

**Syringe Service Programs' (SSP) User Experiences with HIV/HCV/HBV Prevention,
Testing, and Linkage to Care and Treatment**

Generic Information Collection Request under OMB #0920-1091

Section B: Supporting Statement

August 9, 2018

CONTACT

Neal Carnes, PhD
Technical Monitor & Principal Investigator
Centers for Disease Control and Prevention
Division of HIV/AIDS Prevention
1600 Clifton Road, NE, Mailstop MS US8-5
Atlanta, GA 30329
Phone: 404-718-5379
Fax: 404-639-1950
E-mail: mwi2@cdc.gov

TABLE OF CONTENTS

1. Respondent Universe and Sampling Methods.....3
2. Procedures for the Collection of Information.....4
3. Methods to Maximize Response Rates and Deal with No Response.....6
4. Tests of Procedures or Methods to be Undertaken.....7
5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing
Data.....7

EXHIBITS

Exhibit 1.1 Summary of Recruitment Targets.....4
Exhibit 5.1: Study Consultants..... 7

1. Respondent Universe and Sampling Methods

Site Selection

This study will be carried out with syringe service programs (SSPs) operating in three jurisdictions: Louisville, KY, Huntington, WV, and Henderson, NC. The sites were selected in consultation with an expert on SSPs. Criteria for selection included providing services to people who inject drugs (PWID) and live in rural areas. Rural PWID are at increasing risk of HIV, hepatitis C virus (HCV), and hepatitis B virus (HBV) in light of the opioid crisis in the United States.^{1,2} Each site operates in a different state with different laws and regulations governing the operation of SSPs, and each site is structured differently. The Louisville SSP functions as a non-clinical site, meaning they do not provide direct clinical care, rather they refer their clients requesting clinical services to other agencies and programs of the county health department. The Huntington SSP provides direct clinical care, and the Henderson site is a mobile unit that travels to their participants to provide service. These sites can help us understand how variation in SSP implementation may influence the needs and barriers to offering HIV, HCV, as well as HBV testing, treatment, and care services to rural PWID.

In addition, all three sites operate in or near the Appalachia region of the United States. This area has been determined to be vulnerable to HIV and HCV outbreaks based on rates of illicit opioid use, especially when injected.¹ This study considered the unique challenges faced by people who reside in rural areas of the Appalachia region, due to factors such as travel distance to healthcare and greater availability of opioids.^{3,4} Further, this study considered the 2014-15 HIV and HCV outbreak in Scott County, Indiana (a rural county in southern Indiana) when deciding the criteria for site selection.^{5,6} In their assessment of the Scott County outbreak, Peters and colleagues (2016: 236) stated, “The circumstances underlying this HIV outbreak are not unique to this community. Although the magnitude of the outbreak was alarming, the introduction of HIV into a rural community in the United States was not unexpected when considered in the context of increasing trends in injection use of prescription opioid analgesics and the new and steady rise in acute HCV infections in rural areas, particularly central Appalachia.”⁶ As such, we selected our three sites based on their location and variation in service provision to PWID who live in rural areas, in or near the Appalachia region.

Target Population

The study’s target population includes two groups: (1) SSP staff and community stakeholders, and (2) SSP clients. The total sample will include 60 individuals: 15 SSP staff/community stakeholders (five per site), and 45 SSP clients (15 per site). During site visits with the participating SSPs, differences were noted in perceived needs, barriers, and facilitators to accessing SSP services by client gender. As a result, we seek to have a balanced distribution by gender identity among the client sample. This study will sample 21 males, 21 females, and, if possible, three transgender persons. These targets will be evenly divided across the participating SSP sites (seven men, seven women, and one transgender per site). If the transgender slot cannot be filled by a self-identified transgender person, it will be filled with a person of any gender. (Exhibit 1.1: Summary of Recruitment Targets).

Exhibit 1.1 Summary of Recruitment Targets

SSP Location	Male Clients	Female Clients	Transgender Clients (if not possible, either male or female)	Staff and Community Stakeholders	Total
Louisville, KY	7	7	1	5	20
Huntington, WV	7	7	1	5	20
Henderson, NC	7	7	1	5	20
TOTAL	21	21	3	15	60

Inclusion Criteria for SSP clients:

- Report having accessed the SSP’s services more than once
- Report having injected drugs at least once in the past 12 months
- 18 years of age or older
- Able to speak English
- Report living in a rural area
- Voluntarily consent to participate

Inclusion Criteria for SSP staff and/or community stakeholders:

- Must work or volunteer with a participating SSP at the time of their interview or work directly with the SSP clients
- 18 years of age or older
- Able to speak English
- Voluntarily consent to participate

Exclusion criteria:

- Inability to provide voluntary consent (for any reason)
- Failure to meet other inclusion criteria as described above

2. Procedures for the Collection of Information

Trained contract staff from the research team will carry out all information collection activities, not CDC staff. The participating SSP staff as well as contract research staff will distribute recruitment materials (**Attachment 1**). These materials include a telephone number for interested parties to call for screening and scheduling purposes. Interested participants may be screened by phone. If eligible, the contract study team will work with each participant to find a convenient time and location to conduct the interview. Alternatively, interested participants may be recruited in-person, during which the contract research team would describe the study and screen the participant at the time of recruitment.

Recruiting SSP staff and community stakeholders will begin with a request to each participating SSP to compile a list of titles or roles of program personnel, community stakeholders involved with the SSP, and agencies who work directly with SSP clients. Once study clearances have been obtained, contract study staff will request contact information for the roles/agencies on the list. Contract staff will attempt to inform everybody on the list of the study and its purpose.

Participants will be selected from interested volunteers on a first-come first-serve and eligibility basis, and will be asked to share the study's information to potentially eligible people (i.e., snowball referral).

Prior to screening, interested staff, stakeholders, and clients will be told about the purpose of the study, informed how their information will be used, how their identity will be protected and how their information will be presented in a way that does not identify them, and of their right to withdraw from the study at any time without penalty. If they voluntarily agree to proceed, the research staff will conduct the screening in a private area, such as over the phone or in a place others cannot hear their answers. SSP client screening will last approximately 10 minutes, and includes eligibility as well as demographic questions (**Attachments 2a**). SSP Staff and Stakeholder screening to determine eligibility will last approximately 5 minutes (**Attachment 2b**). Once the interested party is determined to be eligible, they will be invited to join the study. If they are not eligible or choose not to participate, their screening information will be destroyed. If they agree to participate, contract study staff will collect the participants contact information (**Attachment 2c**) in order to schedule an interview.

After agreeing to participate, and prior to the interview, informed consent will be covered. As part of the consent process, the interviewer will request permission to audio record the interview in order to have an accurate record of the conversation. Client and staff/stakeholder participants must indicate their consent to the interview and recording by signing the Informed Consent Form (**Attachments 3a and 3b**). Interviewers will remind participants not to use full names or other identifying information during the interview. Client and staff/stakeholder interviews are scheduled to last approximately one hour (**Attachments 2d and 2e**), and all participants will be informed of this prior to the interview. All interviews will be conducted in person.

Contract researchers actively involved in data collection activities will meet the studies training requirements. The contract research team with access to names, contact information, or interview recordings will be required to read and sign a "Rules of Behavior" document, which explains the rules and guidelines for collecting, logging, storing, and destroying personally identifiable information, including names and contact information.

The contact (**Attachment 2c**) and consent forms (**Attachments 3a and 3b**) will be the only forms containing participant names; all other data collection forms will utilize a unique study identification number. The Contact Form will be the only document that links the participant's name to their study identification number. The Contact Form will be maintained only on paper and will never be translated into electronic format. The contract research team will collect contact information on the Contact Form for the purpose of scheduling interviews. The signed Informed Consent and Contact Forms will be stored separately in locked cabinets isolated from other study data.

Audio files will be stored on the recorders. The recorders will be secured in locked offices, cabinets, or drawers and briefcases when not in use; transcription will be done by contract research staff by listening to the interview files on the recording device and transcribing the recordings on stand-alone, password protected computers that are not networked (without

Internet access). Transcriptionists will take care to remove any names, contact information, or other information that could identify the participant or anyone they discuss.

Each interview will be transcribed into an encrypted MS Word document. Transcripts will be stored on, and edited from a CDC-approved encrypted USB drive plugged into a standalone, non-networked computer at study offices. Qualitative data analysis files will be stored in a FISMA-compliant dedicated data server or on a CDC-approved encrypted USB drive plugged into a standalone, non-networked computer at study offices. Any other data that can be kept electronically will also be stored in a secure, FISMA-compliant environment or on a CDC-approved encrypted USB drive plugged into a standalone, non-networked computer at study offices. Backup files will be encrypted and maintained on flash drives securely kept under lock and key. At no point will interview recordings, contact information forms, or consent forms be transmitted to CDC or shared with CDC in any way. CDC will only receive de-identified transcripts of the interviews, and aggregate level data.

This study meets the requirements necessary for a Certificate of Confidentiality, as mandated by Section 301(d) of the Public Health Service (PHS) Act and as amended by Section 2012 of the 21st Century Cure Act, P.L. 114-255 (42 U.S.C. 241(d)).⁷ The Certificate of Confidentiality further protects the privacy of participants by limiting the disclosure of identifiable, sensitive information. With this Certificate, the research team cannot be forced, for example by court subpoena, to disclose identifying information from participants for any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level.

CDC has also completed a Privacy Impact Assessment of the data system used by the contractor team (**Attachment 6**). The contractor team also completes an annual renewal process for their data system, and has a current Authority to Operate approval (**Attachment 6**). Public access to the data will be provided at the completion of the study and after the dissemination of the main outcome findings. The study data sharing and use agreement describes in detail how data access will be provided and provisions for protection of privacy, confidentiality, security, intellectual property, or other rights (**Attachment 5**).

3. Methods to Maximize Response Rates and Deal with No Response

We will use the following procedures to maximize participation and to achieve the desired response rate:

- Recruitment materials will be distributed by and/or posted at the participating SSP sites
- Recruitment materials indicate the voluntary nature of the study
- Staff/Stakeholders will be identified through existing relationships with the participating SSPs
- Interested parties will be informed of the procedures to protect the confidentiality of the information they provide; for example, the issuance of a Certificate of Confidentiality that prevents the release of data in criminal investigations or court hearings
- A \$40 token of appreciation will be provided to participants upon completion of the interview. (Note: at the time of data collection, the participating SSPs do not anticipate direct federal funds to support staff salaries.)

4. Tests of Procedures or Methods to be Undertaken

The research team includes experts with experience conducting HIV research with health departments, community-based organizations, vulnerable populations, and using qualitative methods, including eligibility screening and in-depth interviews. The contracted research team will pilot test the screener and in-depth interview guides with up to nine mock participants to assess question wording, skip patterns, question sensitivity, overall flow of the interview, and to estimate response burden for each respondent. The contract research team will be responsible for collecting, storing, and transmitting all information gathered as part of this study. Interview transcripts and final reports will be reviewed prior to submission to the CDC to ensure no identifying names or locations are included.

5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

Exhibit 5.1 below lists the study team members consulted on the aspects of research design and those who will be collecting and analyzing the information. Please note: The CDC staff are primarily responsible for providing technical assistance in the design and implementation of the research; assisting in the development of the research protocol and data collection instruments for CDC IRB review; working with investigators to facilitate appropriate research activities; and analyzing data and presenting findings at meetings and in publications. The CDC staff will neither collect data from nor interact with research participants. Members of contract research team will collect all study-related data. No names or contact information will be linkable to information reported to the CDC. All members of the research team will work together to analyze the data and generate reports containing summaries of the findings.

Exhibit 5.1: Study Consultants

Team Member	Organization	Phone	Email
Neal Carnes	CDC	404-718-5379	mwi2@cdc.gov
Alice Asher	CDC	404-718-8284	luq1@cdc.gov
Patricia Bessler	CDC	404-639-8239	vey4@cdc.gov
Michele Bohm	CDC	770.488.3928	evd5@cdc.gov
Alisu Schoua-Glusberg	Research Support Services	847-864-5677	alisu@researchsupportservices.com
Casey Tesfaye	Research Support Services	847-864-5677	casey@researchsupportservices.com
Paula Frew	Emory University	404-712-8546	pfrew@emory.edu
Laura Randall	Emory University	404-727-2994	laura.randall@emory.edu
Bryan Gale	IMPAQ International	443-259-5186	bgale@impaqint.com
Valerie Betley	IMPAQ International	443-259-5196	vbetley@impaqint.com
Elizabeth Gall	IMPAQ International	443-259-5216	egall@impaqint.com

References

1. Van Handel MM, Rose CE, Hallisey EJ, et al. County-Level Vulnerability Assessment for Rapid Dissemination of HIV or HCV Infections Among Persons Who Inject Drugs, United States. *J Acquir Immune Defic Syndr*. 2016;73(3):323-331.
2. Wejnert C, Hess KL, Hall HI, et al. Vital Signs: Trends in HIV Diagnoses, Risk Behaviors, and Prevention Among Persons Who Inject Drugs - United States. *MMWR Morb Mortal Wkly Rep*. 2016;65(47):1336-1342.
3. Caldwell JT, Ford CL, Wallace SP, Wang MC, Takahashi LM. Intersection of living in a rural versus urban area and race/ethnicity in explaining access to health care in the United States. *American journal of public health*. 2016;106(8):1463-1469.
4. Keyes KM, Cerdá M, Brady JE, Havens JR, Galea S. Understanding the Rural–Urban Differences in Nonmedical Prescription Opioid Use and Abuse in the United States. *American Journal of Public Health*. 2014;104(2):e52-e59.
5. Twohey M. Mike Pence's Response to H.I.V. Outbreak: Prayer, Then a Change of Heart. *The New York Times*. August 8, 2016.
6. Peters PJ, Pontones P, Hoover KW, et al. HIV Infection Linked to Injection Use of Oxycodone in Indiana, 2014-2015. *N Engl J Med*. 2016;375(3):229-239.