	<input type="checkbox"/> negative	<input type="checkbox"/> N/A	<input type="checkbox"/> confirmed
		Amphetamine:	<input type="checkbox"/> positive	<input type="checkbox"/> negative	<input type="checkbox"/> N/A	<input type="checkbox"/> confirmed
		Cannabinoid:	<input type="checkbox"/> positive	<input type="checkbox"/> negative	<input type="checkbox"/> N/A	<input type="checkbox"/> confirmed
		Oxycodone:	<input type="checkbox"/> positive	<input type="checkbox"/> negative	<input type="checkbox"/> N/A	<input type="checkbox"/> confirmed
		Buprenorphine:	<input type="checkbox"/> positive	<input type="checkbox"/> negative	<input type="checkbox"/> N/A	<input type="checkbox"/> confirmed
		Methadone:	<input type="checkbox"/> positive	<input type="checkbox"/> negative	<input type="checkbox"/> N/A	<input type="checkbox"/> confirmed

No urine toxicology tests were conducted or recorded in the chart during this time period

B2. Was this an office-based or home-based induction? ***for 6-month chart review only***

Office Home N/A

Follow-Up Chart Review

Today's Date (mm/dd/yyyy): ___/___/_____ Staff ID _____

Participant ID _____ Site ID _____

Date of study enrollment (date baseline was completed): (mm/dd/yyyy): ___/___/_____

Date of last medical chart abstraction date for DEC: (mm/dd/yyyy): ___/___/_____

Chart Review Period 6 months 12 months 18 months

Hepatitis C Diagnosis:

4.0 Is the patient currently positive for Hepatitis C? Yes No Unknown

3.1 If yes, is your clinic currently treating the patient for Hepatitis C? Yes No Unknown

CD4 Lab Value and Date PRIOR TO ENROLLMENT:

Please enter the last CD4 lab value and date recorded in the chart **PRIOR** to the date of study enrollment.

4.0a	Date (mm/dd/yyyy) ___/___/_____	4.0b	_____/mm ³	4.0c	_____%
------	------------------------------------	------	-----------------------	------	--------

No CD4 lab data was recorded in the chart prior to the date of study enrollment

CD4 Lab Values and Dates Since the Last Medical Chart Abstraction for DEC:

Please list the participant's CD4 lab dates and values starting with the first date since the last medical chart abstraction for DEC.

	Date of CD4 Lab Test		CD4 Lab Values		
4.0a	Date (mm/dd/yyyy) ___/___/_____	4.0b	_____/mm ³ <input type="checkbox"/> Data pending <input type="checkbox"/> QNS	4.0c	_____%
4.1a	Date (mm/dd/yyyy) ___/___/_____	4.1b	_____/mm ³ <input type="checkbox"/> Data pending <input type="checkbox"/> QNS	4.1c	_____%
4.2a	Date (mm/dd/yyyy) ___/___/_____	4.2b	_____/mm ³ <input type="checkbox"/> Data pending <input type="checkbox"/> QNS	4.2c	_____%
4.3a	Date (mm/dd/yyyy) ___/___/_____	4.3b	_____/mm ³ <input type="checkbox"/> Data pending <input type="checkbox"/> QNS	4.3c	_____%

No CD4 lab data was collected or recorded in the chart during this time period

***QNS = Quantity Not Sufficient**

Viral Load Lab Value and Date PRIOR TO ENROLLMENT:

Please enter the last viral load value and date recorded in the chart **PRIOR** to the date of the study enrollment.

5.0a	Date (mm/dd/yyyy) ____/____/____	5.0b	____ copies/mL <input type="checkbox"/> Undetectable
------	---	------	---

No viral load lab data was recorded in the chart prior to the date of study enrollment

Viral Load Lab Values and Dates Since Last Medical Chart Abstraction Date for DEC:

Please list the participant's viral load lab dates and values starting with the first date since the last medical chart abstraction date for DEC.

Date of Viral Load Lab Test		Viral Load Lab Values	
5.0a	Date (mm/dd/yyyy) ____/____/____	5.0b	____ copies/mL <input type="checkbox"/> Data pending <input type="checkbox"/> QNS <input type="checkbox"/> Undetectable
5.1a	Date (mm/dd/yyyy) ____/____/____	5.1b	____ copies/mL <input type="checkbox"/> Data pending <input type="checkbox"/> QNS <input type="checkbox"/> Undetectable
5.2a	Date (mm/dd/yyyy) ____/____/____	5.2b	____ copies/mL <input type="checkbox"/> Data pending <input type="checkbox"/> QNS <input type="checkbox"/> Undetectable
5.3a	Date (mm/dd/yyyy) ____/____/____	5.3b	____ copies/mL <input type="checkbox"/> Data pending <input type="checkbox"/> QNS <input type="checkbox"/> Undetectable

No viral load lab data was collected or recorded in the chart during this time period

HIV Primary Care Medical Visits and Dates Since Last Medical Chart Abstraction Date for DEC: For each 3-month period listed below, please document the dates of each HIV primary care medical visit at this clinic. A primary care medical visit is defined as a visit with a prescribing provider (MD, DO, PA, or NP) who is monitoring the patient's HIV lab values and HIV care. This does not include nursing visits, specialists, or hospital ER or inpatient visits. Data should be collected from electronic or paper charts.

Primary Care Medical Visits		Primary Care Medical Visits	
	Months 1 - 3 _____		Months 4 - 6 _____
6.0a		6.0b	

	Date (mm/dd/yyyy) ____/____/____		Date (mm/dd/yyyy) ____/____/____
6.1a	Date (mm/dd/yyyy) ____/____/____	6.1b	Date (mm/dd/yyyy) ____/____/____
6.2a	Date (mm/dd/yyyy) ____/____/____	6.2b	Date (mm/dd/yyyy) ____/____/____
6.3a	Date (mm/dd/yyyy) ____/____/____	6.3b	Date (mm/dd/yyyy) ____/____/____
6.4a	Date (mm/dd/yyyy) ____/____/____	6.4b	Date (mm/dd/yyyy) ____/____/____
	No primary care visits were recorded in the chart during this time period <input type="checkbox"/>		No primary care visits were recorded in the chart during this time period <input type="checkbox"/>

Health Care Visits: For each 3-month period listed below, please document the total number of health care visits for each provider. A health care visit is defined as a visit with a non-prescribing provider who is providing supportive medical care, nursing, counseling, education, or management. Data should be collected from electronic or paper charts. For jail interventions: Use this section to record visits that occurred while the participant was NOT IN JAIL.

	Health Care Visits		Health Care Visits
	Months 1 - 3 _____		Months 4 - 6 _____
7.0a	HIV Nursing # of visits _____ <input type="checkbox"/> No visits recorded in this period	7.0b	HIV Nursing # of visits _____ <input type="checkbox"/> No visits recorded in this period
7.1a	HIV Medical Case Manager # of visits _____	7.1b	HIV Medical Case Manager # of visits _____

	<input type="checkbox"/> No visits recorded in this period		<input type="checkbox"/> No visits recorded in this period
7.2a	Pharmacist # of visits _____ <input type="checkbox"/> No visits recorded in this period	7.2b	Pharmacist # of visits _____ <input type="checkbox"/> No visits recorded in this period
7.3a	Social Worker # of visits _____ <input type="checkbox"/> No visits recorded in this period	7.3b	Social Worker # of visits _____ <input type="checkbox"/> No visits recorded in this period
7.4a	Mental Health Counselor # of visits _____ <input type="checkbox"/> No visits recorded in this period	7.4b	Mental Health Counselor # of visits _____ <input type="checkbox"/> No visits recorded in this period
7.5a	Substance Abuse Counselor # of visits _____ <input type="checkbox"/> No visits recorded in this period	7.5b	Substance Abuse Counselor # of visits _____ <input type="checkbox"/> No visits recorded in this period
7.6a	Psychiatrist # of visits _____ <input type="checkbox"/> No visits recorded in this period	7.6b	Psychiatrist # of visits _____ <input type="checkbox"/> No visits recorded in this period
7.7a	Other (please specify) _____ # of visits _____ <input type="checkbox"/> No visits recorded in this period	7.7b	Other (please specify) _____ # of visits _____ <input type="checkbox"/> No visits recorded in this period
HIV Antiretroviral Therapy			
8.0a	Has this person been prescribed antiretroviral therapy at any time in the past 12 months? (Note: this includes new and existing/refill prescriptions)	<input type="checkbox"/> Yes <input type="checkbox"/> No	8.0b Date (mm/dd/yyyy) of prescription ____/____/_____ (Please enter the most recent date of prescription) How many refills? _____

Mental Health and Substance Use Disorders:

16. Has the participant ever been diagnosed with mental health condition(s)?

- Yes No No medical records available since last DEC chart review

9a. If yes, what conditions? (Check all that apply)

- Depression Anxiety Bipolar Psychosis

Other, specify: _____

17. Has the participant ever been diagnosed with a substance use disorder?
 Yes No No medical records available since last DEC chart review

10a. If yes, what substances? (Check all that apply)

- Alcohol Crack/Cocaine Opioids Marijuana Methamphetamine
 Benzodiazepine Nicotine Other, specify: _____

Internal Referrals: *This section refers to participant referrals to services that are housed in your agency and would be recorded in the participant's chart.*

18. Since the last medical chart abstraction date for DEC, was the participant referred for mental health services **within** your agency?

- Yes No N/A

19. Since the last medical chart abstraction date for DEC, was the participant referred for substance abuse treatment services (including residential treatment) **within** your agency?

- Yes No N/A

- Check here if the substance abuse treatment was residential treatment

External Referrals: *This section refers to participant referrals to services that are housed outside of your agency and would be recorded in the participant chart.*

20. Since the last medical chart abstraction date for DEC, was the participant referred for mental health services **outside of** your agency?

- Yes No N/A

21. Since the last medical chart abstraction date for DEC, was the participant referred for substance abuse treatment services (including residential treatment) **outside of** your agency?

- Yes No N/A

- Check here if the substance abuse treatment was residential treatment

22. Name of data sources

- CareWare or other Ryan White data management system
 Electronic Health Record (type): _____
 Other (please describe): _____

Additional notes:



Appendix L: Administering the Participant Chart Review Tool

Instructions for Each Measure

1.0a Participant's HIV Diagnosis Date: Enter the month, day, and year of the participant's earliest documented HIV diagnosis date in the chart. If the HIV diagnosis date documented in the chart is known to be inaccurate, please enter the earliest viral load lab date.

PLEASE NOTE:

- This date may be before enrollment.
- If only year is indicated, enter 01/01 as the month/year.

1.0b Perinatal Infection Status: Was this patient perinatally infected?

FAQ: If there are no previous negative HIV test results found and no indication of a suspected transmission method, should we record "No" or "Unknown"?

Answer: Unknown.

1.0c Participant's AIDS Diagnosis Date: Enter the AIDS diagnosis date that is documented in the medical chart. In lieu of an AIDS diagnosis date, or if any of the following are earlier than the AIDS diagnosis date, please enter the **earliest** of the following dates:

- Date of CD4 count below 200.
- Date of patient-reported AIDS diagnosis year, as reported in a clinician note. For example, if a clinician note states "patient reported AIDS was diagnosis on January 15, 2008", enter 01/15/2008.
- Date of clinician note in which he/she indicates that there is a history of AIDS (maybe self-reported) and there is no diagnosis date indicated. For example, if a clinician note written on 05/15/2015 states "patient reports being diagnosed with AIDS" without a year documented, enter 05/15/2015.

PLEASE NOTE:

- This date may be before enrollment.
- If only year is indicated, enter 01/01 as the month/year.
- If the participant does not have an AIDS diagnosis, check the "N/A" box.
- Please enter all CD4 lab dates, values, and percent up to 6 months prior to the scheduled date of the chart review, starting with the earliest date. Enter up to 6 dates and values.
- If no CD4 data is recorded in the medical record, then select "No CD4 lab data were recorded in the medical record during the past 6 months."

2.0 Date of the Last HIV Primary Care Visit PRIOR to Enrollment: Enter the most recent HIV primary care visit date-recorded in the chart **PRIOR** to the date of study enrollment. This visit does not need to fall into any particular time frame. If there is no date for the last primary care visit prior to enrollment and the patient is newly diagnosed, fill in the box: "Participant is newly diagnosed". If there is no date for the last primary care visit prior to enrollment and the patient is not newly diagnosed but new to the clinic, fill in the box: "Participant is not newly diagnosed but new to the clinic".

FAQ: Is this the last recorded HIV primary care visit anywhere or only at intervention clinic?

Answer: Anywhere.

FAQ: In a situation where a patient met with a provider before being enrolled into the study, for the “LAST HIV primary care visit PRIOR to enrollment” question, I should still just list their most recent correct?

Answer: You want the primary care visit prior to completing the consent into the study and the baseline survey, whenever that occurs.

FAQ: Most of the time folks come into the clinic for HIV care, they are seeing their provider and getting labs done in the same day. Am I correct in documenting this as both an HIV primary care and HIV nursing visit? Initially, I thought it would only count as HIV primary care, but then if a patient were to come in for just labs, this would be considered an HIV nursing visit only-since they are not seeing a prescribing provider- correct? In which case, labs would always be documented as HIV nursing.

Answer: You should record it as a primary care visit and a HIV nursing visit.

3.0-3.1 Hepatitis C Diagnosis: Please indicated whether the patient is currently positive for Hepatitis C and if they are positive, if they are receiving treatment for their Hepatitis C at your clinic.

4.0 - 4.3 Date of CD4 Lab Tests and Values AFTER Enrollment: Please enter the participant's CD4 lab dates and values starting with the first date following study enrollment. Enter up to four test values and dates. Be sure that a numeric value is entered for at least one value and date. Please no missing data.

- Fill in the “data pending” box if there is a date recorded in the chart for a test ordered but the value is pending. Be sure the date that the test was ordered is recorded.
- Fill in the “QNS” (quantity not sufficient) box if the value was not readable on the lab slip.
- If no CD4 labs were conducted in the time period fill in the box at the bottom of the table “No CD4 data was collected or recorded in the chart during this time period”.

5.0 - 5.3 Date of Viral Load Lab Tests and Values AFTER Enrollment: Please enter the last viral load values and dates recorded in the chart starting with the first date following study enrollment. Record the EXACT value if listed in the chart. If no numeric value is given, fill in the box “undetectable”. Record both the cut-off value and fill in the box “undetectable” if both are documented in the chart. If the patient is newly diagnosed or new to the clinic, and no test is recorded, fill in the box: “No CD4 or viral load data was collected or entered into the chart during this time period”.

- Fill in the “Data pending” box if there is a date recorded in the chart for a test ordered but the value is order. Be sure the date that the test was ordered is recorded.
- Fill in the “QNS” (quantity not sufficient) box if the value was not readable on the lab slip.
- If no viral load labs were conducted in the time period fill in the box at the bottom of the table “No viral load lab data was collected or recorded in the chart during this time period”.
- Some lab results may be listed as less than the current test is able to detect.
- Enter these by just filling in the “Undetectable” check box.
- Do NOT also enter “<20” (or similar) in the viral load numeric boxes.
- Numeric boxes should not include characters such as “<”.
- Numbers can be entered starting in the left-most box

6.0 HIV Primary Care Medical Visits and Dates AFTER Enrollment: Data should be collected from electronic or paper charts. In collecting these data, each 3- month period will be prepopulated based on the participant's date of enrollment as follows:

Months 1- 3 : January – March

Enter the dates of the HIV primary care medical visits for the 3-month period listed. Please note, for Months 1-3, you should include any visits that occurred prior to study enrollment date in month 1 [for 6-month chart review only].

If there were NO visits that occurred or were documented in the chart over the 3-month period, check the box “No primary care visits were recorded in the chart during this time period” and leave date fields blank.

7.0 – 7.7 HIV Health Care Visits AFTER Enrollment: *Data should be collected from electronic or paper charts. In collecting these data, each 3- month period will be prepopulated based on the participant’s date of enrollment as follows:*

Months 1- 3 : January – March

Enter the number of health care visits for each listed provider for each 3-month period. Please note, for Months 1-3, you should include any visits that occurred prior to study enrollment date in month 1 [For 6-month chart review only]. For visits with a provider that is not listed, use “other” and specify the provider type.

If there were NO visits that occurred or were documented in the chart over the 3-month period for a provider, check the box “No visits recorded in this period” and leave the number blank.

FAQ: Do we only record health care visits specifically related to HIV care?

Answer: HIV specific for 7.0 and 7.1. If so, which mental health counseling, substance use disorder counseling & psychiatrist visits would qualify? All mental health, substance use, and psych visits would count (regardless of whether or not they are related to HIV) If not, should we include things such as non-HIV primary care, ER visits, specialists, etc. as “Other” visits? Those can be included in “other”.

8.0 HIV Antiretroviral Therapy Prescriptions in the Past 12 Months: *(Note: this includes new and existing prescriptions) Fill in “Yes” if there is a documented prescription in the chart and enter the most recent date of prescription. Also note the number of refills on the prescription.*

9.0 Mental Health: *Fill in “Yes” if there is documentation of a mental health condition. If “Yes” check the corresponding condition, and use “other, specify” if the condition is not listed. If there is no documentation of a mental health condition, and the participant is new to the clinic or newly diagnosed fill in “No medical records available prior to study enrollment”.*

10.0 Substance Use Disorders: *Fill in “Yes” if there is documentation of a substance use disorder. If “Yes” check the corresponding used substances, and use “other, specify” if the substance is not listed. If there is no documentation of a substance use disorder, and the participant is new to the clinic or newly diagnosed fill in “No medical records available prior to study enrollment”.*

FAQ: What if a participant does not have substance use concerns? Should we record “no visits” or “N/A”?

Answer: If a participant does not have substance use concerns (or whatever type of visit is listed in the chart review), the Data Manager should still fill in the “no visits recorded during this period” check box INSTEAD of writing “N/A”. The subsequent question about whether the participant has SUD (or whatever) will help inform the analyst about the “no visits recorded”. The # visits/no visits recorded table should not include missing data because the participant does not need the service noted.

FAQ: Record substance use disorders, not just indication of substance use, correct?

Answer: Correct!

Internal Referrals:

This section refers to participant referrals to services that are housed in your agency and would be recorded in the participant's chart.

11. Since enrolling in this study, was the participant referred for mental health services (including residential treatment) within your agency?

- Mark “Yes” there is documentation that the participant was referred internally for services

- Record the number of internal mental health visits attended by the patient.
- Mark “Yes” even if there is not a **formal** internal referral documented or if the referral date is prior to study enrollment, but the participant is receiving mental health services at your agency.
- Mark “No” if the participant has a diagnosed mental health condition (as recorded in question 8), but was not referred for mental health services.
- Mark “N/A” indicating the participant does not have a diagnosed mental health condition needing a referral for mental health services.

12. Since enrolling in this study, was the participant referred for substance abuse treatment services (including residential treatment) within your agency?

- Mark “Yes” if there is documentation that the participant was referred internally for substance abuse treatment services (both outpatient and residential)
- Record the number of internal substance abuse treatment visits (outpatient only) attended by the participant.
- Mark “No” if the participant has a diagnosed substance abuse condition, but was not referred for substance abuse treatment services.
- Mark “N/A” indicating the participant does not have a diagnosed substance abuse condition needing a referral for substance abuse treatment services.
- Mark the corresponding box if the substance abuse treatment was residential treatment.

External Referrals:

This section refers to participant referrals to services that are housed outside of your agency and would be recorded in the participant's chart.

13. Since enrolling in this study, was the participant referred for mental health services outside of your agency? NOTE: if patient was referred internally, mark “No”

- Mark “Yes” if there is documentation that the participant was referred externally for services.
- Record the number of external mental health visits attended by the participant.
- Mark “No” if the participant has a diagnosed mental health condition, but was not referred for external mental health services or the participant was referred internally for mental health services.
- Mark “N/A” indicating the participant does not have a diagnosed mental health condition needing a referral for mental health services.
- **If yes, record the number of external mental health visits attended as recorded in the chart, OR**
 - If there is no access to data on completion of external mental health services, mark the box “Not recorded in the chart” to indicate that follow-up data is not available in the chart.

14. Since enrolling in this study, was the participant referred for substance abuse treatment services (including residential treatment) outside of your agency?

- Mark “Yes” if there is documentation that the participant was referred externally for substance abuse treatment services.
- Record the number of external substance abuse treatment visits attended by the participant.
- Mark “no” if the participant has a diagnosed substance abuse condition, but was not referred for external substance abuse treatment services or the participant was referred internally for substance abuse treatment services.
- Mark “N/A” indicating the participant does not have a diagnosed substance abuse condition needing a referral for substance abuse treatment services.
- **If yes, record the number of external substance abuse treatment visits attended as recorded in the chart, OR**
 - If there is no access to data on completion of external substance abuse treatment services, mark the check box “Not recorded in the chart” to indicate that follow-up data is not available in the chart.

- *Mark the corresponding box if the substance abuse treatment was residential treatment.*

15. Name of data source (i.e.): *Please mark one category for the source of the data; if other please write in the source.*

FOR BUPRENORPHINE SITES ONLY

B1. Dates and Results of Urine Toxicology Tests: Data should be collected from electronic or paper charts. Enter the dates of the urine toxicology tests and the corresponding results. Check “N/A” if the test was done but not for the related substance. If the test was confirmed by a confirmatory test, check the corresponding box “confirmed”. If no urine toxicology tests were conducted or recorded in the time period check the corresponding box “No urine toxicology tests were conducted or recorded in the chart during this time period”. Confirmed means that this screening urine toxicology test (the typical test ordered by providers and run by labs) was confirmed with a GC/MS test (which is much more expansive and accurate test that it typically sent-out).

B2. Type of induction: Indicate where buprenorphine induction was office based or home-based. ****for 6-month chart review only****

12 and 18 Month Chart Abstraction – additional variables to collect

1. **Date and value of CD4 lab test prior to enrollment:** Please record the most recent date of the client's last CD4 lab test and the value prior to study enrollment. If there is none recorded in the chart please check the box "none recorded".
2. **Date and value of viral load lab test prior to enrollment:** Please record the most recent date of the client's last viral load lab test and value prior to study enrollment. If there is none recorded in the chart please check the box "none recorded".

Appendix M: Participant Encounter Form

Intervention Encounter Form

Date of Contact ___/___/_____

Client ID: _____

Encounter made:

- Yes (with the client or on behalf of the client)
- No

If "No," why?

- Unable to contact
- Cancelled/Rescheduled appointment
- No show
- Other, specify:

Total duration of this encounter (in minutes):

Staff ID: _____

Site: _____

Location of Encounter(s): Check all that apply

- Client residence (permanent or non-permanent residence)
- Intervention clinic
- Medical, social service, or community based organization setting (external to intervention site)
- Name: _____
- Correctional setting
- Other (specify): _____
- N/A (not face-to-face)

Type of Contact	
Face-to-face (Individual)	1
Electronic (email, text, phone, fax)	2
Collateral (client not present)	3
EMR	4
Other	5

Encounter content:

For each encounter that you had with a client in the course of one day, use the columns to the right to enter the type and duration of each type of encounter using the codes above. For example if you took a client to a medical appointment that lasted 1 hour-enter "1" in the "Type" column and "60" in the "duration" column next to the content. Please mark all types of encounters and duration of each type of encounter for the entire day.

Completed?	Encounter Activity	Type	Duration (minutes)
	1. Find client/conduct outreach		
	2. Conduct client intake and/or needs assessment		
	3. Develop a patient care plan		
	4. Conduct acuity assessment		
HEALTHCARE-RELATED ACTIVITIES			
	5. Arrange HIV primary care appointment		
	6. Arrange mental health services appointment		
	7. Arrange for substance use treatment / services appointment		
	8. Arrange other medical care appointment (not for HIV, mental health, or substance use)		
	9. Accompany client to a medical appointment		
	10. Accompany client to a mental health appointment		
	11. Accompany client to a substance use related services appointment		
	12. Discuss medical appointments with client		
	13. Discuss lab values with client		

	APPOINTMENT REMINDERS AND FOLLOW UP		
	14. Provide appointment reminders (medical and non-medical appointments)		
	15. Follow up with provider to discuss client		
	EDUCATIONAL AND EMOTIONAL SUPPORT		
	16. Relationship building (e.g. checking in with client; providing emotional support)		
	17. Talk with a client about disclosure		
	18. Provide coaching on living skills		
	19. Provide general health education / risk reduction education		
	20. Provide basic HIV treatment education, support, and/or advocacy		
	21. Provide safer sex education		
	22. Provide harm reduction education and supplies (i.e. clean syringe/naloxone)		
	23. Mentoring/coaching on provider interactions		
	24. Provide education and emotional support to client's family/partners		
	SOCIAL SERVICES-RELATED ACTIVITIES		
	25. Accompany client to social service appointments (i.e. related to benefits, housing, food, etc.)		
	26. Assist with obtaining transportation services		
	27. Assist with obtaining child care services		
	28. Assist with obtaining housing services (i.e. support for finding or maintaining housing)		
	EMPLOYMENT AND OTHER PRACTICAL & SOCIAL SUPPORT		
	29. Assist client with finding employment/provide employment support		
	30. Assist client in obtaining legal assistance, obtaining legal documents, or obtaining legal advocacy services		
	31. Assist client with obtaining benefits (e.g. SSI, social security, disability, food assistance, or health insurance)		
	32. Provide practical support (i.e. obtaining cell phone, budgeting/financial planning)		
	OTHER ACTIVITIES		
	33. Other 1: (specify)		
	34. Other 2: (specify)		
	35. Other 3: (specify)		
	TRANSITION TO STANDARD OF CARE		
	36. Meet with client to discuss transitioning to the standard of care		
	37. Transition client to treatment with a case manager or treatment at external/partner agency		
	38. Officially transitioned client to the standard of care		
	ENHANCED PATIENT NAVIGATION INTERVENTION: STRUCTURED CURRICULUM SESSIONS		
	39. Session 1: HIV, the Viral Life Cycle & Understanding ART		
	40. Session 2: Communicating with Provider, Adherence & Managing Side Effects		
	41. Session 3: Review understanding of basic lab tests: CD4 & Viral Load		
	42. Session 4: Stigma & Disclosure		
	43. Session 5: HIV and Substance Use		

	44. Session 6: HIV and Mental Health		
	TRANSITIONAL CARE COORDINATION INTERVENTION SPECIFIC ENCOUNTERS		
	45. Create or modify transitional care plan		
	46. Conduct Health Liaison to the court activities		
	47. Provide / arrange transportation/escort from jail		
	48. Provide supply of bridge medications or prescription (during incarceration or post-release)		
	49. Facilitate placement in diversion program, ATI, or compassionate release		
	BUPRENORPHINE INTERVENTION SPECIFIC ENCOUNTERS		
	50. Provide client education and support prior to treatment initiation		
	51. Provide client support during treatment initiation		
	52. Provide client support during maintenance or stabilization		
	53. Provide client with referral to supplementary or higher level of addition treatment		
	54. Conduct monitoring appointment		
	55. Obtain prior authorization for buprenorphine prescription		
	56. Obtain buprenorphine for client		
	57. Urinalysis		

Progress notes (Optional):

Appendix N: Administering the Participant Encounter Form

What types of activities should be documented on the participant encounter form?

Dos & Don'ts:

- **Do document each activity you completed with a participant in the course of a day.**
- **Do document attempted encounters with participants.**
- **Do document activities related to scheduling future appointments with the Clinical Coordinator**, such as scheduling, rescheduling, or cancelling appointments between the community health worker and the participant.
- **Do NOT document any evaluation activities on the participant encounter form:**
 - Do not fill out an encounter form to document enrolling a client into the evaluation or for conducting a baseline interview.
 - Do not fill out this form to document contact attempts to bring a participant in for a scheduled participant interview.
 - Do not fill out this form to document conducting follow-up interviews.

Additional Reminders:

- Enter “type” and “duration” for each checked/selected encounter activity.
- For “other” activities, enter the text field specifying what the other activity was.
 - The more “others” you have, the more complicated your analysis will be. Data managers should audit the “other” responses on a quarterly basis to give the Clinical Coordinator guidance on how to better mark their responses or to identify new responses that need to be added to the form.
 - If you add additional responses to the form, remember to submit the updated form to your IRB

How do I fill out the encounter form?

1. Enter the date of the encounter.
2. Identify if the encounter was made
3. Encounter location
 - a. If you select “Medical, social service, or community based organization setting” or “Other” as the location of encounter, please specify where the encounter occurred in the supplied text box.
Note: If you select “Other” for location, please do not use names of facilities or locations, but rather describe them and the services they provide. For example, instead of writing “Boston HOPE Project” for a location, write “Housing service agency”.
4. Look through the activities on the encounter form and click on the checkbox next to each activity that you completed with the participant on the day for which you are submitting the form.
 - a. If you do not see any activities on the encounter form that match what you did with the client, select the “Other” activity option at the bottom of the form and write in a brief description of what you did with the participant.
Note: Do not use names of programs or facilities, rather describe them. For example, instead of writing “Went to B&G Club with client,” write “Accompanied client to basketball facility.” In general, provide as many specific details as possible about the activity itself.
5. For each activity you selected, indicate what type of activity you conducted and the location you conducted the activity. If you select other for “Type” or “Location,” please specify in the “other” text box. If you select “Other” for location, please do not use names of facilities or locations, but rather describe them and the services they provide. If an encounter was made with another provider on behalf of or for the participant (without the participant present), select “Collateral” for “Type”.
6. Duration (in minutes)
7. Progress Notes (if applicable)

Question by Question Guidance for Encounter Form

Date of contact: The date the encounter contact(s) occurred.

Staff ID: The assigned staff ID of the Clinical Coordinator who had the encounter contact(s).

Client ID: The assigned participant study ID number.

Encounter made:

- Mark “yes” if there was a direct encounter with the participant or an encounter on behalf of the participant.
- Mark “no” if you attempted to have an encounter or had an appointment for an encounter but it did not occur.
 - Mark the corresponding reason as to why an encounter did not occur. If the reason is not listed, mark “other” and write in the reason.

Location of encounter(s): Mark all of the locations in which the encounter(s) occurred in the day of the encounter.

If the location was in a setting external to the intervention site, write in the name of the location.

If the encounter occurred at a location not listed, mark “other” and write in the location.

Type of contact: Use the following number codes to indicate the type(s) of contact of the activities conducted in the following “Encounter content” section.

- | # | Type of Contact |
|---|--------------------------------------|
| 1 | Face-to-face (individual) |
| 2 | Electronic (email, text, phone, fax) |
| 3 | Collateral (client not present) |
| 4 | EMR |
| 5 | Other |

Encounter content: Indicate all encounter activities conducted for the day of the encounter, including the type of contact and the duration (in minutes) of each activity.

Total duration of this encounter (in minutes): The total number of minutes of the encounter(s) with the participant in the day of the encounter.

Progress Notes (Optional): Use this space for progress notes that you would like to share with the evaluation team.

Encounter Activities and Definitions

For each of the activities conducted in a day with a client please note the *Type* of contact using the corresponding numbers above (1 – 5) and *Duration* as the total number of minutes spent on the activity.

Activity	Definition	Example of Activities	Type	Duration (minutes)
1. Find client/conduct outreach	Any activity that helps to locate or reach out to a client in the community	“Arranged time to meet with client”		
2. Conduct client intake and/or needs assessment	Completing an intake or follow-up needs assessment	“First meeting with patient” “Assessed immediate needs of the patient”		
3. Develop patient care plan	Completing patient care plan or patient agreement (for buprenorphine treatment). Work to identify goals and develop action items to meet those goals. Goals may be related to any health or health care (including HIV, mental health, substance use, other health or health care areas). NOTE: Creating a transitional care plan (for the jail-based intervention) should be marked in activity 41, not here	“Create patient care plan” “Complete patient care agreement”		
4. Conduct acuity assessment	Completing the patient acuity tool.	“Complete patient acuity assessment” “Assess patient acuity”		
HEALTHCARE ACTIVITIES				
5. Arrange HIV primary care appointment	Any activity that helps the client get a HIV primary care appointment	“Scheduled first appointment with HIV primary care provider”		
6. Arrange mental health services appointment	Any activity that helps the client get a mental health or psychosocial service appointment or meeting	“Called mental health provider with client to schedule next appointment”		
7. Arrange for substance use treatment / services appointment	Any activity that helps the client get a substance use service providers	“Arranged admission to detox”		
8. Arrange for other medical care appointment (not for HIV, mental health, or substance use)	Any activity that helps the client get an appointment with any medical provider EXCLUDING HIV primary care, mental health, substance use treatment, or psychosocial service providers	“Assisted in making eye appointment”		
9. Accompany client to a medical appointment	Any activity in which Intervention Staff goes with a client to a scheduled or unscheduled visit with a medical provider, including primary health providers, specialty health providers, lab	“Accompany client to dental appointment” “Accompany client to hospital” “Accompany nurse to home visit”		

Activity	Definition	Example of Activities	Type	Duration (minutes)
	technicians, pharmacists, ER or Urgent Care providers, etc. <u>EXCLUDING</u> mental health, substance use treatment, or psychosocial service providers	"Dropped off client at doctor's appointment"		
10. Accompany client to mental health appointment	Any activity in which Intervention Staff goes with a client to a scheduled or unscheduled mental health or psychosocial service appointment or meeting	"Took client to support group meeting"		
11. Accompany client to a substance use related services appointment	Any activity in which Intervention Staff goes with a client to a scheduled or unscheduled substance use treatment service appointment or meeting	"Accompany client to detox" "Went with client to a NA meeting"		
12. Discuss medical appointments with client	Any discussion that covers what occurred in a medical appointment (defined as a scheduled or unscheduled visit with a medical provider, including primary health providers, specialty health providers, lab technicians, pharmacists, ER or Urgent Care providers, etc.)	"Client shared what happened at her dental appointment" "Spoke with client about a recent hospital visit" "Discuss hospital discharge plan with doctor" Followed up with client about mental health appointment Followed up with client after medical appointment		
13. Discuss lab values with a client	Specifically review lab values as they relate to medical care, treatment, and HIV-related health status.	"Reviewed lab values with participant"		
APPOINTMENT REMINDERS AND FOLLOW UP				
14. Provide appointment reminders (medical and non-medical appointments)	Any activity done to remind client of an upcoming appointment	"Called client to remind of appointment with HIV provider tomorrow"		
15. Follow up with provider to discuss client	Any activity where the interventionist meets, works with, or contacts the client's provider to discuss the client.	"Called dentist to see if client has scheduled appointment after being referred" "Schedule appointment with nutritionist who she had been referred to" "Sent message to client's nurse through the EMR"		

Activity	Definition	Example of Activities	Type	Duration (minutes)
		Spoke with nurse case manager in regards to client Discuss patient care plan with housing SW Followed up with nurse to discuss patient Discuss client with nutritionist Discuss patient with in-house SW		
EDUCATIONAL AND EMOTIONAL SUPPORT				
16. Relationship building (e.g. checking in with the client; providing emotional support)	Any contact that with a client to check on how they are doing generally, to follow up on previous conversations about general well-being, or to check and see if they need anything	“Check in with client” “Home visit to see how client is feeling” “Wellness checks” Stopped by residence to drop off clothing and talk Text patient a supportive message Discussed stress-reducing strategies Met with client after court Met with client after appointment		
17. Talk with a client about disclosure	Any discussion that covers reasons for wanting to or not wanting to disclose, or discussions to check-in with clients after disclosure	“Discussed client’s fears about telling his family that he is HIV-positive”		
18. Provide coaching on living skills	Any discussion about basic tools to use in order to navigate everyday life	“Discussed ways to better communicate with landlord” “Talked about strategies to reduce stress”		
19. Provide general health education/risk reduction education	Any discussion that covers general health education or risk reduction.	“Discuss personal hygiene and sharing razors, needles, etc.”		
20. Provide basic HIV treatment education, support, and/or advocacy	Any discussion that covers information around how HIV treatments work, how to take them, or tips for treatment adherence/management	“Discuss HIV treatment” “Discuss needs related to HIV treatment” Discuss medication/side effects Review the basics of lab tests Talked with client about meds Help with finding a good support group for HIV		

Activity	Definition	Example of Activities	Type	Duration (minutes)
21. Provide safer sex education	Any discussion around safe sex practices	“Discuss client safety and healthy relationships”		
22. Provide harm reduction, education, and supplies (i.e. clean syringe/naloxone)	Any work done that enables the client to reduce substance use (including reviewing treatment options), OEND (Overdose Education and Naloxone Distribution)	“Discuss cutting down substance use with client” Discuss substance use disorder treatment center with client Spoke with client about needing substance use treatment “Assisted client in obtaining naloxone prescription”		
23. Mentoring/coaching on provider interactions	Any discussion that helps prepare the client to communicate more effectively with medical, mental health, substance use treatment, or other service providers	“Brainstormed ideas to prepare for next medical visit with HIV primary care provider”		
24. Provide education and emotional support to client’s family/partners	Any discussion with a participant’s family or partners (with the client’s consent) in order to help the family/partner be a better support system for the participant.	“Spoke with client’s boyfriend about harm reduction, safer sex practices, and HIV medication regimen”		
SOCIAL SERVICES-RELATED ACTIVITIES				
25. Accompany client to social service appointments (i.e. related to benefits, housing, food, etc.)	Any activity in which Intervention Staff goes with a client to a scheduled or unscheduled visit with a non-housing social service provider (e.g. food, social security, etc.)	“Accompany client to social security office” “Accompany client to SNAP”		
26. Assist with obtaining transportation services	Any activity in which the Intervention Staff helps the client gain access to transportation, including coordinating car/taxi service, providing bus cards to clients, helping client determine what transportation to use in arriving to appointments, etc.	“Give bus pass” “Called a cab to pick up the client and take him to his appointment” “Showed client how to use Maps application to find best bus route”		
27. Assist with obtaining child care services	Any activity in which the Intervention Staff helps the client gain access to child care	“Helped client find day-care”		
28. Assist with obtaining housing services (i.e. support for finding or maintaining housing)	Any activity in which the Intervention Staff helps the client obtain or maintain housing.	“Read through lease agreement with client to understand expectations in new apartment” “Assist client with housing referral” “Assist with obtaining shelter”		
EMPLOYMENT AND OTHER PRACTICAL AND SOCIAL SUPPORT				

Activity	Definition	Example of Activities	Type	Duration (minutes)
29. Assist client with finding employment/provide employment support	Any activity that assists in identifying employment opportunities, and supporting client in obtaining or maintaining employment for the client	<p>“Accompany client to job interview”</p> <p>“Discuss vocational goals”</p> <p>“Fill out job application”</p>		
30. Assist client in obtaining legal assistance, obtaining legal documents, or obtaining legal advocacy services	Any activity that assists the client in identifying, obtaining, or managing legal assistance or advocacy	<p>“Accompanied client to court”</p> <p>“Accompany client to probation appointment”</p> <p>“Assist client with warrants”</p> <p>“Advocacy for benefits”</p> <p>“Client is incarcerated”</p> <p>Contact ID office</p> <p>Contacted public defender</p> <p>Drafted letter for court</p> <p>Spoke with public defender</p>		
31. Assist client with obtaining benefits (e.g. SSI, social security, disability, food assistance, or health insurance)	Any activity that assists the client in obtaining benefits such as SSI, social security, disability, or health insurance benefits.	<p>“Made appointment to meet about social security benefits.”</p> <p>“Provided assistance for social security disability application.”</p> <p>“Assisted client in enrolling in health insurance”</p> <p>Completed ADAP and Ryan White</p> <p>Check status of FEMA application</p>		
32. Provide practical support (i.e. obtaining cell phone, budgeting/financial planning)	Any activity in which the Intervention staff is completing tasks for or with the client that they need in order to improve their health or well-being and are unable to complete on their own	<p>“Accompanied client to grocery store”</p> <p>“Assist client with laundry”</p> <p>“Assist client with paying bills”</p> <p>“House cleaning”</p> <p>“Accompanied client to grocery store”</p> <p>“Assist client with laundry”</p> <p>“Assist client with paying bills”</p> <p>Assist patient with utility assistance documents</p> <p>Accompany patient to financial counseling</p> <p>Provided resources to reduce internet services</p> <p>Assisted client with snack bag request</p> <p>Enrolled patient in GED classes</p>		
OTHER ACTIVITIES				

Activity	Definition	Example of Activities	Type	Duration (minutes)
33. Other 1:	Any activity that does not fit into an encounter outlined in another section of the encounter form.			
34. Other 2:	Any activity that does not fit into an encounter outlined in another section of the encounter form.			
35. Other 3:	Any activity that does not fit into an encounter outlined in another section of the encounter form.			
TRANSITION TO STANDARD OF CARE				
36. Meet with client to discuss transitioning to the standard of care	Any discussion that prepares a client to transition from the intervention activities and from working with the interventionist to the standard of care.			
37. Transition client to treatment with a case manager or treatment at external/partner agency	Any activity related to transitioning a client to the standard of care outside of the organization.	“Held meeting with client and case manager”		
38. Officially transitioned patient to standard of care.	Any activity related to transitioning a client to the standard of care within the organization.			
ENHANCED PATIENT NAVIGATION INTERVENTION: STRUCTURED CURRICULUM SESSIONS				
39. Session 1: HIV, the Viral Life Cycle	Complete the curriculum outlined for session 1			
40. Session 2: Communicating with Provider, Adherence & Managing Side Effects	Complete the curriculum outlined for session 2			
41. Session 3: Review understanding of basic lab tests: CD4 and Viral Load	Complete the curriculum outlined for session 3			
42. Session 4: Stigma & Disclosure	Complete the curriculum outlined for session 4			
43. Session 5: HIV and Substance Use	Complete the curriculum outlined for session 5			
44. Session 6: HIV and Mental Health	Complete the curriculum outlined for session 6			
TRANSITIONAL CARE COORDINATION INTERVENTION SPECIFIC ENCOUNTERS				
45. Create or modify transitional care plan	Working with the client to create or modify transitional care plan.	“Complete transitional care plan”		

Activity	Definition	Example of Activities	Type	Duration (minutes)
46. Conduct health liaison to the court activities				
47. Provide/arrange transportation/escort from jail	Any activities that support the safe transportation of the client from the jail post-release.	"Arranged for a taxi for client"		
48. Provide supply of bridge medications or prescription (during incarceration or post-release)	Any activity that supports the uninterrupted availability of prescriptions for the client post-release	"Met with provider in the jail to receive prescription for client"		
49. Facilitate placement in diversion program, ATI, compassionate release	Any activity that connects a patient with resources geared towards diversion, ATI, or compassionate release			
BUPRENORPHINE INTERVENTION SPECIFIC ENCOUNTERS				
50. Provide client education and support prior to treatment	Any activities related to educating patient about buprenorphine treatment.	"Provided patient with handouts on buprenorphine treatment" "Discussed what to expect when starting buprenorphine treatment"		
51. Provide client support during treatment initiation	Any activities related to helping a client through either the home or office based initiation process.	"Provided patient with home induction handout"		
52. Provide client support during maintenance or stabilization	Any activities related to helping a client during their maintenance or stabilization phases.	"Discussed buprenorphine adherence with patient" "Discussed patient emotions related to being on buprenorphine treatment"		
53. Provide client with referral to supplementary or higher level of addiction treatment	Any activity to connect a client to a supplementary or higher level of addiction treatment.	"Connected patient with inpatient treatment facility"		
54. Conduct monitoring appointment	Meeting with the patient to monitor his/her dosage, treatment, or experience on buprenorphine.	"Met with client to adjust dosage"		
55. Obtain prior authorization for buprenorphine prescription	Work done to overcome insurance barriers to obtaining buprenorphine.			
56. Obtain buprenorphine for client	When the provider obtains buprenorphine from the clinic pharmacy for a client.			
57. Urinalysis	Any time spent requesting urinalysis, reviewing urinalysis values.			

Progress Notes (Optional): *You may use this space for progress notes that you would like to share with the evaluation team*

Appendix O: Staff Key Informant Interview Guide

Project Staff- Specific Interview Guide

Project staff: Clinical supervisor, administrative supervisor, Clinical Coordinator

Thank you for taking the time to speak with me today. As a person with a specific role in implementing this intervention, you have a unique perspective on the implementation of the Bup intervention. Today I'd like to focus on your unique and individual perspective. Do you have any questions before we start?

Patient population:

1. We would like to learn about your work with women of color living with HIV.
 - How do you determine who is the right population for the intervention?
 - Do you think there are any groups of patients who should be candidates for the intervention who are not eligible? Who are they? Why are they not eligible?
 - How do you identify specific patients to target for the intervention?
 - Are there certain patients who meet the “criteria” but who you don't think are appropriate? Can you describe?
 - Are there certain patients who you think would be a good fit for the intervention but who don't meet the criteria? Can you describe?
2. We've heard that sometimes different types of patients or clients need modifications or adaptations of the designed program. Do you find that you have to make different kinds of modifications or adaptations to different types of patients at your site?
 - Can you explain some of the specific ways in which the intervention is done differently for different kinds of patients?
 - What kinds of factors is this based on?
 - Does it help them access other community based services? What kinds of services?

Implementing the intervention:

3. We'd like to learn more about how the intervention has been implemented at your clinic. These interventions are based on previous studies, but now we're really focused on how they work on the ground, in real-world settings. If you can think back to the initial intervention plan that was mapped out in the intervention implementation guide, to what degree is the intervention being implemented as designed in the adapted intervention and implementation plan?
 - What are your thoughts about the manner in which the intervention is being implemented? Do you think it is being done the way it was designed – if not, what is being adapted and why? What things are typically done as designed? What things tend not to be done as designed?
 - Do you think the intervention is done at all differently by different staff? What is this based on?
 - What kinds of modifications have been made due to specific site issues/concerns/constraints? What are those site issues?
 - What kinds of modifications need to be made to address your patient population?
4. In your experience, what are the barriers and facilitators to implementing the intervention?
 - What factors have helped your site to put the Bup intervention into practice?
 - What have been the challenges or barriers to implementing the Bup intervention?
 - What has worked the best?
 - What do you think would help it to be easier to implement?
 - What have been the keys to success in linking patients to resources in the community?
 - What are some of the challenges that still exist?

Patient-centeredness and patient experience in the intervention:

5. We've learned a lot about how the staff and leadership at your clinic feel about the intervention. Now we want to talk a bit about the patient experience in the intervention. How do you think patients view the Bup intervention?
 - How do they tend to react to it? What do you think the experience of being in the intervention is like for them? What have they told you about it?
 - In what ways do you think it meets their needs?
 - When patients are first told about the intervention and their eligibility for it, how long does it take for them to get started? Are there any concerns about timeliness? If so, what are they?
 - Can you give me an example of how you involve the patient in making decisions about their health care needs and treatment?
 - Can you give me an example of discussions you have around patient's self-management of health care? Does staff use motivational interviewing techniques to guide these discussions?
 - Can you give me an example of how you incorporate families into planning and delivering patient care?

Integration into the larger clinic setting:

6. Now let's talk about how this intervention fits within the larger scope of the services that are offered at your clinic. How would you describe how the Bup intervention fits into other programs and services at your site to improve outcomes for people with HIV?
 - Tell us about communication between intervention team members and the clinic team members? How do the intervention staff contact clinic team members? Are they part of regular "huddles?"
7. How does the Bup intervention fit into the rest of the workflow at your agency?
 - Do you think the Bup intervention duplicates some or part of other activities you are currently doing at your agency? How? What makes it different than other activities? What make it the same?
 - How has this intervention increased or decreased the workload on staff?
 - Would you make any changes to the staffing plan if you were to continue this program? If so, how?
8. What policies and procedures are in place to protect patient and staff safety?
 - What, if any, safety or confidentiality concerns do you have for patients related to the intervention?
 - What, if any, safety concerns do you have for staff related to the intervention?
 - What are your general agency safety policies or standard operating procedures around safety (such as visiting clients/patients at their homes, accompanying clients/patients to other care visits off site, transporting clients/patients)? Are these policies any different for this intervention?

Final wrap up questions:

- What would make your job easier in working with clients who have received services through this intervention?
- If you were providing advice to other agencies about replicating your model what are some of the key recommendations that you make?
 - Probes: models of staff? External partners? Funding?

Clinic and Administrative Leadership- Specific Interview Guide

Clinical leadership, administrative leadership, 1 person nominated by the site

Thank you for taking the time to speak with me today. As a person with a leadership role at the clinic, you have a unique perspective on the implementation of the Bup intervention and the ways in which it has (or has not) integrated into the larger scope of HIV services at your clinic. Do you have any questions before we start?

1. In your opinion, what are the barriers and facilitators to implementing of the Bup intervention?
 - What factors have helped your site to put the Bup intervention into practice?
 - What have been the challenges or barriers to implementing the Bup intervention?
 - What has worked the best?
 - What do you think would help it to be easier to implement?
 - What have been the keys to success in linking patients to resources in the community?
 - What are some of the challenges that still exist?
2. Now let's talk about how this intervention fits within the larger scope of the services that are offered at your clinic. How would you describe how the Bup intervention fits into other programs and services at your site to improve outcomes for people with HIV?
 - Tell us about communication between intervention team members and the clinic team members? How do the intervention staff contact clinic team members? Are they part of regular "huddles?"
3. How does the Bup intervention fit into the rest of the workflow at your agency?
 - Do you think the Bup intervention duplicates some or part of other activities you are currently doing at your agency? How? What makes it different than other activities? What make it the same?
 - How has this intervention increased or decreased the workload on staff?
 - Would you make any changes to the staffing plan if you were to continue this program? If so, how?

Final wrap up questions:

- What would make your job easier in working with clients who have received services through this intervention?
- If you were providing advice to other agencies about replicating your model what are some of the key recommendations that you make?
 - Probes: models of staff? External partners? Funding?

Appendix P: Qualitative Client Interviews

Interview Guide

Intro: Thank you for agreeing to talk with me today about your experiences with health care and other providers related to getting your needs met and the Bup program. Our talk should take about one hour and at the end you will receive a gift card for your participation in this interview. If you have questions/concerns or feel uncomfortable you can stop me at any point. If you do not want to answer any question you do not have too. None of this information will be shared with your providers and your answers will not affect the services you receive here or elsewhere. The information you provide in this interview will be summarized and shared with other's interview responses as a collection of information from many participants. It will not be shared individually.

Do you have any questions before we start?

1. When did you start coming to this clinic? What is the main reason that motivates you to seek care at this clinic?
2. When did you first hear about this Bup program?
 - a. PROBE: When did you first hear about receiving services from [insert name of Clinical Coordinator].
3. When someone in the clinic first told you about this atie program or the opportunity to work with [insert name of Clinical Coordinator], what did they say about it?
4. What made it sound like it was something you wanted to do?

[Satisfaction: Were clients satisfied with the intervention?]

5. Tell me about your experience in the Bup program. Working with [name] as a Clinical Coordinator? What do you think about it?
 - a. PROBE: What have you liked about it?
 - b. PROBE: What would make it better?
6. Who do you work with in the Bup program most closely?
7. What about [name], what have you thought about working with them?
8. Who do you think this program would be good for? Would you refer a friend to this intervention?

[Patient Centeredness: Do patients experience care in accordance with their needs and preferences?]

9. Thinking back to when you first started working with [name of Clinical Coordinator], what were your immediate needs? [PROBE: medical care, other services like housing or benefits counseling, etc?]
 - a. In what ways did [name of Clinical Coordinator] help you with your needs? [PROBE: come up with a treatment plan, provide referrals, provide ongoing support]
 - i. [If client received referrals] Can you tell me more about receiving a referral? Were you able to attend the appointment? Did it meet your needs?
10. How are things going now in terms of your [largest immediate needs identified in question 9]?
11. What services or needs were you not able to get? What barriers to care did you have prior to working with [name of Clinical Coordinator]? How did the Bup intervention help you try to get those services you needed?
12. In general, how do you feel your HIV medical team treats you? How do you feel the other staff treats you? Can you give me an example of how they have treated you?
 - b. What about other staff at the clinic/office? How would you describe a 'good' experience? A 'bad' one?
 - c. How do you feel about interacting with the clinic staff? What do you like? Dislike?
 - d. If you need any help regarding your health or other concerns, who do you usually ask? How do you ask about it?
13. How do you feel about interacting with your HIV medical provider? What do you like? Dislike?
14. In general, do you feel you're able to get the things you need to support your health here?
 - e. Are you able to access services through this clinic/intervention in a way that met your needs?
 - f. PROBES: Schedule/timing of appointments; Travel to get here; Child care; Work or school schedule
15. How do you get in contact with [name of Clinical Coordinator]? Were you usually able to contact him/her quickly or get a message to him/her?

[Function: Which models improve physical and mental health function?]

16. We're curious about how the Bup program impacted you and your health.
 - a. In what ways did working with [name of interventionist] impact or change your *physical* health? [Probes: did you have trouble walking, feel pain, etc
 - i. How did working with [name of Clinical Coordinator] impact or change your physical health?
 - b. In what ways did working with [name of Clinical Coordinator] impact or change your *mental* health?
 - i. How did working with [name of Clinical Coordinator] impact or change your mental health?
 - c. In what ways did working with [name of Clinical Coordinator] impact or change your *quality of life*? How would you describe your overall ability to take care of your daily needs?
 - i. How did working with [name of Clinical Coordinator] impact or change your overall quality of life?
17. What other medical care in addition to HIV care have you used as a result of participating in this intervention (i.e. oral health, eye health, STI screening)?
 - d. Did any of these services result in better health?

[Symptomatology: Do the evidence-informed interventions lead to improvements in the common outcome measures put forward to monitor HHS funded prevention, treatment and care services with respect to 1) ART among persons in HIV medical care and 2) viral load suppression among persons in HIV medical care.]

18. What impact did the Bup program and working with [name of Clinical Coordinator] have on helping you get access to HIV care?
 - a. How did the Bup program and working with [name of Clinical Coordinator] help you access HIV care?
 - b. Can you give me an example of how it helped you?
19. What impact did the Bup program have on helping you build a stronger relationship with your HIV provider?
 - a. How did the Bup program and working with [name of Clinical Coordinator] help you build a stronger relationship with your HIV provider?
 - b. Can you give me an example of how it helped you?
20. What impact do you think this program had on being adherent to your HIV medications? Can you give an example of how [name of Clinical Coordinator] supported your adherence?

Closing: We're coming to the end of the interview now. Thank you very much for your time and for sharing your thoughts and experiences with me.

21. Is there anything else you'd like to say, or that you think is important to discuss that I haven't asked you about?
22. If you could change one aspect of the clinic and the way it provides HIV services what would it be?
23. Would you like to hear about what we find from these interviews? What is the best way to contact you when the results are available?