

Dated: April 1, 2004.

Alvin Hall,

*Director, Management Analysis and Services
Office, Centers for Disease Control and
Prevention.*

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-32-04]

Proposed Data Collections Submitted for Public Comment and Recommendations

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 498-1210. Send written comments to CDC, Desk Officer, Human Resources and Housing Branch, New Executive Office Building, Room 10235, Washington, DC 20503 or by fax to (202) 395-6974. Written comments should be received within 30 days of this notice.

Proposed Project

Final Evaluation of the Effectiveness
of Targeted Lookback for Identifying

Transfusion Recipients who receive Blood that may have been Contaminated with Hepatitis C Virus—New—National Center for Infectious Diseases (NCID), Centers for Disease Control and Prevention (CDC).

In 1998 the Food and Drug Administration (FDA) issued guidelines to blood collection establishments and transfusion services for the notification of persons who received blood or blood components from donors who subsequently tested positive for antibody to hepatitis C virus (anti-HCV) using a licensed multiantigen screening assay. Blood collection establishments were to identify potentially HCV-contaminated blood products and inform transfusion services of these units. The transfusion services made an attempt to notify the recipients of these products and encouraged recipients to be tested for HCV infection. Recently, the FDA revised their original guidance to extend the lookback period for these multiantigen screened donors, and include in the lookback process donors who tested anti-HCV positive using the earlier single-antigen screening assay.¹

CDC, in collaboration with the FDA, has been charged with the responsibility of evaluating this nationwide notification process. An interim nationwide survey (Evaluation of the Effectiveness of Targeted Lookback for Identifying Transfusion Recipients who receive Blood that may have been Contaminated with Hepatitis C Virus,

OMB No. 0920-0462) of blood collection establishments and transfusion services was conducted in December 1999 to determine the progress that had been made to date, and to summarize the lookback results. The objective of this currently proposed study is to resurvey the blood collection establishments and transfusion services to obtain final results and assess the overall effectiveness of the targeted lookback for identifying persons infected with HCV. The evaluation has two specific aims:

1. Determine the effectiveness of targeted lookback for identifying prior transfusion recipients with HCV infection, including the proportion of recipients identified who are still alive, the proportion of those alive who were successfully notified, the proportion of those notified who have already been tested, the proportion of those notified who get tested as a result of the notification, and the proportion of those tested who are HCV positive.

2. Determine the cost-effectiveness of targeted lookback, including resources (person-hours, costs of recipient notification and testing, etc.) utilized by blood collection establishments and transfusion services for implementation of the lookback protocol.

The evaluation will include the following components: (1) A nationwide survey of blood collection establishments; (2) A nationwide survey of transfusion services. The estimated annualized burden is 15,480 hours.

Survey site	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hrs)
Blood Collection Establishment	HCV Targeted Lookback Blood Collection Establishment Final Questionnaire.	160	1	3
Transfusion Services	HCV Targeted Lookback Transfusion Service Final Questionnaire.	5,000	1	3

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Grants for Education Programs in Occupational Safety and Health; Notice of Availability of Funds

Announcement Type: New and
Competing Continuation.

Funding Opportunity Number: RFA
OH05-001.

*Catalog of Federal Domestic
Assistance Number:* 93.263.

Key Dates:

Letter of Intent Deadline: None.

*Pre-Application Technical Assistance
Conference Call:* May 13, 2004 (see
Section VIII of this announcement).

Application Deadline: July 1, 2004.

Executive Summary: The Centers for
Disease Control and Prevention (CDC)

¹ Food and Drug Administration. Guidance For Industry. "Lookback" for Hepatitis C Virus (HCV): Product Quarantine, Consignee Notification, Further Testing, Product Disposition, and Notification of Transfusion Recipients Based on Donor Test Results Indicating Infection with HCV. Rockville, MD: Center for Biologics Evaluation and Research (CBER), December 2001.