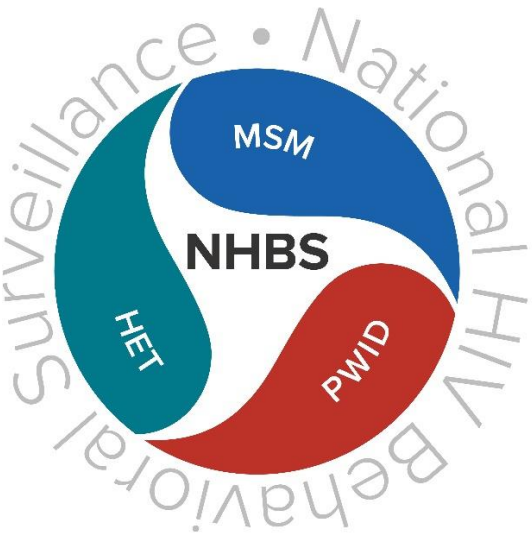
National HIV Behavioral Surveillance (NHBS):
People Who Inject Drugs (PWID)

NHBS-PWID2024 Formative Assessment Manual



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1 Formative Assessment Overview

1.0 Overview

The purpose of this document and the accompanying appendices is to provide NHBS project areas with guidance on conducting formative assessment activities to inform the implementation of the National HIV Behavioral Surveillance data collection cycle among persons who inject drugs (NHBS-PWID). Project areas are expected to review information in the *NHBS Round 7 Model Surveillance Protocol* to understand the methods for recruiting, interviewing, and HIV testing in NHBS prior to starting formative assessment activities.

1.1 Formative Assessment Goal and Objectives

The overall goal of formative assessment in NHBS-PWID is to inform the successful implementation of NHBS among PWID. The information gathered during formative assessment enables project areas to tailor field operations to local settings and to identify and address any barriers to operations.

The specific objectives of formative assessment in NHBS-PWID are to:

- Garner the support of the PWID community and key partners.
- Describe the social, demographic, and peer network characteristics of PWID.
- Identify local drug use patterns.
- Identify potential "seeds," or initial recruits, for respondent-driven sampling (RDS), and their willingness to use peer recruitment.
- Obtain information needed for conducting field operations (e.g., accessible field site locations(s), ideal hours of operation, logistics for interviewing and HIV testing, and appropriate staff).
- Identify potential barriers to peer recruitment and participation among PWID and develop solutions to address them.
- Develop questions of local interest for HIV prevention among PWID.
- Develop a plan to monitor operations and recruitment through ongoing formative assessment.
- Develop a plan for data dissemination to occur at the conclusion of data collection.

1.2 Operational Considerations

Below are key operational considerations for formative assessment for the NHBS-PWID cycle.

Recruitment. Respondent-driven sampling (RDS) is used to recruit PWID in NHBS. In RDS, recruitment is started with a limited number of "seeds," or initial recruits, who are identified through formative assessment, community partner referrals or street outreach conducted by NHBS staff. Initial recruits who are eligible to participate and complete the interview are offered to recruit up to 5 persons they know who inject drugs using coupons. Those persons, in turn, recruit others using coupons if they are eligible and complete the survey. This recruitment process continues until the sample size is reached or

the sampling period ends. RDS operations include managing field sites, scheduling appointments to complete NHBS activities at the field sites, and check-in/out processes with the Coupon Manager.

Interview. Interviews occur at field sites and are administered by project interviewers. The interview includes 4 main parts: eligibility screener, consent, core behavioral survey and project area's local questions. The development of local questions is informed through formative assessment.

HIV Testing. Testing occurs at field sites on the same day as the interview. Testing is performed by collecting blood specimens for rapid testing in the field or laboratory-based testing. All participants receive counseling and referrals to services.

1.3 Informed Consent

The Centers for Disease Control and Prevention (CDC) has determined that NHBS is surveillance and not research. Project areas should follow local policies and procedures for human subjects protection. These policies may require project areas to submit the NHBS protocol to their local IRB(s).

Regardless of IRB submission requirements, because formative assessment interviews involve engagement with human subjects, project areas should obtain informed consent from individuals participating in these activities. Appendices A, B, and C of the *NHBS Round 7 Model Surveillance Protocol* contain model formative assessment consent forms that project areas can customize for local use.

Because discussions with health department staff are not considered engagement with human subjects, project areas can gather formative information from these staff without IRB approval or consent forms. For example, project areas could meet with health department staff to identify potential field site locations, to plan field operations, to identify key informants for interview, and to develop local survey questions.

1.4 Cultural Competence and Humility

Project areas should plan to provide cultural competency training for NHBS-PWID staff prior to data collection. Cultural competency training could explore respectful terminology and reducing stigma. Project areas may seek out collaborators at local organizations to provide this training. Whenever possible, such training should be conducted by persons with lived experience. Any cultural competency training should be grounded in insight garnered from direct engagement with the PWID population, as expertise garnered indirectly from research may be insufficient to describe the specific needs of the local population.

2 Formative Assessment Approach and Methods

2.0 Overview

Planning for a successful formative assessment includes identifying qualified staff, determining methods that will be used to meet the formative assessment objectives, and developing a rapid analysis plan to interpret findings.

2.1 Staffing

Ideally, project staff conducting formative assessment should include an ethnographer or a researcher with close knowledge of ethnographic methods and the NHBS population, the project coordinator, and at least two additional staff members.

2.1a Ethnographer

Project areas may wish to hire an ethnographer to lead their formative assessment activities. If an ethnographer is hired, the principal investigator is responsible for making sure that the ethnographer's work remains focused on the NHBS formative assessment goals and objectives (**Section 1.1**). The ethnographer must understand that the purpose of the formative assessment process is to inform and guide the successful collection of NHBS data.

The ideal ethnographer has training in qualitative methods in public health with experience working with a range of ethnographic methods, such as observations, key informant interviews, focus groups, and brief intercept surveys. To be most effective, the ethnographer is ideally a recognized expert on the local PWID population and its various sub-populations.

If an outside researcher is hired as the ethnographer, it is critical that NHBS project staff remain actively involved in formative assessment activities to gain knowledge about the local PWID population and to build rapport for the project. Project staff should train the ethnographer in NHBS methodology that will be used during the cycle. The ethnographer should train project staff in the formative assessment process and its methods of data collection, and they should oversee the project staff's work. The ethnographer should also provide the principal investigator and project coordinator with periodic updates on the progress of formative assessment and the findings and ensure that community connections established during formative assessment are shared with other NHBS staff who will be implementing data collection. To ensure that formative assessment activities are completed successfully and in a timely manner, the principal investigator or project coordinator should meet with the ethnographer at the beginning of the project cycle to develop a set of deliverables and a timeline for achieving them.

2.1b Project Coordinator

The project coordinator is responsible for reviewing secondary data to inform the local HIV epidemiology, assisting the ethnographer, and monitoring the formative assessment activities. Very importantly, the project coordinator is responsible for incorporating the formative assessment findings into staff trainings and plans for data collection and ongoing formative activities. The project coordinator should help the ethnographer by providing them with background information on the

project area, the recruitment methodology, and the HIV epidemic among the local PWID population. The project coordinator should also help the ethnographer identify and contact community partners and key informants for interviews.

If a project area does not hire an ethnographer or other outside researcher to lead its formative assessment activities, the project coordinator should assume the duties outlined for the ethnographer in **Section 2.1a**.

2.1c Project Staff

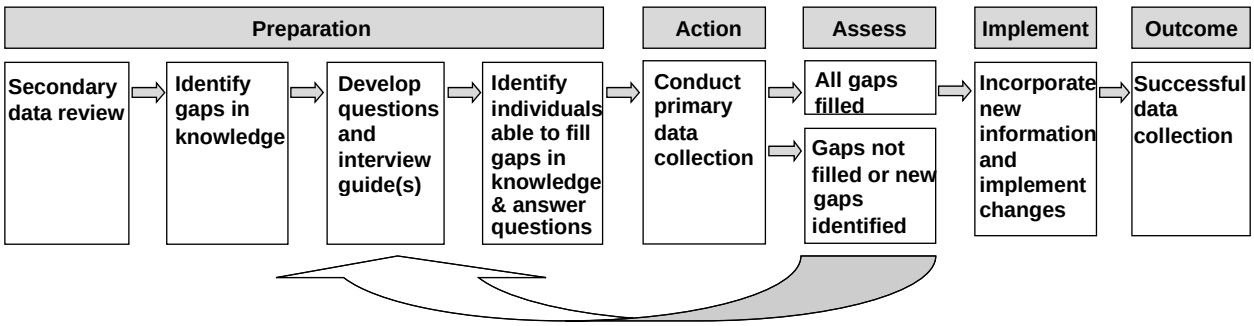
At least two project staff should assist the ethnographer with formative assessment activities. Their responsibilities could include the following:

- Garnering community support
- Collecting secondary data for review
- Identifying and contacting community members, community organizations, and key informants to participate in interviews or focus groups
- Helping with interviews and focus groups
- Conducting observations
- Conducting brief intercept surveys
- Preparing for implementation of NHBS methodology

2.2 Formative Data Collection Methods

During formative assessment, NHBS project areas will gather information through two main approaches to data collection: 1) reviews and analyses of secondary data (e.g., HIV surveillance data) and 2) primary formative data collection (e.g., interviews with key informants). To maximize the effectiveness of these formative assessment activities, project areas should employ an iterative process; information obtained from reviewing secondary data should inform primary data collection, which should then validate or provide further insight into the findings from reviewing secondary data (**Figure 1**).

Figure 1. Suggested workflow for formative assessment activities



2.2a Secondary Data Review

Secondary data are data that have been previously collected by other researchers, surveillance systems, or registries. Previous NHBS cycles are key sources of data and operational information. Reviewing lessons learned from the previous cycles can help identify potential recruitment and operational barriers and solutions for overcoming them, as well as areas that need more exploration. Finally, other important secondary data sources may include reviews of local behavioral survey and prevention activities (e.g., peer recruitment among PWID for other surveys) among NHBS populations of interest including within health departments or local academic institutions.

Secondary data are a critical component of formative assessment because they lay the foundation for the next steps in formative assessment and provide an epidemiologic profile of the local HIV situation. Gaps in information in the secondary data will help project areas develop primary data collection plans and determine where to focus their primary data collection efforts. Project areas can also use the secondary data to identify potential collaborators, key informants within the health department and populations of interest, as well as to identify possible focus group participants. After formative assessment activities have been completed and field operations have begun, the secondary data can serve as a reference when monitoring NHBS sample characteristics and assessing whether sub-populations are well-represented in the NHBS sample.

2.2b Primary Data Collection Methods

There are several primary data collection methods that can be used to obtain data necessary for informing operations. Below are commonly used methods for NHBS and recommendations on how to develop data collection tools for each method. See **Chapter 3** for details on how these methods can be used to inform implementation of RDS.

Key Informant Interviews. Key informants are cultural and subject matter experts who can provide insight into populations of interest. For the purpose of NHBS, there are two main types of key informants: "community key informants" and "professional key informants." Community key informants (CKIs) are members of the community or volunteers at community-based organizations (CBOs) rather than paid professionals. An example CKI in NHBS-PWID may be a client of a local syringe services program (SSP) who also exchanges syringes for others in the community who do not attend the program. Since CKIs are interviewed on their personal time, they should receive compensation for participating in the interview. Professional key informants (PKIs) are paid staff and managers of CBOs and other public health and research organizations with knowledge of the PWID population and are typically not entitled to compensation for their time. Interviews should ideally take place in-person rather than virtually; however, the key informant's preference should be accommodated.

It is often helpful for project areas to start primary data collection by interviewing key informants with more general information to gain an overall understanding of the population, and then move to sources with more in-depth information to address any issues that remain unclear or are of particular importance locally. In addition, to help ensure the reliability and validity of the data, project areas should interview several key informants and cross-check the information they provide.

The interview guide for key informant interviews should be semi-structured to allow for detailed and in-depth discussions (see **Appendix A Model Interview Questions**). Separate interview guides should be developed for CKI and PKI interviews to ensure the questions are tailored appropriately. Topics discussed should include the social and demographic characteristics and social networks of PWID as well

as recruitment, implementation, and logistics-based strategies for data collection (e.g., the best days, times, and locations for data collection and barriers to recruitment and participation).

Focus Groups. Focus groups are small group discussions facilitated by a moderator. They are especially helpful for gaining insight into commonly held perceptions within the populations of interest and for eliciting information on community norms. Focus groups can also be used to confirm formative assessment findings or to explore findings in greater depth. Due to their interactive nature, focus groups often yield information that is different from the information gathered with other data collection methods. A skilled moderator is critical to the success of a focus group. The moderator's role is to promote interaction between members of the group and to make sure that the discussion remains on topic.

Typically, a focus group lasts from 1 to 1.5 hours and has 6 to 12 members. Groups with fewer than 6 members tend to lose energy while those with more than 12 members may not allow everyone to participate fully. As with CKIs, focus group participants participating outside of their professional capacity should be compensated for their time. Focus groups should take place in-person rather than virtually.

Focus group participants should be recruited from within the project area and can include the population's members and community leaders, as well as staff from CBOs that serve the population. To facilitate a free and open discussion, focus groups should be composed of members with similar demographic characteristics. For example, focus groups could be organized based on age, race/ethnicity, HIV status, or professional category. It is also important for focus groups to provide a comfortable and trusting environment for all who participate.

Focus group interviews should be semi-structured and questions should be tailored based on the characteristics of the group (see **Appendix A Model Interview Questions**). Discussions may include topics such as: social, sexual, and drug-using networks in the community; venues or geographical areas that are significant to PWID; strategies for garnering community support for NHBS; marketing NHBS locally; best approaches for recruiting PWID for participation; and the identification of key community members or gatekeepers.

Formative interviews must not be video-or audio-recorded. Therefore, it is important to have designated notetakers sit in on the CKI and PKI interviews and focus group discussions.

Observations. Unlike information collected from interviews, observations rely solely on what is seen by the observer. They can be used to both validate and build on information gathered through other data sources. Observations can provide insight into the behavior of the population, issues related to field sites, or a specific topic of interest. Observations can occur in settings such as neighborhoods, service organizations, parks, or SSPs, and high drug activity areas. For example, if a particular community center is being considered as a possible field site, observations can be conducted at the community center to learn about accessibility, safety, and appropriateness. Note that observations may not be recommended for specific sub-populations or settings, based on perceptions of privacy concerns or potential harm to project staff relationships with the community.

Researchers have identified eight aspects of observations that can help guide project staff when conducting observations. These aspects have been adapted for NHBS and are summarized in **Table 1**.

Table 1. Aspects of observations

Domain	Description
Settings	Where does the observation take place? When? What is the physical layout?
People	What types of people are present? How old are they? What is their race/ethnicity? How many are present?
Activities	What is going on? What are the people doing?
Events	Is this a regular occurrence or is it a special event?
Signs	Are there clues that provide evidence about meanings and behaviors?
Time	In what order are things happening? Is there a reason for this?
Goals	What are the people trying to accomplish?
Networks	How do the people present seem to know one another? Is it social or related to a type of business? Do the relationships change over time?
Adopted from: Stimson GV, Fitch C, Rhodes T (1998). The rapid assessment and response guide on injecting drug use. World Health Organization Substance Abuse Department. (Available here)	

Observation data can include detailed field notes, maps, or numerical data (e.g., number of people accessing services at an SSP in a 60-minute period). When developing the observation data collection form, project areas should consider the type of information they are planning to gain and the best way to document the different types of information. Observation forms may be structured, meaning they consist of standard observation-related questions; semi-structured, meaning they consist of a mix of standard observation-related questions and open-ended notes; or they may be unstructured, meaning they consist of open-ended notes. Structured or semi-structured observation forms are recommended when collecting consistent data points across observations (e.g., HIV-related services offered at clinics). Observations at places like health clinics often require an invitation to observe the setting and may include gathering information about the setting through discussion with a staff person and/or collecting information from a website. Semi-structured observations may be useful when identifying potential locations for NHBS participant referrals (see **Appendix B Model Semi-Structured Service Provider Observation Form**). Examples of observation locations that may involve more open-ended, less structured observation-related questions are parks, street corners, or other public places. Unstructured observations may be useful when exploring potential field site locations (see **Appendix C Model Unstructured Field Site Observation Form**).

Brief Intercept Surveys. Brief intercept surveys (BIS) are very short surveys that focus on a few key topics, like assessing network size or acceptability of a field site location or gauging interest in participating in NHBS (see **Appendix A Model Interview Questions**). They can be open- or close-ended and should not take more than five minutes to administer. If project areas need additional information on specific sub-populations or communities, they can target their BIS to these groups. Consent is not needed for BIS, and compensation should not be provided.

2.3 Garnering Community Support

The success of NHBS will depend largely on a project area's ability to garner support from the community, as well as the broader PWID population. Greater community acceptance of NHBS will result in a higher rate of participation in the survey. To have the most impact, project areas should elicit support from a wide variety of community members and organizations. Community partners should have diverse backgrounds and they should represent different sub-populations of interest, especially those sub-populations most impacted by the HIV epidemic and those underrepresented in previous cycles (e.g., young persons in NHBS-PWID).

Examples of community partners include the following:

- Persons who inject drugs
- Staff of substance use treatment and recovery programs
- Staff of syringe services programs (SSPs)
- Staff of community-based organizations (CBOs)
- Providers of HIV and STD prevention and treatment services to PWID
- Members of community advisory boards
- Researchers whose work focuses on PWID
- Political leaders and government officials
- Police and law enforcement officials, if appropriate locally

When garnering community support, project areas should explain the goals and objectives of NHBS and describe its data collection methods, and prior findings (e.g., sharing locally developed fact sheets and data products). Project areas should emphasize that the key objective of NHBS is to understand HIV and other health disparities in the population to better serve their health needs and to guide the development and implementation of high-impact HIV prevention programs for them.

2.3a Methods of Garnering Community Support

Meetings. Meetings with community partners provide an opportunity for project areas to explain the project, describe its goals, introduce staff members, share the project logo to increase brand recognition, and answer questions. Meetings can be one-on-one or involve multiple partners, and may include public meetings (e.g., at a local community center or CBO) and can be in-person or remote. These meetings are also an excellent forum for presenting findings from previous NHBS cycles, demonstrating how NHBS data are used to develop and evaluate local policies and programs, and identifying and assessing important topics for local questions in the upcoming cycle. These meetings can also serve as a jump off to PKI interviews which are described above (**Section 2.2b**). By involving community partners in the development of local questions, project areas can gain valuable knowledge and community insight, while giving community partners a vested interest in the success of NHBS. As a result, community partners may become more likely to support and promote the project.

Collaborations. Project areas should collaborate with other health department programs, CBOs, and academic institutions that conduct HIV prevention outreach and research among PWID. Project areas should meet with the managers of these organizations and programs to explain NHBS goals and objectives, the population sampled, the overall methods and field operations, and discuss the opportunity to collaborate to provide appropriate referrals to health and social programs. These collaborations foster cooperation and positive community relations.

Marketing Materials. Project areas should create a logo and marketing materials, like informational flyers or posters, to identify the project and promote community awareness. During formative data collection, community partners, and members of the population should be asked about the types of logos and marketing materials that would be most appealing to potential participants. They should also be asked about the most effective marketing strategies for reaching the local population.

The logos and marketing materials developed by project areas should be culturally appropriate and respectful of the PWID population. Before logos and marketing materials are printed and distributed, they must be reviewed by the project area's CDC Project Officer, and approvals must be obtained. Note that project areas should not include the CDC logo or name on any of their marketing materials.

If project areas wish to use Facebook or other social networking sites to market NHBS, they should create project accounts and pages. With social media accounts (e.g., Facebook page, Instagram account, or TikTok account), project areas can control privacy settings and ensure that the page adheres to local policies regarding content and the handling of user comments. Project areas should note that NHBS-related content posted on social media sites should be treated the same as all other NHBS marketing materials; the content must be reviewed by the local program and the project area's CDC Project Officer, and it should not display the CDC logo or name. Information from CDC on social media tools, guidelines, and best practices for public health can be found at: http://www.cdc.gov/socialmedia/tools/guidelines/index.html.

Community Advisory Boards. Another means of garnering support for NHBS is through meetings with health department community advisory boards (CABs), such as the local HIV prevention planning group or HIV care consortium. CAB members already have vested interest in the health department's public health activities, and thus, would be ideal allies for NHBS. Project areas could introduce the project to their CABs, describe its goals, and present findings from previous cycles. CAB members, in turn, could become ambassadors for promoting the project in the community of interest and they could provide access to other community partners. Depending on their experience and expertise, CAB members may also be able to provide technical assistance and advice to project areas. If the health department does not have a CAB, project areas can form an NHBS CAB composed of local community members.

2.4 Ongoing Formative Assessment

Ongoing formative assessment is the collection and examination of additional quantitative and qualitative data to improve field operations and ensure the successful recruitment and enrollment of participants. Project areas should conduct ongoing formative assessment throughout the survey data collection period to maintain community support, identify and address barriers to survey participation, and monitor participant enrollment and demographic characteristics. Project areas do not have to hire additional staff to conduct ongoing formative assessment. They can use their existing staff, including the project coordinator, field supervisor, interviewers, and data manager.

2.4a Data Collection Methods

Project areas should always begin with the least labor-intensive and time-consuming methods (e.g., reviews of recruitment and enrollment data, observations, and informal conversations with participants and field staff) and then, if simpler methods do not yield results, they should proceed to more labor-intensive and time-consuming methods (e.g., key informant interviews, brief intercept surveys, and

focus groups). For example, project areas may conduct exit interviews with participants as a means of better understanding any issues relating to recruitment or participant experiences during the survey. Exit interviews are brief open-ended interviews similar to BIS that take place after all survey data collection is complete and participants have been checked-out. Project areas can use the same methods outlined above in addition to recruitment monitoring reports described in the *NHBS-PWID2024 Operations Manual*. Whenever project areas identify an operational or enrollment problem using ongoing formative assessment, they should discuss the problem with their CDC Project Officer and develop a plan to resolve it.

2.4b Data Monitoring

Project areas should continuously monitor their operations and corresponding data. Each cycle requires a unique set of elements that should be monitored. Detailed information on data monitoring can be found in the *NHBS-PWID2024 Operations Manual*.

2.5 Rapid Data Analysis

Following data collection, project areas will need to rapidly analyze data. Project areas can use several approaches described below to analyze their formative and ongoing formative data rigorously and rapidly to inform NHBS operations.

2.5a Data Collection Debriefs

Following each session of data collection, for example following a CKI interview or a field observation, project areas should conduct a structured debrief with formative assessment staff. The debrief should identify key emerging themes based on notes or other information collected. For example, following a CKI interview, the interviewer and notetaker should meet to discuss the information shared by the participant. Prior to the interview, project areas should identify key topics to debrief on and then type or write notes while the interviewer and notetaker meet to discuss the interview (see **Appendix D Model Interview/Focus Group Debrief Form**). Debriefs should be shared back with the larger formative assessment team so everyone is aware of the emerging findings and data collection plans.

2.5b Rapid Analysis Matrices

In addition to debriefs, rapid analysis matrices are another rapid analysis tool that can be used during and following qualitative data collection (see **Appendix E Model Rapid Analysis Matrices**). Rapid analysis matrices are tables designed to facilitate comparisons of key findings across data collection sessions. Each row represents a unique interview, focus group, or observation. Each column represents a theme or topic covered in the data collection session, such as barriers to interviewing or ideal field staff qualities. The interviewer/facilitator, notetaker, or observer should complete the entry into the rapid analysis matrix within a day or two of each data collection session. The debrief session notes, interview/focus group notes, and/or observation form can be used to help fill in the rapid analysis matrices. A brief summary of findings should be entered into each matrix cell; complete sentences do not need to be used. Direct quotes can be included as appropriate. Examples of matrix entries are included in **Appendix E Model Rapid Analysis Matrices**.

Organizing qualitative data in rapid analysis matrices allows project staff to identify patterns in the data rapidly. For example, in the barriers to interviewing column, an analyst would be able to review entries across rows (data collection sessions) and assess which barriers were the most commonly mentioned.

2.5c Identifying Emerging Themes

Debriefs and matrices can be used to inform a larger discussion about the key ideas and reoccurring themes that are emerging across interviews. After conducting several interviews, focus groups, observations, or BIS, project areas can reflect on the key themes that emerged from each debrief and/or matrix. When the same themes begin to repeat, it likely means that data collection has reached saturation, or the point when new information is no longer gathered; this indicates that data collection may end.

2.5d Triangulation of Data

"Triangulation" means cross-checking findings by using multiple data sources, data collection methods, or investigators. Since formative assessment that relies on only one data source or collection method is subject to the errors associated with that source or approach, triangulation helps to validate the results and ensure that the information is complete. One way project areas can triangulate their formative assessment data is to compare information on the same topic that has been obtained from different data sources. Another strategy is to use at least two different data collection methods (e.g., key informant interviews, focus groups, observations, or brief intercept surveys). Lastly, project areas should always compare primary and secondary data findings; this is essential for the success of formative assessment.

3 Focus Areas Specific to RDS

3.0 Overview

Formative assessment is key to successful implementation of RDS by providing essential information necessary to:

- Understand characteristics of the peer networks of the local population of PWID.
- Identify ideal characteristics for seeds.
- Identify optimal field site locations and operations.
- Garner community support for NHBS (**Section 2.3**).

3.1 Peer Networks

In NHBS, a "peer network" is defined as the group of people that a person knows in the project area. A person's peer network is composed of friends, relatives, sex and drug use partners, and other people with whom the person associates. In NHBS-PWID, people in a person's peer network must also inject drugs. Primary data can provide insight into the characteristics of the peer networks of the PWID population, which is critical to understanding how RDS sampling is likely to proceed and how recruitment can be optimized to enroll a representative sample from the PWID population. For example, in one city, members of the PWID population interact as a single peer network, while in a second city, members of the PWID population form two separate peer networks that rarely interact with each other. In the second city, project staff would have to recruit seeds from both peer networks in order to efficiently reach the entire PWID population. They would also have to ensure that their field site is equally accessible to members of both peer networks. Alternatively, they could set up two field sites, with one field site readily accessible to members of one peer network and the other field site readily accessible to members of the other peer network.

Project areas can learn about peer networks by asking key informants and focus group participants about the characteristics of their social connections; and by asking key informants and focus group participants where they go to work, shop, socialize, and buy and use drugs. These places may be in person or virtual.

The locations where these activities occur can play an important role in shaping peer networks when segments of the PWID population are geographically isolated from one another. When people who live in different areas of the city go to the same areas to work, shop, socialize, or buy and use drugs, they increase the likelihood that they will meet and interact with one another. This, in turn, increases the likelihood that they will recruit one another to participate in NHBS. On the other hand, when people who live in different areas of the city work, shop, socialize, and buy and use drugs solely in their own communities, they decrease the likelihood that they will meet and interact with people from other areas. As a result, they will be less likely to recruit one another to participate in NHBS.

3.2 Seeds

There are multiple criteria to consider when identifying initial recruits, or seeds, in RDS (see Chapter 4 of the NHBS *Round 7 Model Surveillance Protocol*). Ideal seeds are dynamic individuals who are extremely knowledgeable about the PWID population, well-connected to it, and have a vested interest in its well-being. They should also have network ties to the major sub-populations in the project area. Since seeds are the initial recruiters in RDS, it is essential that they be highly motivated to provide support for the project and encourage others to participate. Selecting effective and well-connected seeds facilitates recruitment and promotes longer recruitment chains which help reduce bias in the sample.

During formative assessment, project areas should identify the demographic characteristics of individuals with network ties to the important sub-populations (e.g., young PWID) and choose seeds with those characteristics. Usually, seeds are selected from a variety of sub-populations. However, with strong justification and CDC Project Officer approval, project areas may choose to select most, or all, of their seeds from a single sub-population if that sub-population is relevant to the local HIV epidemic, was underrepresented in previous NHBS cycles (as applicable), and is networked to the broader PWID population (i.e., has weak homophily).

Project areas can identify their seeds during formative assessment through key informant interviews, focus groups, and brief intercept surveys. After explaining the RDS methods and the seed criteria, project areas can ask interviewees if they could refer potential seeds to the project or if they would be interested in being a seed themselves.

In addition to using the referral card (see *NHBS-PWID2024 Operations Manual*), formative assessment participants identified as potential seeds may be offered the option to provide a phone number to NHBS project staff so they can be re-contacted at the beginning of data collection to schedule their interview. This option could only be offered permitting local policy and necessary approvals (e.g., from the IRB). Contact information will need to be securely stored in a locked cabinet without any additional identifying information such as a name, and it will need to be kept separate from any formative data collected on the individual. A sample contact form that can be used to store the information is shown in **Figure 2**. If project areas choose to use this method of contact, they should work with their CDC Project Officer to get approval of their data security and confidentiality plans for securing the phone numbers. All phone numbers for potential seeds must be discarded prior to data collection so that no survey data can be linked to their phone numbers. Note that collecting contact information is limited to potential seeds and does not apply to other NHBS participants.

Figure 2. Sample contact form for potential seed participants

Seed Contact Form

Project Staff Name: _____

Interview Location: _____

Phone #: _____

Okay for us to identify ourselves as ***[Project Name]*** when we make the phone call?
□ Yes □ No

Okay for us to text you at this phone #?
□ Yes □ No

Unless we are instructed otherwise, our standard message is:
*Example: Hello, this is (staff member's name) from **[Project Name]** contacting you to schedule an appointment for your interview. Please call [or text] me back at XXX-XXX-XXXX between 10:00 AM and 4:00 PM on Monday through Friday. Thanks and have a great day.*

[If calling only] If no one answers, is it okay to leave this message on voicemail or an answering machine?
□ Yes □ No

Add any additional instructions (no identifying information):
_____

3.3 Field Site Logistics and Operations

Project areas will operate out of field site(s) like an office or a van parked at a specific location. Project areas must select field sites that are readily accessible to all members of the PWID population. The locations of field sites should not create a barrier to participation for any sub-populations, especially those sub-populations that have been underrepresented in previous cycles (e.g., young PWID). Project areas should ask members of the PWID population which days and hours of operation would be most convenient for them to participate in an interview. Project areas should conduct interviews at a variety of times to accommodate PWID who work or are busy during those times. Project areas should also determine whether potential participants will be allowed to "walk-in" to be interviewed anytime during operating hours, and how to provide incentives remotely.

Project areas will also need to assess what is feasible, safe, and acceptable for HIV testing. For example, project areas will need to identify whether DBS can be safely collected. Project areas will also want to collect information on how to ensure acceptance of their methods and operations.

When assessing the suitability of field sites, project areas should consider the following questions:

Is the field site accessible, safe, and appropriate for the PWID population? Project areas should investigate whether there are any barriers that would keep PWID or specific sub-populations from coming to the field site. For example, can all members of the PWID population easily access the field site using public transportation? Project areas should determine if the community (residents, local businesses, law enforcement, etc.) around the field site is accepting and welcoming of PWID and NHBS activities. A field site must also be safe for both the participants and the project staff.

An appropriate field site will not bias the sample of participants. Therefore, a field site should not be located in a facility that primarily or exclusively provides a specific service to PWID, such as medical or mental health care, HIV or STD testing, HIV care or prevention, or drug treatment or prevention. A facility that exclusively provides social services to PWID is also not appropriate. Based on previous RDS studies, it is likely that placing a field site in a facility that provides a specific service to the PWID population would bias the sample toward those who receive that service. For example, a field site in an HIV clinic would likely bias the sample toward HIV-positive participants. On the other hand, a field site may be located in a facility that provides a vast array of services since it is not likely that the sample would become biased toward those who receive any one particular service.

What is the appropriate number of field sites? While there should be a sufficient number of field sites so that all members of the PWID population have access to a field site, there should not be too many field sites that the chance of cross-recruitment of participants between field sites is reduced. When there is no cross-recruitment of participants between field sites, separate RDS samples are generated at each field site, which is very challenging to analyze. Based on experience from previous NHBS cycles and other RDS studies, project areas should operate as few field sites as are necessary to reach the sub-populations that are most important to the local HIV epidemic or that have been underrepresented in previous NHBS cycles.

What are the ideal logistics for field site operations? Project areas should ask members of the PWID population which days and hours of operation would be most convenient for them to go to the field site for an interview. Field sites should be open outside normal business hours at least one day per week to accommodate PWID who work or are busy during those times. Project areas should also determine whether PWID would prefer to set up appointments to be interviewed or to walk-in to be interviewed anytime during operating hours.

4 Formative Assessment Products

4.0 Overview

As part of the formative assessment process, project areas are required to submit the products below to document timelines, formative assessment plans and findings. The purpose and content of each of these documents is described in this section. Models for these products are provided in the Appendix that accompanies this Manual as noted in **Table 2**.

Table 2. Formative Assessment Products and Due Dates

Product	Brief Description	Appendix Document	Due to CDC Project Officer
Implementation Timeline	Timeline of all major cycle milestones and benchmarks that need to be completed to start survey data collection on time. The timeline is updated as needed throughout the planning phase.	Appendix F	January 19
Interim Data Report (Secondary Data Tables; Secondary Data Findings & Primary Data Collection Plan)	Secondary Data Tables: Summary tables that provide data on demographic characteristics, structural and contextual factors and the HIV prevention context. Interim Data Report: Summary of secondary data findings and implications for planning primary data collection for formative assessment.	Appendix G (Secondary Data Tables) Appendix H (Interim Data Report Template)	February 16
Formative Assessment Tools	Package of materials used during formative assessment including consent forms, interview guides, and community engagement materials.	Appendices A, B, and C (Model data collection tools)	February 23
Final Data Report	Summary of formative assessment findings and recommendations for survey data collection.	Appendix I	April 19

Note: CDC requires two weeks to review all documents.

4.1 Implementation Timeline

The implementation timeline should present all activities conducted in preparation for field operations to help project areas plan and manage the process and initiate survey data collection on time. **Appendix F** of this manual is a model Implementation Timeline for NHBS-PWID2024 that project areas can customize for local use.

The timeline should show the period when tasks will be performed and the dates when they will be completed. Project areas should include each formative assessment tool (e.g., professional key informant guide, observation tool) on a separate row in the timeline with a corresponding completion date (by February 23). The timeline should also include any other tasks that may impact formative assessment or preparation for operations, especially those tasks that have delayed the start of survey data collection in the past (where applicable). If the timeline is modified after submission, project areas should discuss the needed changes with their CDC Project Officer and submit a revised timeline.

4.2 Secondary Data Tables

The Secondary Data Tables provide information on the local HIV epidemiology and prevention context for NHBS data collection. **Appendix G** of this manual includes model secondary data and descriptive tables described in more detail in **Section 4.2a and Section 4.2b, respectively**.

4.2a Data Tables

Data tables summarize information from secondary data sources including US Census data for the adult population residing in each principal city of the funded MSA or MSA Division, HIV surveillance data overall and for PWID, and data from previous NHBS cycles among PWID or other local research surveys. The list of data tables is below and model table shells that project areas can use to develop these tables are included in **Tables 1-7 of Appendix G** of this manual.

- **Table 1.** Characteristics of the adult population
- **Table 2.** New HIV diagnoses among adults
- **Table 3.** New HIV diagnoses among PWID
- **Table 4.** Characteristics of PWID in previous NHBS cycles
- **Table 5.** HIV-positive test results and HIV prevalence among PWID in previous NHBS cycles [and other local studies]
- **Table 6.** Evaluation of field sites and hours/days of operation in PWID2022
- **Tables 7a-7c.** Other relevant data from additional data sources [*if available*]

Table 1 on the characteristics of the adult population in the principal city of the funded MSA or MSA Division is only produced during the first year of each new funding period. If there are no substantial changes to this information, a copy of the first year's table should be used. If there are substantial changes to the information that could affect field operations, project areas should update the table with the most recent data available.

Data for new HIV diagnoses in **Tables 2-3** should be restricted to those HIV cases that were reported through December 2023 and were newly diagnosed with HIV between January 2018 and December 2022. If possible, cases should be adjusted for reporting delays and cases that do not have a known HIV transmission category should be adjusted using the multiple imputation (MI) method developed by CDC's HIV Surveillance Branch or a redistribution method developed by the local health department.

4.2b Descriptive Tables

Descriptive tables provide a structure to summarize key contextual information to understand the local HIV policy landscape, prevention and social service programs. Additional information is provided below, and model table shells are included in **Tables 8-9 of Appendix G** of this manual.

- **Table 8.** Program and client characteristics from syringe services programs (SSPs)
- **Table 9.** HIV policy landscape

Table 8 provides information on the operations, reach, and demographics of clients at each SSP in the MSA. Information for each SSP should be entered into one column in the table, if data are available. Program information should be gathered through contacts at SSPs. Project areas may also consider including information from surrounding MSAs, where relevant. Some descriptive information about many SSPs can be found here: https://nasen.org/map/.

Table 9 includes key policies which impact HIV prevention locally, either directly (e.g., impacting service provision) or indirectly (e.g., promoting stigma), and those which may impact NHBS participation. Examples include HIV criminalization laws, drug paraphernalia laws, and SSP authorization. Policy information specific to SSPs has been collected by the Policy Surveillance Program and can be found here: http://lawatlas.org/datasets/syringe-services-programs-laws.

4.2c Additional Secondary Data Sources

Project areas can include additional tables in their Secondary Data Tables document (**Appendix G**) to present information from other data sources important to their principal city. Additional data sources that may be considered are listed in **Table 3**. Project areas should include references for the sources of all data included in the Secondary Data Tables in a footnote of each table, as applicable.

Table 3. Sample Sources of Data for Additional Tables

Data Sources	Description	Data Contents	Web link
The Policy Surveillance Program	A cross-sectional dataset that presents state-level statutes and regulations that impact SSPs in effect as of August 1, 2019.	The map identifies the method of authorization for SSPs, requirements for the establishment of SSPs, the types of services provided directly and by referral, drug paraphernalia possession laws, and whether an SSP is operating in the jurisdiction.	http://lawatlas.org/datasets/syringe-services-programs-laws
North America Syringe Exchange Network (NASEN)	A directory of SSPs who have authorized NASEN to publish their information solely for NASEN directory purposes. It is not, nor is it intended to be, a comprehensive listing of all SSPs in the United States.	Directory of SSPs (including map) which can be filtered by state, by type, and by service.	https://nasen.org/map/

National Drug Early Warning System (NDEWS) Reports	A synthesis of available data describing the epidemiology of drug abuse for both the country and participating metropolitan areas.	Drug abuse indicator data, findings from surveys, and other quantitative information compiled from local, state, and federal sources. Data are enhanced with qualitative information obtained from ethnographic research, focus groups, and other community-based sources. Local contacts with expertise on drug abuse could be obtained from the list of epidemiologists from sentinel sites.	http://www.ndews.org
National Survey on Drug Use and Health (NSDUH)	Annual survey of prevalence, patterns, and consequences of drug and alcohol use and abuse in the general, non-institutionalized civilian population ages 12 years and over in the U.S.	Demographic and drug use data among individuals.	http://www.samhsa.gov/data/population-data-nsduh
Hepatitis C Surveillance	Probable or confirmed cases of hepatitis C reported to jurisdictions, mostly by clinical laboratories, health care facilities, and health care providers.	Data on demographics, risk behaviors, and exposures among newly reported cases of acute or chronic hepatitis C virus infection.	https://www.cdc.gov/hepatitis/statistics/2021surveillance/hepatitis-c.htm
Treatment Episode Data Set (TEDS)	Information collected by states from local alcohol and drug abuse treatment facilities characterizing admissions to alcohol and drug treatment.	Demographic and drug history information about individuals admitted to treatment; changes in treatment admissions.	http://www.samhsa.gov/data/client-level-data-teds
State Unintentional Drug Overdose Reporting System (SUDORS)	Information collected by states abstracting data for drug overdose deaths from death certificates and medical examiner/coroner reports.	Characteristics and circumstances surrounding drug overdose deaths.	https://www.cdc.gov/drugoverdose/fatal/sudors.html
Behavioral Health Treatment Services locator	Searchable database of treatment facilities in the U.S. for substance abuse/addiction and/or mental health problems.	Location of the programs in a map of the city as well as general information about each program.	https://findtreatment.samhsa.gov/locator/home

Youth Risk Behavior Surveillance System (YRBSS)	National school-based survey conducted by CDC and state, territorial, and tribal governments, along with local education and health agencies. National and select state, district, territorial, and tribal results are available.	Data on health seeking and risk behaviors, including injection drug use.	http://www.cdc.gov/healthyyouth/data/yrbs/

4.3 Interim Data Report

After completing the secondary data tables, project areas will complete the Interim Data Report that summarizes their secondary data findings and primary data collection plan for formative assessment. A model table designed to present secondary data findings and the primary data collection plan is included in **Appendix H Interim Data Report Template**. Project areas can choose to complete the report using a narrative, if preferred.

Secondary Data Findings. Project areas will summarize key secondary data findings which could inform or impact any part of the NHBS process, including formative assessment, NHBS survey data collection, or community engagement. Secondary data findings should be drawn from the Secondary Data Tables (**Appendix G**) and if available, from lessons learned in previous NHBS-PWID cycles and findings from other local surveys of PWID and prevention activities. Findings should be grouped by formative assessment topic areas:

I. Social, demographic, and peer network characteristics of PWID
II. Local drug use patterns
III. RDS implementation and field operations
IV. Barriers to participation
V. Garnering community support
VI. Data dissemination

Primary Data Collection Plan. Project areas will list formative topics/questions or gaps in knowledge identified during secondary data review that need further assessment using primary formative methods. Formative assessment methods are discussed in **Chapter 2**. The primary data collection plan will inform the development of the formative assessment tools (see **section 4.4**) and should be discussed with the project area's CDC Project Officer during regular calls.

Project Officer approval of the primary data collection plan is required prior to conducting primary data collection activities. Furthermore, some formative assessment documents may need to be developed before the formative assessment plan depending on local IRB processes which should be discussed with the project area's CDC Project Officer.

4.4 Formative Assessment Tools

Formative Assessment Tools include all documents that are part of the IRB submission (if applicable) for formative assessment, and/or those that will be used with participants. These should be submitted to the project area's CDC Project Officer for review prior to IRB submission (if applicable). These may include:

- Consent Forms for the types of interviews implemented: PKI/CKI/Focus Group (see Appendices A, B, and C of the *NHBS Round 7 Model Surveillance Protocol)*
- Interview Guides for the types of interview implemented: PKI/CKI/Focus Group (**Appendix A** provides sample questions)
- Brief Intercept Survey Forms (**Appendix A** provides sample questions)
- Observation Forms (**Appendices B and C** are model observation forms)
- Formative Assessment Recruitment Materials

4.5 Final Data Report

In the Final Data Report, project areas will summarize key findings from the formative assessment activities and outline their implications for NHBS operations (see **Appendix I**). This report includes the following sections:

Primary Data Collection Methods. Project areas will outline information about the specific methods that were used during formative assessment (e.g., PKI, CKI, focus groups, observations, BIS), along with the relevant demographic data about the participants. **Appendix I** provides model methods tables.

Formative Findings and Implications for NHBS. Project areas will present key information learned from formative assessment and how it impacts NHBS, including survey data collection, testing, and ongoing formative assessment. As in the Interim Data Report, findings should be grouped by key formative assessment topic areas. Primary data should be triangulated with secondary data findings as needed to support final conclusions. **Appendix I** provides a model table that project areas can modify for local use. Project areas can choose to complete the section using a narrative format, if preferred.