

**Local Needs Assessment of Program Collaboration and Service
Integration Among Infectious Disease Prevention Providers for
Persons Who Use Drugs Illicitly**

Generic Information Collection request under 0920-0840

Section A: Supporting Statement

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CONTACT

**Eric Pevzner, PhD- Project Officer
Centers for Disease Control and Prevention
National Center for HIV, Viral Hepatitis, STD and TB Prevention
Division of Tuberculosis Elimination
International Research and Programs Branch**

**Phone: 404-639-6094
ecp9@cdc.gov**

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**Local Needs Assessment of Program Collaboration and Service
Integration Among Infectious Disease Prevention Providers for
Persons Who Use Drugs Illicitly**

Supporting Statement

A. JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention proposes to conduct a formative research study to develop practical guidance on how to provide and evaluate program collaboration and service integration (PCSI) to prevent infectious diseases among persons who use drugs illicitly, hereafter referred to as persons who use drugs. This practical guidance will support the recommendations found in the soon-to-be published MMWR article, "U.S. Public Health Guidance for Integrated Prevention for HIV, Viral Hepatitis, Sexually Transmitted Diseases, and Tuberculosis among Persons Who Use Drugs Illicitly in the United States." This formative research will add to the CDC portfolio of effective interventions for at-risk populations by confirming the current array of integrated and collaborative services available for persons who use drugs, synthesizing "lessons learned" from integrated and collaborative service providers, and developing a document that outlines these lessons for other prevention providers who serve persons who use drugs.

The proposed study will use qualitative interviews, observations, and analysis of primary source documents to: a) determine what type of health services are currently offered to their clients (including addiction treatment, infectious disease screening and treatment, primary care, and mental health services) to persons who use drugs b) using the CDC's definition of PCSI as a model, describe the extent to which agencies integrate these services for their clients who use drugs c) among the services reported by agencies, record the providers' "lessons learned" in implementing integrated and collaborative health services for this population d) develop a document that synthesizes the suggested "lessons learned" for prevention providers and includes a chart that describes activities and indicators that providers can use to evaluate (or prepare for) service integration e) determine this document's impact on the knowledge, abilities, beliefs and intentions of infectious disease prevention providers who serve persons who use drugs.

The information gained from this study can benefit other researchers in several ways. First, this study will provide information feasibility, acceptability and therefore the viability of disseminating new "lessons learned" targeting prevention providers who work with persons who use drugs. Second, the information learned during the development process can aid other researchers who wish to design programmatic guidance for other important health topics. Third, the findings can be used to better understand how prevention providers are using program collaboration and service integration to adapt to anticipated changes in healthcare infrastructure as a result of the Affordable Care Act. Finally, researchers can build on the results of this study to create new, provider-focused interventions that are low-cost and can be widely disseminated.

Infectious diseases, including HIV, viral hepatitis, STDs, and TB, disproportionately affect persons who use drugs. For example, in the United States, approximately 12% of new HIV cases, 50% of new Hepatitis C cases, and 2% of Hepatitis A cases are associated with the injection of illicit drugs. The misuse of licit substances such as prescription medications or alcohol, as well as the ingestion and inhalation of licit or illicit drugs, have been shown to increase infectious disease risk. Health officials and providers who desire to improve delivery of comprehensive interventions and integrated services for persons who use drugs need to use the best available evidence to meet the local community needs regarding the prevention of these infectious diseases. They need to assess the extent to which integrated services already exist, and identify gaps and barriers to integration as well as opportunities that may be available to strengthen services through collaborations with new partners in new settings.

Fulton and DeKalb Counties are ideal locations to develop a PCSI guidance instrument for prevention providers who serve persons who use drugs. Atlanta functions as a representative Southern city in the National Institute for Drug Abuse's (NIDA) Community Epidemiology Work Group, which noted that 8,948 individuals in the Atlanta area entered substance abuse treatment for drug and/or alcohol use in 2007 alone. Infectious disease statistics in Atlanta make it an area of national interest. Over one half the AIDS cases in Georgia are located in Atlanta, and Atlanta consistently ranks among the top 10 cities in the nation in its ratio of HIV infections to overall population. Furthermore, according to an NIH funded Emory Center for AIDS Research (CFAR) study in 2010, the HIV epidemic in metro Atlanta is concentrated in a geographic cluster in the downtown area, which consists of

157 census tracts. While the demographics of this area (low-income, African American, high crime, high prevalence of drug use, etc.) have been well documented, over 40% of HIV service providers in Atlanta are also located in this area; however, the organizational infrastructure for preventing infectious diseases (such as HIV/AIDS, viral hepatitis, STD, and TB) for persons who use drugs in comparison to the PCSI model has not been systemically assessed or analyzed, in Atlanta. Although studies outside of the CDC have examined service integration for persons who use drugs, this will be the first study to investigate service integration for persons who use drugs with respect to CDC's definition of PCSI as the "gold standard" for service providers.

The development of this program guide will enable our team to obtain the perspectives of local health and social service providers who are knowledgeable about the affected population and about the array of available services for persons who use drugs in Fulton and DeKalb Counties of Atlanta, GA. Results will produce a timely tool that will help providers adapt to a changing health service infrastructure and inform the further study of contextual factors that encourage or impede the integration of services for persons who use drugs.

1.1 Privacy Impact Assessment

The Centers for Disease Control and Prevention will collect information in identifiable form (IIF). IIF will be collected from participants using interviews. Research staff will obtain verbal consent prior to beginning any interview or focus group by reading aloud the consent form to all participants and then document verbal consent or refusals to participate (**Attachment 2a- Consent Form**). Research staff at CDC will collect phone numbers to contact participants to take part in the interviews. Hand written notes will be taken during the interviews and observations and later entered into MS Word for the purposes of analysis. Other IIF collected include age, ethnicity, sexual orientation and gender.

The main purpose of collecting this information is to describe the participants' characteristics in the study. Knowledge of the participant's characteristics will assist with the development of the proposed and future interventions. Respondents' names will not be used in data collected. ID numbers will be used in place of names.

This information will be kept in a locked file cabinet, password protected computers, and will be accessible only by the project staff. Hand-written notes will be stored in a locked file cabinet in the CDC Project Officer's office. Participants' names will be kept separate from interview transcripts. Interview transcripts and notes in MS Word format will be kept in a password-protected file to which only the project officers and research staff will have access. Only the Project staff will have access to the password for the master data file. The collected data is the property of The Centers for Disease Control and Prevention. After data analysis is completed, The Centers for Disease Control and Prevention will destroy all participant IIF and data. No individuals' identifiable information (IIF) will be used in any reports.

Overview of the data collection system

The study will be completed in 2 phases aimed at developing practical guidance for program collaboration and service integration (PCSI) among infectious disease prevention providers who provide services for persons who use drugs. Participants in each of the 2 phases will consist of current prevention providers who serve persons who use drugs including:

- 1) Staff from health and social service agencies or programs that provide services to prevent HIV, STDs, TB, and hepatitis among persons who use drugs
- 2) Staff from agencies or programs in a position to provide supportive and social services to persons who use drugs (i.e., substance abuse and mental health treatment programs)
- 3) Members of Community Advisory Boards associated with the above mentioned types of service providers and agencies.

All participants in both phases will be recruited and screened using a purposive sampling method in which key informants are selected based on variables of interest, primarily their experience and knowledge of services for people who use drugs, their role in relation to these services, and their willingness share their perspectives through a semi-structured interview. An initial list of informants will be developed in collaboration with state contacts working in HIV/AIDS, hepatitis, tuberculosis, STDs, and substance abuse and mental health, and then expanded through chain referral (i.e., snowball sampling). In order to ensure that the identified providers are included we will screen potential participants using a screening form. (See **Attachment 1a-Study Screener**)

Based on similar research studies with the target populations, approximately 200 people in total will need to be screened in order to select the site(s) that will serve as models for “lessons learned” in Phase 2. We will obtain informed consent for the participants prior to beginning each data collection.

Phase 1 will consist of a round of 50 interviews of 60-90 minutes each. These interviews will be used to confirm the extent to which service providers are currently providing integrated or collaborative health services (including addiction treatment, infectious disease screening and treatment, primary care, and mental health services) to persons who use drugs. (**See Attachment 1b-Phase 1 interview guide**).

Phase 2 will consist of a round of 50 interviews that will focus on recording the provider’s assessment of the barriers and effective strategies to implementing integrated or collaborative health services for persons who use drugs (i.e. “lessons learned”). (**See Attachment 1c- Phase 2 Interview Guide**) Phase 2 interviews will also be 60-90 minutes each. Phase 2 interview data will be used to develop a document that synthesizes the suggested “lessons learned” for prevention providers. This document will include a chart that describes activities and indicators that providers can use to evaluate (or prepare for) service integration.

Items of Information to be collected

Interviews will be with 1 or 2 individuals and are expected to last between 90 and 120 minutes. The interview guides are included here as **Attachments 1b and 1c**. The Phase 1 open-ended interviews include questions about:

- 1) The current array of treatment and/or prevention services the organization offers (or has offered) for persons who use drugs,
- 2) The current and past collaborations with other organizations for the purpose of providing services for persons who use drugs.

The Phase 1 interviews will be concluded with a checklist which covers information about the organization providing specific integrated health services including:

- STD services
- HIV services
- TB services
- Substance abuse services

- Mental health service

Phase 2 interviews will be with 1 or 2 individuals and are expected to last between 90 and 120 minutes. The interview guide is included here as **Attachment 1c**. The Phase 2 open-ended interviews include questions about:

- 1) Detailed descriptions of program services for persons who use drugs,
- 2) The benefits and challenges to providing integrated and/or collaborative services

Phase 1 and Phase 2 observations of the common areas of the service providers' facilities will be recorded as field notes. Notes might include (but will not be limited to) information about the layout, number, and purpose of rooms; signage; social and professional interactions; and available amenities.

The following types of documents will be requested from the prevention providers who participate in Phase 2 (see **Attachment 1c- Phase 2 Interview Guide**):

- Mission statement
- Pamphlets for clients
- Letter to funders/donors
- Recent grant application

Identification of Website(s) and Website Content Directed at Children Under 13 Years of Age

This information collection does not involve websites or website content directed at children under 13 years of age.

2. Purpose and Use of Information Collection

The purpose of the project "Local Needs Assessment of Program Collaboration and Service Integration Among Infectious Disease Prevention Providers for Persons Who Use Drugs Illicitly" is to develop practical guidance on how to provide and evaluate program collaboration and service integration (PCSI) to prevent infectious diseases among persons who use drugs. To develop the guidance, the working group will conduct a situational assessment using a methodological approach referred to as rapid assessment process. The Rapid Assessment Process (RAP) will assist the working group in collecting information such as the perspectives of local health and social service providers regarding the current level of program collaboration and service integration for the prevention of HIV, STDs, TB and Hepatitis among those who use drugs; identify organization(s), including those that address

HIV, viral hepatitis, STDs, TB, substance abuse, or mental health needs, currently providing any integrated services for persons who use drugs; and characterize the range of integrated services that currently exist in DeKalb and Fulton counties. This practical guidance will support the recommendations found in the soon-to-be published MMWR article, "U.S. Public Health Guidance for Integrated Prevention for HIV, Viral Hepatitis, Sexually Transmitted Diseases, and Tuberculosis among Persons Who Use Drugs Illicitly in the United States." This formative research will add to the CDC portfolio of effective interventions for at-risk populations by confirming the current array of integrated and collaborative services available for persons who use drugs, synthesizing "lessons learned" from integrated and collaborative service providers, and developing a document that outlines these lessons for other prevention providers who serve persons who use drugs. The types of data collection activities used are the following:

Qualitative interviewing will be used with volunteer respondents between the ages of 18-80 who currently work in organizations providing health services to persons who use drugs in order to confirm the extent to which service providers are currently providing integrated or collaborative health services and to record the "lessons learned" from service providers who offer these services. Results from the Phase 1 interviews will be used to identify exemplary integrated or collaborative service providers. Results from Phase 2 interviews will be used to develop and refine programmatic guidance material for use by other health service providers so that they may better meet the needs of persons who use drugs

The purpose of this data collection is to conduct field tests of new methods and interventions. The objective of such testing is to evaluate the feasibility of the "new" strategies in CDC-funded projects. Specifically, this project is new and innovative because it is the CDC's first attempt to record the "lessons learned" from prevention providers who provide integrated and collaborative services for persons who use drugs. The information that will be collected in the interviews will be used to develop a document that synthesizes the suggested "lessons learned" for prevention providers and includes a chart that describes activities and indicators that providers can use to evaluate (or prepare for) service integration that meets the needs of persons who use drugs.

To assure that the PSCI activities of the health service providers are accurately documented, information provided in the

qualitative interviews will be triangulated with official documents provided by the organizations (such as mission statements, pamphlets for clients, letters to donors, and recent funding applications) and with observations of the agencies' common areas. The information that will be collected in these materials will be used to revise and augment the information conveyed in the interviews in order to inform the creation of a "lessons learned" document for prevention providers that providers can use to evaluate (or prepare for) service integration that meets the needs of persons who use drugs.

2.1 Privacy Impact Assessment

The information collected and "lessons learned" from the interviews will be presented as a final report that describes the current range of services available to persons who use drugs illicitly. Best practices and case study examples illustrating services that are well-integrated and therefore easily accessible to clients will be highlighted in the report as a model for future replication.

Participants will have the opportunity to provide consent or to decline being involved with the interviews, therefore, it is not anticipated that their privacy will be compromised as a result of this data collection effort.

3. Use of Improved Information Technology and Burden Reduction

Hand written notes will be taken during the interviews and later entered into MS Word for the purposes of analysis. The MS Word files will be formatted and entered into NVivo 8, a qualitative data analysis program that reduces the burden of coding and analyzing interview data.

4. Efforts to Identify Duplication and Use of Similar Information

NCHHSTP has verified that there are no other federal collections that duplicate the data collection tools and methods included in this request.

5. Impact on Small Businesses and Other Small Entities

No small businesses will be involved in this data collection.

A.6. Consequences of Collecting the Information Less Frequently

The activities involve a one-time collection of data. There are no legal obstacles to reducing the burden.

7. Special Circumstances Relating to Guidelines of 5 CFR 1320.5

This request fully complies with the regulation 5 CFR 1320.5.

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

A Federal Register Notice for the generic clearance 0920-0840 was published on January 15, 2010.

9. Explanation of Any Payment or Gift to Respondents

Project participants will not receive payment for participating in interviews.

10. Assurance of Confidentiality Provided to Respondents

The Privacy Act does not apply to the data collect as a result of the staff interviews. After the interview is complete, all handwritten notes will be transcribed into MS Word for analysis. Interview transcripts and notes in MS Word format will be kept in a secure password-protected file to which only the project officers and rapid assessment team members will have access. Handwritten notes will be stored in a locked file in the CDC project officer's office, which is equipped with a lock. Participants' names and contact information will be kept separate from the interview transcripts. No individuals' identifiable information will be used in any reports.

Respondents will be told that no information in identifiable form will be available to or shared with anyone outside of the CDC. Analysis of the dataset will take place at the CDC. The information collected in this project will be owned by the CDC. CDC will be the only entity with access to the information collected.

Prior to participating in any phase of the study participants will be required to give informed consent. The consent form will be read aloud to the participant. Verbal consent will be obtained prior to the start of the interview and after participants have had the opportunity to ask questions (**Attachment 2a**).

All consent forms with participant names and signatures will be kept in a locked file cabinet in the CDC project officer's office, separate from the data files. Participants will be provided with copies of their consent forms.

10.1 Privacy Impact Assessment Information

A consent process will be completed where participants may willingly consent or decline to participate in the interviews. Opportunities to consent, if any, to sharing and submission of information;

A consent process will be completed where participants may willingly consent or decline to have their comments shared during the interviews included in the final documents that will be disseminated.

The information collected will be kept in a locked file cabinet, password protected computers, and will be accessible only by the project staff. Hand-written notes will be stored in a locked file cabinet in the CDC Project Officer's office. Participants' names will be kept separate from interview transcripts. Interview transcripts and notes in MS Word format will be kept in a password-protected file to which only the project officers and research staff will have access. Only the Project staff will have access to the password for the master data file. The collected data is the property of The Centers for Disease Control and Prevention. After data analysis is completed, The Centers for Disease Control and Prevention will destroy all participant IIF and data. No individuals' identifiable information (IIF) will be used in any reports.

A system of records will be created for this project to ensure that files are maintained in a secure manner.

11. Justification for Sensitive Questions

This project asks local health and social service staff about services that they provide for persons who use drugs. Some project participants may feel uncomfortable answering some of the questions related to client services due to the sensitive nature of illicit drug use. Questions of a sensitive nature are questions that address any agency practices or policy that may either promote or impede clients from easily accessing health and/or social services. The purpose of asking these questions is to identify any practices or policy or processes that support

service integration and easy access for clients. An example of questions of a sensitive nature may include, but are not limited to: "Does your agency have a policy regarding clients participating in services such as group sessions or other interactive meetings while under the influence?" If yes, in your opinion, do you feel that the policy either promotes or inhibits clients from readily accessing your agency's services?" These questions are necessary to understand and assess levels of program collaboration and service integration in order to develop a document that synthesizes "lessons learned" for prevention providers, as well as a chart to describe activities and indicators that can be used to evaluate service integration. The verbal consent process will inform participants that they will be asked questions regarding services for persons who use drugs, and they may refuse to answer if they feel uncomfortable.

12. Estimates of Annualized Burden Hours and Costs

12.A. Estimated Annualized Burden Hours

Participants in this project are local health and social service staff. In order to organize the project interviews, a 1-minute screener will be administered to 100 local organizations providing services to persons who use drugs. A total of 50 adults will participate in 90-minute interviews for phase 1. For phase 2, a 1-minute screener will be administered to 100 local healthcare social workers, and a total of 50 adults will participate in 90-minute interviews.

Exhibit 12.A Estimated Annualized Burden Hours

Type of Respondent	Form Name	Number of Respondents	Number of Responses Per Respondent	Average Burden Per Response (in Hours)	Total Burden Hours
Healthcare Social Worker	Study Screener - Phase 1	100	1	1/60	2
Healthcare Social Worker	Interview Guide - Phase 1	50	1	1.5	75
Healthcare Social Worker	Study Screener - Phase 2	100	1	1/60	2
Healthcare Social Worker	Interview Guide - Phase 2	50	1	1.5	75
Total					154

12.B. Estimated Annualized Burden Costs

The annualized costs to the respondents are described in Exhibit A.12.B. The United States Department of Labor Statistics May, 2010. http://www.bls.gov/oes/current/oes_nat.htm was used to estimate the hourly wage rate for healthcare social workers for the purpose of this generic request. The figure of \$23.65 per hour was used as an estimate of average hourly wage for healthcare social workers across the country. The total anticipated annual cost to participants for collection of information in this project will be \$1,797.40.

Exhibit 12.B: Estimated Annualized Burden Costs

Type of Respondent (Form Name)	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Healthcare Social Worker (Project Screener - Phase 1)	2	\$23.65	\$47.30
Healthcare Social Worker (Interview guide - Phase 1)	75	\$23.65	\$1,773.75
Healthcare Social Worker (Project Screener - Phase 2)	2	\$23.65	\$47.30
Healthcare Social Worker (Interview guide - Phase 2)	75	\$23.65	\$1,773.75
Total	174		\$3,642.10

13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers

There are no costs to respondents or record keepers.

14. Annualized Cost to the Government

This activity will require the participation of CDC staff members. A principal investigator will be responsible for designing the study, leading the team of researchers, preparing the IRB and OMB human subjects documents, working with the designated contractor, and providing project oversight. Also necessary is a Co-principal investigator who will assist in the

project administration and logistics, and work with the principal investigator to obtain OMB and IRB approvals. Finally, a team of graduate research students from Emory University are assisting with administering the survey. These researchers are hired under an ongoing contract with Emory University.

Exhibit 14: Estimates of Annualized Cost to the Government

Expense Type	Expense Explanation	Annual Costs (dollars)
Direct Costs to the Federal Government	CDC, Principal Investigator (GS-14, 0.25 FTE)	\$28,626
	CDC, Co-Principal Investigator (GS-13, 0.20 FTE)	\$19,949
	Subtotal, Direct Costs	\$48,575
Cooperative Agreement or Contract Costs	Emory graduate research assistant employees	\$(5x \$2000,00 per semesterx2) = \$20,000
	Subtotal, Cooperative Agreement or Contract Costs	\$20,000
	TOTAL COST TO THE GOVERNMENT	\$68,575

15. Explanation for Program Changes or Adjustments

Not applicable - request is for a sub-collection under a generic approval.

16. Plans for Tabulation and Publication and Project Time Schedule

Data collection for Phase 1 will be completed during the 2-3 weeks after OMB approval is granted. Phase 1 data analysis will be completed 6-8 weeks after OMB approval is granted. Phase 2 of data collection will be completed 12 - 14 weeks after approval, and the guidance will be developed based on the data from Phase 2. Dissemination of results will begin 12 months after OMB approval.

Exhibit 16: Project Time Schedule

Activity	Time Schedule
Recruit and conduct Phase 1 interviews	2-3 weeks after OMB approval
Analyze Phase 1 data	6-8 weeks after OMB approval
Recruit and conduct Phase 2 interviews	12-14 weeks after OMB approval
Analyze Phase 2 data	4-5 months after OMB approval
Draft up guidance	6-8 months after OMB approval
Disseminate findings	10-12 months after OMB approval

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

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.