

Study to Assess Hepatitis Risk

Attachment 2

60 day Federal Register Notice

new public-private partnership will develop a unified approach to realize an effective, interoperable nationwide health information system that supports the health and well-being of the people of this country. The input from this public comment period will be used to inform the plans for transitioning the locus of activity from a Federal advisory committee to a independent public-private partnership.

HHS and the AHIC are eager to hear the thoughts of your organization with respect to the AHIC successor entity. To facilitate your participation in this process, you are encouraged to provide your comments organized by the following concepts:

- Purpose and scope of the successor entity
- Membership, including classes and sectors
- Governing body and decision-making process
- Protections, incorporation, management, and staffing
- Value of participation in the successor entity for stakeholders

All comments in any format will be accepted.

DATES: Comments should be received by the Office of the National Coordinator for Health Information Technology, Department of Health and Human Services, on or before 5 p.m. EST on August 31, 2007.

ADDRESSES: electronic responses are preferred and may be recorded via the Web site at <http://www.hhs.gov/healthit/community/background/AHICsuccessor.html> or may be sent via e-mail addressed to AHICsuccessor@hhs.gov in the Office of the National Coordinator for Health Information Technology, Department of Health and Human Services. Please include "AHIC Successor White Paper Comments" in the subject line.

Paper-based responses will also be accepted. Please send to: Office of the National Coordinator for Health Information Technology, Department of Health and Human Services, Attention: AHIC Successor White Paper Comments, Mary C. Switzer Building, 330 C Street, SW., Room 4080, Washington, DC 20201, or fax to (202) 690-6079, Attention: AHIC Successor White Paper Comments.

FOR FURTHER INFORMATION: Visit <http://www.hhs.gov/healthit/community/background/AHICsuccessor.html>.

Dated: July 27, 2007.

Michelle Murray,
Office of Programs and Coordination, Office
of the National Coordinator for Health
Information Technology.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60-Day-07-07BN]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404-639-5960 and send comments to Maryam I. Daneshvar, CDC Acting Reports Clearance Officer, 1600 Clifton Road, MS-D74, Atlanta, GA 30333 or send an e-mail to omb@cdc.gov.

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; and (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. Written comments should be received within 60 days of this notice.

Proposed Project

Pilot Project to Estimate the Incidence of Hepatitis C Virus (HCV) Infection Among Young Injection Drug Users (IDUs) Using Serial Cross-Sectional Seroprevalence Surveys—New—National Center for HIV, Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Hepatitis C is the most prevalent bloodborne infection in the United States; approximately 3.2 million persons are chronically infected with HCV. National recommendations for prevention and control of HCV infection emphasize primary prevention activities to reduce the risk of HCV transmission. Identifying and reaching persons at risk for HCV infection to provide risk-reduction counseling is thus critical to prevent infection. Currently the Centers for Disease Control and Prevention (CDC) monitors the national incidence of acute hepatitis C through passive surveillance of acute, symptomatic cases of laboratory confirmed hepatitis C. However, only a minority of people with acute infection have symptoms at all (<25%) and passive surveillance only captures a small fraction of acutely infected people, i.e., those who have symptoms and receive medical attention and appropriate laboratory testing during the acute phase of the disease. Injection drug users (IDUs), who are the primary risk group for acute hepatitis C (70% of identified acute cases), have additional barriers to health care access and/or utilization resulting in the potential for a further underestimation of overall incidence. Thus, it is necessary to consider strategies other than passive surveillance for incidence monitoring. One such strategy is to conduct Serial Cross-Sectional Seroprevalence Surveys (SCSS) among populations at increased risk of infection such as IDUs.

For the proposed pilot project, funding will be awarded to selected U.S. sites that will develop and test different methods to recruit a sample of young IDUs that is most representative of the population of young IDUs at risk for HCV infection. These sampling methods will be compared and contrasted to identify a methodology to be used in ongoing SCSSs among young IDUs. Better methods of identification of persons at risk will enhance current surveillance efforts to monitor the incidence of HCV infection which in turn are the best means to direct and assess primary prevention strategies, determine new transmission patterns, and identify and control outbreaks. Moreover, methods developed in this study can be used in other areas to gather representative data on incidence of acute disease and the burden of disease caused by HCV infection.

In addition, instruments for collecting behavioral/risk factor data from IDUs will be developed and pilot tested. It is estimated that data will be collected over 15 months from a total of 2000