

Demonstration Project of HCV Rapid Testing in HIV Testing
Settings

Generic Information Collection request under 0920-0840

Section A: Supporting Statement

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Attachment 2 Informed Consent Forms

- 2a. Staff Interview and Focus Group Consent (Denver Public Health)

2b. Client Interview and Focus Group Consent (Denver Public Health)

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Attachment 3 Informational Materials

3a. Fact Sheet - Hepatitis C Information About Testing

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4a. Local IRB Approval- Colorado Multiple Institutional Review Board (Denver Public Health)

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Attachment 5 Local Screening Forms - not used in data collection, used only to recruit from current clients

5a. Denver Public Health Demographic Form

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Supporting Statement

A. Justification

A.1 Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention proposes to conduct a formative research study that will provide vital information about the factors associated with voluntary HCV rapid testing and counseling among individuals seeking services in HIV testing settings. Collecting this information will aid the development of HCV counseling and testing interventions for those seeking services in HIV testing settings adding to CDC's portfolio of effective HCV prevention interventions. The proposed study will use interviews and focus groups completed by clients and staff that are potentially affected by the implementation of HCV rapid tests into their current setting to understand attitudes, barriers, facilitators, and feasibility and acceptability of HCV testing and counseling. The findings of this study can be used by researchers and administrators in HIV testing settings to assist in protocol development and guidance for implementing rapid HCV testing into HIV testing settings.

Rapid diagnostic tests for the assessment of the presence of HIV antibodies have been on the U.S. market since 2001 and have become an integral part of HIV prevention services. Recently, several diagnostic test manufacturers have developed hepatitis C virus (HCV) antibody rapid tests. Given the overlap in risk behaviors and high-prevalence populations between HIV and HCV, it is reasonable to think that HIV testing centers will be among the first to adopt the HCV rapid tests.

HIV testing sites that have previously conducted conventional hepatitis C testing (EIAs with RIBA confirmation) would be expected to have high internal capacity to support implementation of rapid HCV testing. To implement rapid HCV testing, it would be expected that sites with prior hepatitis C testing experience would need to update pre-existing protocols for conventional testing and make necessary revisions in prevention counseling. HIV testing sites that do not currently conduct hepatitis C testing would be expected to develop protocols to integrate rapid HCV testing.

The purpose of this study is to revise and field test protocols and prevention counseling messages for HCV rapid tests. Two HIV testing sites are funded. These include a syringe service

program and a STD clinic which provide services to persons at risk of hepatitis C.

A.1.2 Privacy Impact Assessment

The grantees, Denver Public Health and Community Health Awareness Group, will collect personally identifiable information (PII). Research staff at Denver Public Health will collect phone numbers to contact participants in order to contact them for participation in interviews and focus groups. Community Health Awareness Group will use Client ID as a proxy to contact participants for participation in interviews and focus groups. Other PII collected include whether participant is a staff member or a client and anti-HCV positive or negative. The main purpose for collecting this information is to characterize the participants in the study. Knowledge of participant's role will assist in the design and targeting of HCV prevention interventions. Steps will be taken to ensure privacy of data. Voice recorded data and transcripts will be stored on secured servers with secure password protected files or in a locked file cabinet in the Principal Investigator's (PI) locked office. Only the PI and Project Director (PD) will have access to the password for the master data file. ID numbers will only be used to identify participants in the study. A list linking ID numbers to names will be kept separately in a locked location in the PI's office.

Audio recordings of interviews and focus groups will be transcribed by an outside contractor; transcripts will be stored on password-protected computers and in locked files. The audio tapes will be destroyed after transcription. A list linking ID numbers to participant names will be kept in a separate locked file cabinet in the PI's locked office. The collected data is the property of the grantees. After data analysis is completed, the grantees will destroy all participant PII and data.

CDC will not receive any PII. If there were a need to send data to CDC for review, all PII collected by local partners would be unlinked or stripped from the database that is submitted to CDC.

A.1.3 Overview of the data collection system

Independently, and not as an agent of the government, the contractors will revise current hepatitis C testing protocols to integrate HCV rapid testing into the HIV testing site. Protocol revisions will include how rapid tests will be used in

conjunction with conventional testing. Prevention counseling messages related to HCV will be revised/developed including pre-test messages, knowledge enhancement and post-test messages. The messages to be used are the attached Fact Sheets (Attachment 3a and 3b).

Using the revised protocol and prevention counseling messages, the grantees will conduct a formative evaluation of the protocol and messages by implementing rapid HCV testing. Data collection from interviews and focus groups will cease no later than 12 months from the end of approval.

The sample will consist of approximately 120 staff and clients who are at least 18 years of age and seeking services within the grantee's catchment areas (Denver, CO. and Detroit, MI).

A total of 600 rapid HCV tests (300 at each site) will be conducted. Qualitative data collection will consist of at most 12 focus groups with 6-8 participants, for a total of 72-96 participants. Participants will be recruited and screened by the Project Director (PD) or an outreach worker, who will collect contact information for those who meet the inclusion criteria. Individuals may be recruited for an individual interview (at most 12 interviews per site), for a total of 24 participants. Based upon participants' willingness to participate in a focus group or interview, the participant will be contacted and notified of the specific date, time and location of the group or the interview. See Attachment 5a and 5b for a copy of the screening forms.

Inclusion criteria for client participants include clients who are at risk for HCV and do not self-report as HCV positive, according to the screening forms (Attachment 5a and 5b). Eligible client participants are those clients that receive a rapid HCV test. Participants are then asked to participate in a focus group or interview based upon their willingness. The client participants are then placed into different focus groups based on the result of the rapid test (positive or negative). Inclusion criteria for staff are testers and counselors willing to participate in a focus group or interview at each site.

A.1.4 Items of Information to be collected

Focus Groups will consist of 6-8 participants each. Interviews and Focus groups will be conducted and expected to last approximately 90 minutes. Questions to participants will include:

- attitudes toward HCV testing,

- perceptions of barriers and facilitators of HCV testing
- strategies to improve HCV testing
- comfort and skills needed to discuss HCV

A.1.5 Identification of Website(s) and Website Content Directed at Children Under 13 Years of Age

There will be no websites or internet content directed at children under the age of 13.

A.2. Purpose of Use of the Information Collection

The purpose of this contract is to revise and field test protocols and prevention counseling messages for HCV rapid tests. One HIV testing site that is currently providing conventional HCV testing and one HIV testing site that does not currently provide HCV testing has been funded. The HIV testing sites include a syringe service program and a STD clinic which provide services to persons at risk of hepatitis C.

A.2.1 Qualitative interviewing for surveillance, research, and intervention methods and material development

Qualitative interviewing will be used with volunteer participants to identify the factors associated with voluntary HCV counseling and testing among those seeking services in HIV testing settings. The results will be used to inform researchers and administrators of HIV testing settings of the barriers and facilitators of implementing rapid HCV tests into HIV testing settings.

A.2.2 Cognitive interviewing for development of specific data collection instruments

Cognitive interviewing will be used with volunteer participants to refine protocols and counseling messages related to implementation of rapid HCV tests.

A.2.4 Usability testing of technology-based instruments and materials

There will be no testing of technology-based instruments or materials.

A.2.5 Field Testing of New Methodologies and Materials

The purpose of this data collection is to conduct a field test of new protocols and counseling messages, included as Fact Sheets (Attachments 3a and 3b). The objective of such testing is to evaluate the feasibility of the "new" strategies.

A.3. Use of Improved Information Technology and Burden Reduction

There will be no use of improved information technology.

A.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.

A.5. Impact on Small Business or 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.

A.7. Special Circumstances relating to the Guidelines of 5 CFR 1320.5

The request fully complies with the guidelines of 5 CFR 1320.5.

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

A Federal Register notice for the generic clearance 0920-0840 was published on March 11, 2009.

A.9. Explanation of Any Payment or Gift to Respondents

Participants will receive tokens of appreciation for their participation in the study: \$25 (Denver Public Health) and \$20 (Community Health Awareness Group) per person for 90-minute focus groups or interviews for clients. Staff participants will not receive additional payments beyond their usual salary/wages.

The token is being offered to show appreciation for participating in focus group sessions or interviews. Through previously

conducted research with this target population, the investigators have determined that this level of token is the most reasonable amount to ensure participation and meet the goals of this information collection.

While tokens of appreciation will be utilized for the participation in this information collection, there is no intention to continue their use if these study materials are proven to be effective and widely adopted.

A.10. Assurance of Confidentiality Provided to Respondents

After the interviews and focus groups are completed all contact information for participants will be destroyed. After the audio files from the focus groups are transcribed, they will be erased from the recorder and deleted from the computer. Each name on the audio files will be changed to an ID code in the typed transcripts. To compile data to a master file each interview will be stored on a secure USB drive for transfer to the master file. The password protected master file will be located on a secure password protected computer in the PI's locked office. Data will be routinely purged from the USB drives and laptop computers after transfer is complete to the master file.

Analysis of the data sets will take place at the grantee sites. The information collected in this project will be owned by the grantees. They will be the only entity with access to the PII and information collected. If any data are shared with CDC, it will be de-identified and transferred securely to CDC via the Secure Data Network's (SDN) file transfer service.

Prior to participating in any part of the study at Denver Public Health, participants will be required to give informed consent. Written consent will be obtained for the interviews and focus groups (Attachment 2a and 2b). All consent forms with participant names and signatures will be kept in a locked file cabinet in a locked room separate from the data files. They will be taken to this location as soon as possible after the data collection has been completed. Participants will be provided with copies of their consent forms. Participants at Community Health Awareness Group will not be required to give informed consent, however each participant will receive an information sheet explaining the evaluation (Attachment 2c).

A.11. Justification for Sensitive Questions

The interview and focus group guides ask questions that may be perceived as sensitive in nature. Questions about testing for hepatitis C are needed to assess HCV prevention, testing and treatment services and how these may relate to disclosure attitudes and behaviors. Participants are also asked about diagnosis of HCV. These questions are needed to assess how these factors affect HCV status disclosure, as well as other risk or protective behaviors. Furthermore, these questions are needed to gain information and insight that will be used to strengthen CDC's prevention efforts for those at-risk for hepatitis C seeking HIV testing services. In no case will a participant's social security number be obtained by agency staff.

A.12. Estimates of Annualized Burden Hours and Costs

A.12.A Estimates of Annualized Burden Hours and Costs

There will be two types of respondents in this study: Clients seeking HIV testing setting services at risk for hepatitis C and staff participating in rapid HCV testing and counseling. To ensure participants are screened and identified, a 5-minute risk screener will be conducted. Approximately 120 participants (staff and clients) will participate in 90 minute focus groups or interviews.

Exhibit A.12.A. Estimate of Annualized Burden Hours

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Respondent (in hours)	Total Burden (in hours)
General HIV testing setting client	Screening and Contact Form (Either Attachment 5a OR 5b, depending upon site)	600	1	5/60	50
General Client or Staff	Interview Guide or Focus Group Guide (Attachment 1a)	120	1	90/60	180
Total					230

A.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, 2009. (http://www.bls.gov/oes/current/oes_nat.htm) was used to estimate the hourly wage for the general public for the purpose of this generic request. The figure of \$20.90 per hour was used as an estimate of average hourly wage for adults. Thus, the total anticipated annual cost to participants for collection of information in this project will be \$4,807.00.

Exhibit A.12.B: Estimated Annualized Burden Costs

Type of Respondent (Form Name)	Total Burden Hours	Hourly Wage Rate	Total Respondent Cost
General HIV testing setting client (Screening and Contact Form)	50	\$20.90	\$1,045.00
General Client or Staff (Interview or Focus Group Guide)	180	\$20.90	\$3,762.00
Total	975		\$4,807.00

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

There are no other costs to respondents or record keepers.

A. 14. Annualized Cost to the Federal Government

This activity will involve participation of one CDC project officer and CDC supervisor who will assist with project design, obtain IRB and OMB approvals, and provide project oversight. Travel expenses include two site visits.

Exhibit A.14: Estimates of Annualized Cost to the Government

Expense Type	Expense Explanation	Annual Costs (dollars)
Direct Costs to the Federal Government	CDC Project Officer (GS-14, 0.05 FTE)	\$5,725.25
	CDC Project Manager (ORISE Fellow, GS-9, 0.25 FTE)	\$13,485.00
	CDC Travel for Site Visits (2 trips)	\$6,000.00
	Subtotal, Direct Costs	\$25,210.25
Cooperative Agreement or Contract Costs	Cooperative Agreement to grantees.	\$508,085.00
	Subtotal, Cooperative Agreement or Contract Costs	\$508,085.00
	TOTAL COST TO THE GOVERNMENT	\$533,295.25

A.15. Explanation for Program Changes or Adjustments

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

A.16. Plans for Tabulation and Publication and Project Time Schedule

Data collection will be completed during the first year after OMB approval is granted.

Exhibit A.16: Project Time Schedule

Activity	Time Schedule
Recruit and Screen Clients	1-7 months after OMB approval
Conduct Focus Groups	4-9 months after OMB approval
Conduct Interviews	4-9 months after OMB approval
Focus Group and Interview Analysis	9-10 months after OMB approval
Manuscript Development Share Findings with Stakeholders	10-12 months after OMB approval

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

OMB Expiration Date will be displayed.

18. Exceptions to Certification for Paperwork Reduction Act (PRA) Submissions 5CFR 1320.3(h)(1)-(10)

There are no exceptions to the certification.