



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-15-15ARG]; [Docket No. CDC-2015-0047]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC),
Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing efforts to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. This notice invites comment on "Prevent Hepatitis Transmission among Persons Who Inject Drugs". The purpose of this study is to address the high prevalence of HCV infection by developing an integrated approach for detection, prevention, care and

treatment of infection among persons aged 18-30 years who reside in non-urban counties.

DATES: Written comments must be received on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments, identified by Docket No. CDC-2015-0047 by any of the following methods:

- Federal eRulemaking Portal: [Regulation.gov](http://www.regulation.gov). Follow the instructions for submitting comments.
- Mail: Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to [Regulations.gov](http://www.regulations.gov), including any personal information provided. For access to the docket to read background documents or comments received, go to [Regulations.gov](http://www.regulations.gov).

Please note: All public comment should be submitted through the Federal eRulemaking portal ([Regulations.gov](http://www.regulations.gov)) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact the Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329; phone: 404-639-7570; E-mail: omb@cdc.gov.

SUPPLEMENTARY INFORMATION:

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy

of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information.

Proposed Project

Prevent Hepatitis Transmission among Persons Who Inject Drugs - New - National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Hepatitis C virus (HCV) infection is the most common chronic blood borne infection in the United States; approximately 3 million persons are chronically infected. Identifying and reaching persons at risk for HCV infection is critical to prevent transmission and treat and cure if infected. CDC monitors the national incidence of acute hepatitis C through passive surveillance of acute, symptomatic cases of laboratory confirmed hepatitis C cases. Since 2006, surveillance data have shown a trend toward reemergence of HCV infection mainly among young persons who inject drugs (PWID) in nonurban counties. Of the cases reported in 2013 with information on risk factors 62% indicated injection drug use as the primary risk for acute hepatitis C. The prevention of HCV infection among PWIDs requires an integrated approach including harm reduction interventions, substance abuse treatment, prevention of other blood borne infections, and care and treatment of HCV infection.

The purpose of the proposed study is to address the high prevalence of HCV infection by developing and implementing an integrated approach for detection, prevention, care and treatment of infection among persons aged 18-30 years who reside in non-urban counties. Awardees will develop and implement a comprehensive strategy to enroll young non-urban PWID, collect

epidemiological information, test for HCV infection and provide linkage to primary care services, prevention interventions, and treatment for substance abuse and HCV infection. In addition to providing HCV testing, participants will be offered testing for the presence of co-infections with hepatitis B virus (HBV) and HIV. Rates of HCV infection or re-infection will be evaluated through follow-up blood tests. Furthermore, adherence to prevention services and retention in care will be assessed through follow up interviews.

The project will recruit an estimated total of 1,500 young PWIDs to enroll 1,000. The participants will be recruited from settings where young PWIDs obtain access to care and treatment services. Recruitment will be direct and in-person by partnering with local harm reduction sites. Recruiters will enroll subjects across recruitment sites primarily through drug treatment programs and syringe exchange programs, as well as persons referred to these sites as a result of referral from other programs and respondent driven sampling. Those who consent to participate will be administered an eligibility interview questionnaire by trained field staff. If found eligible, the participant will take an interviewer-administered survey that includes information on initiation of drug use, injection practices, HCV and HIV infection status, access to prevention and medical care, desire to receive and barriers to receiving

HCV treatment, and missed opportunities for hepatitis prevention. Participants will receive counselling regarding adherence to medical and/ or drug treatment services and prevention services. Participants will be interviewed for a maximum of 5 times within any 12-month interval during the course of the study: Consent and interview at enrollment/baseline for an estimated 60 minutes, and 30-minute follow-up interviews every 3 months thereafter. Participants who are recruited early in the study have more follow-up interviews than those who are recruited in the later part of the study during the 3-year project. However, recruitment will be spread over 2 years and on average, the duration of follow-up is estimated to be one year.

Participation in interviews and responses to all study questions are totally voluntary and there is no cost to respondents other than their time. The maximum burden is 3,375 hours.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (in hrs.)	Total Burden (in hrs.)
Young PWIDs	Screener	1500	1	15/60	375
Eligible young PWIDs	Initial Survey	1000	1	60/60	1000
Eligible young PWIDs	Follow-up	1000	4	30/60	2000

	survey				
TOTAL					3375

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