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 A: Supporting Statement

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- **Goals of the study:** The goal of the study is to understand current availability, perceived need and factors influencing the delivery of HIV, hepatitis C virus (HCV), and hepatitis B virus (HBV) services offered to rural clients of syringe service programs (SSPs) serving outbreak prone areas.

- **Intended use:** Study outcomes will be reported to participating SSPs, as well as local, state, and national stakeholders that design and implement HIV, HCV, and HBV services for people who inject drugs (PWID). The findings will also provide CDC a better understanding of the factors that influence the perceived need, use, and offering of services in areas prone to HIV, HCV, and HBV outbreaks.

- **Methods to be used to collect data:** Data will be collected through a screening process as well as during one-on-one, semi-structured, in-depth interviews (IDIs).

- **The subpopulation to be studied:** The sample will consist of 60 individuals evenly divided between three participating SSPs (20 participants per site). Of these 60, 45 will be clients of the SSPs (15 per site) and 15 will be participating SSP staff or local stakeholders that work or volunteer with SSP clients (5 per site). The three participating SSP sites operate in Louisville, KY, Huntington, WV, and Henderson, NC.

- **How data will be analyzed:** We will conduct thematic coding of the 60 in-depth interview transcripts using computer-assisted qualitative data analysis software. In addition, we will describe the sample's demographic and eligibility characteristics using statistical software.

Supporting Statement

A. Justification

1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention's (CDC) Division of HIV/AIDS Prevention, (DHAP) requests OMB approval for 1 year for a qualitative, extramural research study entitled, "Syringe Service Programs' (SSP) User Experiences with HIV/HCV/HBV Prevention, Testing, and Linkage to Care and Treatment" under the Using Qualitative Methods to Understand Issues in HIV Prevention, Care and Treatment in the United States Generic Clearance (OMB #0920-1091, expires 09/30/2021). CDC will sponsor this data collection activity. Data collection will be carried out by the CDC's contractor, Research Support Services, in conjunction with its subcontracting partners, Emory University and IMPAQ International.

This information is collected under the authority of the Public Health Service Act, Section 301, "Research and Investigation," (42 U.S.C. 241); and Sections 304, 306 and 308(d) which discuss authority to maintain data and provide assurances of privacy for health research and related activities (42 U.S.C. 242 b, k, and m(d)). This information is also being collected in conjunction with the provisions of the Government Paperwork Elimination Act and the Paperwork Reduction Act (PRA). This information will only be used by the Centers for Disease Control and Prevention (CDC) staff to evaluate Syringe Service Programs' (SSP) User Experiences.

This study will interview participants to assess existing and potential HIV, HCV, and HBV services at three SSPs that serve rural clients who inject drugs and live near or in the Appalachia region of the U.S. The study will result in four reports (one for each participating site, along with one report summarizing findings across all three sites) that present a comprehensive picture of client needs and SSPs' capacity to offer these services. The study will interview SSP clients, staff, and stakeholders' about the need for HIV, HCV, and HBV services, as well as the barriers and facilitators to accessing and providing these services. By conducting this study, we intend to identify some of the challenges that prevent SSP clients from seeking testing and care services, increase use of available services, and help reduce disparities among rural PWID.

SSPs have been shown to be an effective component of a comprehensive, integrated approach to HCV and HIV prevention among people who inject drugs (PWID).[1,2] SSPs serve as a bridge to condom access, risk-reduction education, testing for HIV and HCV, referrals to health services (e.g., treatment for HIV, HCV, or substance use disorder, including medication-assisted treatment with methadone or buprenorphine), pre-exposure prophylaxis (PrEP) to prevent HIV infection, and safe syringe disposal.[3] In addition, SSPs help decrease the risk of passing HCV by providing clean syringes.[4,5]

While the HIV prevalence rate among PWID has been declining, recent outbreaks have occurred due to the opioid overdose epidemic and injection drug use. Injection drug use and associated behaviors need to be addressed for several reasons, including the recent 364% increase of HCV transmission in rural areas.[3,6] Opioid addiction, especially related to injection behavior, is of growing concern given the vulnerability to HIV and HCV outbreaks in rural areas of the country.[7]

At present, we have limited knowledge about SSP clients' experiences and perceived needs for HIV, HCV, and HBV services. This gap in knowledge is of particular concern in relation to PWID living in rural areas of the Appalachian region of the United States, who are at increased risk of an HIV and/or HCV outbreak.[7] What we know is that SSPs help reduce HIV, HCV, and HBV infections among PWID by reducing syringe sharing, providing better access to sterile needles, educating PWID about safer injection practices, and linking clients to treatment and care for these diseases as well as related conditions such as substance abuse and mental health disorders.[8,9]

2. Purpose and Use of the Information Collection

The purpose of this study is to assess: 1) HIV, HCV, and HBV services offered by SSPs that serve residents of outbreak prone rural areas, 2) SSP clients' perceived need for HIV, HCV, and HBV services, 3) the barriers and facilitators SSP clients experience related to accessing these services, and 4) the SSPs experience in offering these services. Our study method involves collecting qualitative data via in-depth interviews (IDIs) with 45 SSP clients and 15 SSP staff and/or community stakeholders (e.g. health department staff, emergency medical response providers, or healthcare providers). The study will take place with three SSPs serving rural residents living in, or near, the Appalachia region. The study findings will provide CDC an understanding of the HIV, HCV, and HBV services offered and needed in these areas. In addition, these findings will also help U.S. state, county, and community-based agencies to create or strengthen their SSP programs.

The primary target audience for the study's findings are the participating SSPs, the CDC, as well as health departments and federally-, state-, or locally funded provider agencies implementing SSPs. We anticipate that the findings will be of practical use for these agencies when creating new SSPs or

strengthening the services offered by existing SSPs. Study findings will also provide an understanding of HIV, HCV and HBV services from the perspective of SSP clients, staff, and stakeholders. Study findings will also be used to describe the HIV, HCV, and HBV services offered at SSPs, and help to develop best practices and/or recommendations for SSPs.

Exhibit 2.1: Overview of Key Variables

SSP Staff and Stakeholder Data (Att 2b and 2e)	SSP Client Data (Att 2a and 2d)
• The general services the SSP offers, and what services they would like to offer • The HIV, HCV, and HBV services they offer, and at what frequency do their clients access these services • Perception of clients' risk in acquiring HIV, HCV, and HBV • HIV, HCV, and HBV services they do not offer • Substance use and overdose treatment services offered • The communities response to the SSP • The unique challenges their rural clients face	• The SSP services they use • The services they need, but the SSP does not offer • The influence the SSP has on their life • Their general health status as well as their experience with health conditions associated with injecting drugs • Their perceived risk for HIV, HCV, and HBV • Their history of accessing HIV, HCV, and HBV services • Their history of accessing drug treatment and their on-going need for drug treatment services • Their perceptions of the local drug users' needs and how to address these needs

3. Use of Improved Information Technology and Burden Reduction

The contracted research team will recruit and screen potential SSP clients by telephone or in-person. The contracting team will conduct one-on-one interviews at a time and location that is publically accessible and convenient for the participants. Telephone interviews or visual remote interviews (such as web or Skype interviews) are not a good vehicle for developing rapport between the interviewer and participant during an interview on topics that may be viewed as sensitive (e.g. disease status and risk behaviors). Body language and facial cues are critical to understand where additional questions may be needed or when the interviewer should stop probing. Telephone or web interviews limit the interviewer's ability to read both. Thus, the research team will conduct the interviews in person.

SSP clients, staff, and stakeholders will be informed of their privacy rights and protections prior to answering any questions. In addition, they will be asked to provide a signed informed consent prior to the interview. After receiving permission from the participant, the contracting team will audio-record the interviews and transcribe the recordings shortly after the interview. This limits the burden on the participant (no additional burden after completing the interview) and allows the interviewer to focus on building and maintaining rapport with the participant.

4. Efforts to Identify Duplication and Use of Similar Information

At present, we do not know the scope of HIV, HCV, and HBV services offered by SSPs, and SSP clients' experiences and perception of need related to these services. This gap in knowledge is particularly concerning for people living in rural areas, which are at inflated risk of an HIV/HCV

outbreak, and have historically not benefited from the services offered by SSPs. This study intends to fill this gap in knowledge. While we expect that some of the services offered by SSPs will be similar across all three sites, we also expect that many of the findings will be unique to each site. Thus, CDC believes that this information is not captured elsewhere, and that no other data collection effort has been conducted or is planned to collect similar information from this population with these sites. Additionally, the CDC conducted a review of similar studies and determined that this study is collecting unique information. Therefore, our evaluation indicates the collection of this new primary data is unique. There would be no reason for another Federal Agency to evaluate these research questions.

5. Impact on Small Businesses or Other Small Entities

This information collection does not involve burden to small businesses or other small entities.

6. Consequences of Collecting the Information Less Frequently

This information collection will provide the qualitative data needed for federal policy makers to understand local trends and to assess need for, barriers, and facilitators to HIV, HCV, and HBV services offered by SSPs that serve residents in rural areas. If this case study were not conducted, it would not be possible to form an understanding of the need for HIV, HCV, and HBV services in this population. Collecting this type of jurisdiction-specific information is important, as it will allow us to provide feedback to agencies, organizations and other stakeholders that is relevant to the local context and can be used to tailor HIV, HCV, and HBV efforts to have the greatest impact among rural PWIDs. The length of data collection is 3-4 months and data will only be collected once.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This data collection effort does not involve any special circumstances.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

A 60-day FRN notice to solicit public comments was published for the Generic umbrella collection (0920-1091) in the Federal Register on 02/24/2015, Volume 80, Number 36, Page Number 9727-9728. No public comments were received.

In addition, Emory University, Research Support Services, and IMPAQ International were consulted for the development of this study. There were no unresolved issues associated with the consultation process. Aside from the official 60 day public comment period for the Generic data collection, there were no other public contacts or opportunities for public comment on this information collection.

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9. Explanation of Any Payment or Gift to Participants

Each interview participant will receive a $40-cash value token of appreciation. Offering tokens of appreciation helps recruit historically underrepresented and stigmatized groups,[10] such as rural-residing people who inject drugs (PWID) and those that provide services to rural PWID. A recent study of recruitment and retention found it difficult to obtain information from participants because many were reluctant to provide their names and contact information because of concerns about being seen giving these personal details to the researchers. In this study, offering a token of appreciation improved participation.[11] Further, a meta-analysis found that studies using tokens of appreciation yielded an average increase in response rates of 19.1 percentage points, representing a 65% average increase in response.[12] In light of these findings and the on-going opioid crisis' relationship to increasing rates of overdose, hepatitis A, B and C, as well as HIV in the areas under study, we hope to enhance our response rate in areas of greatest need. Indeed, the rural service areas of the participating SSP sites have experienced considerable burden due to the opioid epidemic, and may benefit directly from the findings.[13,14] Given the declaration of a public health emergency pertaining to opioid use, it is important to interview those struggling with the disease, those addressing their concerns, and to do so in the areas greatly affected. Research indicates our target population would be incentivized to share sensitive and critical information by a token of appreciation. In fact, offering a token of appreciation has been effective in drawing PWID to participate in research.[15] A review of the ethical and practical concerns with providing tokens of appreciation to PWID concluded, "They offer good value-for-money in interview research with drug users, potentially lowering costs and perhaps even improving the quality of research products," (p. 107).[16]

The amount of the token of appreciation is based on the proportionate cost of living in rural areas compared to urban areas.[17] We should appreciate the rural PWID's participation in an hour-long interview the same as an urban resident participating in a study. In addition, OMB has reviewed and approved $40 tokens of appreciation in other data collections under this Generic ICR including LEAP (OMB 0920-0840) and LEAP Part II (OMB 0920-1091). Specific to PWID, OMB has approved tokens of appreciation at a value of $50 for other data collection efforts (National HIV Behavior Surveillance: OMB 0920-0770).

In sum, this data collection is important to address the ongoing opioid epidemic in rural areas serviced by the SSP's that have agreed to participate and the infectious disease outbreaks occurring in these

areas. Prior studies have shown tokens of appreciation for PWID to be effective without biasing the results. Although there has been some debate on the necessity of offering tokens of appreciation, numerous studies have shown that tokens of appreciation can significantly increase response rates, and the use of modest tokens of appreciation is expected to enhance survey response rates without biasing responses.[18,19] (Note: at the time of data collection, the participating SSPs do not anticipate direct federal funds to support staff salaries.)

10. Protection of the Privacy of Information Provided by Participants

The Privacy Officer for CDC/ASTDR has reviewed this ICR and determined the Privacy Act applies to this collection of information. However, participant names and contact information will not be transmitted to the CDC. CDC has completed a Privacy Impact Assessment (PIA) of the data system used by the study contractor team (**Attachment 6**). The active PIA was approved under the title, Pulse. The system covered by the PIA has been retitled, iQualR, to reflect the owner authorized to operate the system, Research Support Services (RSS).

The contractor, Research Support Services, and its subcontractors, Emory University and IMPAQ, will be responsible for collecting all data for this study. We will inform participants that their responses will be kept private to the extent permitted by the law. All participants interviewed will be informed that the information collected will not be attributable directly to the participant and will only be discussed among members of the research team. Terms of the CDC contract authorizing data collection require the contractor to maintain the privacy of all information collected. Accordingly, individuals' data will be kept private and protected to the extent permitted by law.

Section 301(d) of the Public Health Service (PHS) Act, as amended by Section 2012 of the 21st Century Cure Act, P.L. 114-255 (42 U.S.C. 241(d),[20] states that the Secretary shall issue Certificates of Confidentiality to persons engaged in biomedical, behavioral, clinical, or other research activities in which identifiable, sensitive information is collected. This study meets those requirements. The Certificate of Confidentiality further protects the privacy of subjects 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 study participants for any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level.

Given this information collection is to assess HIV, HCV and HBV services offered by SSPs that serve PWIDs in at-risk rural areas, we are sensitive to the need to protect personal health information (PHI) as well as personally identifiable information (PII), including name and contact information. To ensure that participants' PHI and PII is protected, we will take several measures to separate name and contact information from study-related data. All researchers with access to PHI and PII will be required to read and sign a "Rules of Behavior." Contact information collected for the purposes of recruitment (i.e., name, telephone number, and email address) will be collected via paper form only, will be used only for the purpose of scheduling interviews. All participants will be assigned a unique study identification number, which will be the only link between the PHI and PII contained on the contact information sheet and the interview responses. Both contact information and interview responses will be stored securely in locked cabinets, separately from one another. All research documents and audio recordings will be kept in a locked file cabinet in a secure place. The participant interview transcript will be kept in a password-protected file and only authorized staff will be able to access the information. If any personal characteristics are accidently disclosed by the participant during the interview, that information will be fully redacted from the interview transcripts and data sets used for analysis. We will train researchers who play a role in data collection and analysis in proper procedures for data handling. A limited number

of key staff authorized by the contractors will have access to personal identifiers, and this information will be destroyed as quickly as possible after it no longer is required for study purposes, no later than the end of the contract. The contractors will be prepared to describe these procedures in full detail and to answer any related questions raised by interviewees. CDC will never have access to any participant names or contact information.

In conjunction with the data policy, members of Contractor project staff are required to:

- Comply with a privacy pledge and security manual procedures to prevent improper disclosure, use, or alteration of private information. Staff may be subjected to disciplinary and/or civil or criminal actions for knowingly and willfully allowing the improper disclosure or unauthorized use of information.
- Access information only on a need-to-know basis when necessary in the performance of assigned duties.
- Notify their supervisor, the project director, and the organizational security officer if information has either been disclosed to an unauthorized individual, used in an improper manner, or altered in an improper manner.
- Report immediately to both the project director and the organizational security officer all contacts and inquiries concerning information from unauthorized staff and non-research team personnel.

The security procedures implemented by project staff cover all aspects of data handling for hard copy and electronic data. Transcripts of interviews (stripped of personal identifying information) will be stored on encrypted flash drives. The contractor will investigate immediately if any item is delayed or lost. When not in use, all completed hardcopy documents will be stored in locked file cabinets or locked storage rooms. Unless otherwise required by CDC, these documents will be destroyed when no longer needed for the project.

Public access to the data will be provided at the completion of the study and after the dissemination of the main outcome findings. Any data made publicly available after the completion of the study will be de-identified and will not be linked to participant names or contact information (**Attachment 5**).

11. Institutional Review Board (IRB) and Justification for Sensitive Questions

IRB Approval

This study has been approved by the CDC IRB (**Attachment 4**).

Sensitive Questions

This study aims to learn perceptions of needs for HIV, HCV, and HBV services among rural clients of SSPs, as well as the challenges SSPs face in offering or linking their clients to these services. As such, our information collection involves measuring sensitive information about drug users, and testing as well as treatment for communicable diseases. All contracting staff will be trained to provide participants with city-specific contract information for HIV and mental health care organizations, as needed. No sensitive information will be collected during the in-depth interviews with participants about the people they work with. We will inform all participants that they may skip any question or stop participation at any time for any reason.

12. Estimates of Annualized Burden Hours and Costs

12A. **Estimated Annualized Burden Hours**

The recruitment and enrollment period is four months. This data collection will include 60 individuals. Forty-five individuals will be adult (18 ≥ years of age) clients of a participating SSP. We expect to screen 90 SSP clients, and we expect 50% to be eligible and to participate in the data collection, which yields a final SSP client sample size of 45. Contractor staff will screen potential SSP client participants for eligibility in person or by phone, which will take approximately ten minutes **(Attachment 2a).** If the SSP client is eligible and agrees to participate, contractor staff will collect contact information (**Attachment 2c**), which will take approximately five minutes. The SSP client interview **(Attachment 2d)** will take 60 minutes to complete and will be administered once.

We will also interview 15 SSP staff and community stakeholders. We expect to screen 30 SSP staff and stakeholders, and we expect 50% to be eligible and to participate in the data collection, which yields a final SSP staff and stakeholder sample size of 15. The SSP staff and stakeholders will be screened for eligibility in person or by phone, which will take approximately five minutes (**Attachment 2b**). Eligible staff and stakeholders who agree to participate will be asked for contact information (**Attachment 2c**), which will take approximately five minutes. The staff and stakeholder in-depth interview **(Attachment 2e)** will take 60 minutes to complete and will be administered once.

Exhibits 12.1 and 12.2 provide details about how the estimates of burden hours and costs were calculated. The estimated total number of burden hours is 82.5.

Exhibit 12.2: Estimated Annualized Burden Hours

Type of Participant	Form Name	No. of Participants	No. of Responses Per Participant	Average Burden Per Response (in Hours)	Total Burden Hours
General Public-Adults	SSP Client Screening Form (Att. 2a)	90	1	10/60	15
General Public-Adults	SSP Staff Screening Form (Att. 2b)	30	1	5/60	2.5
General Public - Adults	SSP Contact Form (Att. 2c)	60	1	5/60	5
General Public - Adults	SSP Client In-Depth Interview Guide (Att. 2d)	45	1	1	45
General Public - Adults	SSP Staff In-Depth Interview Guide (Att. 2e)	15	1	1	15
				Total	**82.5**

12B. **Estimated Annualized Burden Costs**

The annualized costs to the participants are described in Exhibit 12.2. The United States Bureau of Labor Statistics' employment and wages estimates from May, 2017 (http://www.bls.gov/oes/current/oes_nat.htm) were used to estimate the hourly wage rate for the general public for the purpose of this GenIC request. The total estimated cost of the burden to participants is

approximately $2,008.05. This cost represents the total burden hours of general participants multiplied by the average hourly wage rate ($24.34).

Exhibit 12.3: Estimated Annualized Burden Costs

Type of Participant	Form Name	Total Burden Hours	Hourly Wage Rate	Total Participant Costs
General Public-Adults	SSP Client Screening Form (Att. 2a)	15	$24.34	$365.10
General Public-Adults	SSP Staff Screening Form (Att. 2b)	2.5	$24.34	$60.85
General Public-Adults	SSP Contact Form (Att. 2c)	5	$24.34	$121.70
General Public-Adults	SSP Client In-Depth Interview Guide (Att. 2d)	45	$24.34	$1095.30
General Public-Adults	SSP Staff In-Depth Interview Guide (Att. 2e)	15	$24.34	$365.10
				Total $2,008.05

13. Estimates of Other Total Annual Cost Burden to Participants and Record Keepers

There are no other costs to participants for participating in this survey.

14. Annualized Cost to the Federal Government

The annualized cost to the government is $446,248. Direct costs include the salaries of a CDC Technical Monitor ($21,350) and a CDC Scientist ($21,350). The contract cost is $403,548.

Exhibit 14.4: Annualized Cost to the Government

Expense Type	Expense Explanation	Annual Costs (dollars)
Direct Costs to the Federal Government	CDC, Technical Monitor (GS-12 0.25 FTE)	$21,350
	CDC Scientist(GS-12, 0.25 FTE)	$21,350
	Subtotal, Direct Costs	**$42,700**
Contract Costs Research Support Services, (RSS)	**Annual Contract Costs (RSS, #200-2013-57341)**	**$ 403,548**
	TOTAL COST TO THE GOVERNMENT	**$ 446,248**

15. Explanation for Program Changes or Adjustments

This is a new GenIC information collection request (ICR).

16. Plans for Tabulation and Publication and Project Time Schedule

Tabulation will include descriptive characteristics of participants collected during screening (e.g., age, race/ethnicity, job category). Data collection will occur between October 2018 and January 2019, analyses will be carried out in February – April 2019, and the final data set and report will be submitted in May 2019. The project timeline is detailed in exhibit 16.1.

Exhibit 16.5: Project Time Schedule

Activity	Time Schedule
Develop data collection tools, sampling and data plans, study protocol	September 2017 – July 2018
OMB Submission	August 2018
Recruitment	1-4 months after OMB Approval (anticipated: November 2018 – February 2019)
Data Collection	1-4 months after OMB Approval (anticipated: November 2018 – February 2019)
Data analysis finalized and report drafted	5-7 months after OMB Approval (anticipated: March – May 2019)
Final data set and final report submitted to CDC	8 - 10 months after OMB Approval (anticipated: June - August 2019)

In compliance with the CDC policy on data management and access, we will develop a final, de-identified (names and contact information will be removed) qualitative database for this study along with the corresponding data documentation, which will be made publicly available within 30 months of the end of data collection.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

We do not seek approval to eliminate the expiration date.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exemptions to the certification.

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