

HEPATITIS C LOOKBACK

INFORMATION FOR TRANSFUSION SERVICES

U.S. Department of Health and Human Services, Food and Drug Administration, CBER, August 2007, updated December 2010; 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.

When is hepatitis C lookback performed?

Hepatitis C Lookback is performed whenever a repeat blood donor is found to be certainly or possibly infected with hepatitis C, usually as a result of testing at the time of a subsequent blood donation. Less often, a donor is diagnosed with hepatitis C by a physician or another blood center. The test results that trigger HCV lookback include: Anti-HCV repeat reactive, positive second licensed Anti-HCV screening assay and/or HCV NAT positive.

Why is lookback performed?

The purpose of lookback is to identify recipients who **may have been exposed** to the hepatitis C virus (HCV) and make appropriate efforts to assure that they are notified and counseled regarding testing for HCV. Lookback gives these patients the opportunity to undergo medical evaluation and receive treatment if indicated.

Who is responsible for performing HCV lookback investigations?

Lookback is carried out both by the blood supplier and by the transfusion service. Identification of involved donations and notification of consignees is the responsibility of the blood supplier. Notification of the recipients (and/or their physician) is the responsibility of the transfusion service.

What should the transfusion service do after receiving a lookback notification?

The transfusion service is ultimately responsible for notifying and counseling the recipient. Each transfusion service should establish policies and procedures that comply with current FDA regulations.

If you have additional questions or concerns please contact the Medical Surveillance Department at LifeStream (909) 885-6503.

INFORMATION FOR PHYSICIANS ABOUT HEPATITIS C LOOKBACK AND HEPATITIS C VIRUS (HCV)

HCV LOOKBACK

The US Department of Health and Human Services (HHS) has recommended that patients who may have received *previously donated* blood components from a donor who *now* tests positive for HCV be contacted and notified of the potential transfusion exposure to HCV. The process of tracing and notifying such recipients is referred to as “**lookback**.” At the time of previous donations the blood donors were non-reactive in required tests, but may have been infected with HCV. It therefore is not known if the previously donated units of a now HCV-positive donor were infected with HCV.

LifeStream provides notifications based U.S. Department of Health and Human Services, Food and Drug Administration, CBER, August 2007, Updated December 2010; [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.](#)

HEPATITIS C

We have enclosed a list of State and National Resources regarding Hepatitis C. Updated and current information is also available through the NIH <http://www.nih.gov> site and the American Liver Foundation <http://www.liverfoundation.org>

HCV Testing

The standard test for HCV antibodies is a screening enzyme immunoassay (EIA), commercially available through most reference laboratories or, possibly, local hospitals. If the EIA is reactive, the patient should undergo supplemental (confirmatory) testing such as a second licensed Anti-HCV screening assay. Additionally polymerase chain reaction (PCR) testing is available to determine presence of virus both qualitatively and quantitatively.

Clinical outcomes and follow-up

Most HCV infections are asymptomatic in the acute and chronic phases. Persistent infection occurs in up to 85% of HCV-infected individuals, usually in the form of chronic hepatitis. Cirrhosis can occur in up to 20% of patients and hepatocellular carcinoma in 1-5% after twenty years of infection. The risk of hepatocellular carcinoma increases 1-4% per year in the setting of cirrhosis. Consumption of alcohol, even in small amounts, is associated with a graver prognosis in any stage of hepatitis C. Infected persons should be counseled not to drink alcohol in any form or amount.

Treatment options

Research in this area is occurring at a brisk pace. Treatment with interferon alfa alone or in combination with other antivirals has shown a positive response in 10-15% of treated patients, however, it is expected that treatment recommendations and protocols will change significantly in the months and years ahead. Physicians are referred to the NIH and medical literature for updates on hepatitis C therapies.

Prevention of transmission

HCV-contaminated blood is highly infectious. Infected individuals should be counseled not to donate blood or tissues or share razors, toothbrushes, needles, clippers, tweezers, or any other items that might be contaminated with blood or body fluids. There is no evidence suggesting that the virus can be spread through casual household contact. Rarely, HCV can be sexually transmitted, and the NIH Consensus Guidelines are useful for counseling patients about any possible need to modify sex practices. Pregnancy is not necessarily contraindicated, but infected individuals should seek medical input.

STATE AND NATIONAL RESOURCES HEPATITIS

American Association for the Study of Liver Diseases
(AASLD)
1001 N. Fairfax, Suite 400
Alexandria, VA 22314-2720
703-299-9766
<http://www.aasld.org>

American College of Gastroenterology (ACG)
P.O. Box 342260
Bethesda, MD 20827-2260
301-263-9000
<http://www.acg.gi.org>

**American Liver Foundation (ALF)
39 Broadway Suite 2700
New York, NY 10006
212-668-1000 or 800-223-0179
<http://www.liverfoundation.org>

**Centers for Disease Control and Prevention
(CDC), Hepatitis Branch: Mailstop G-37
1600 Clifton Road N.E.
Atlanta, GA 30333
800-232-4636
<http://www.cdc.gov/hepatitis>

American Gastroenterological Association
4930 Del Ray
Bethesda, MD 20814
301-654-2055
<http://www.gastro.org>

Hep C Connection
1325 S. Colorado Boulevard, Build B, Suite 302
Denver, CO 80222
303-860-0800 or 800-522-HEPC (4372)
<http://www.hepc-connection.org>

**Hepatitis Foundation International
504 Blick Drive
Silver Spring, MD 20904-2901
800-891-0707 or 301-622-4200
<http://www.hepfi.org>

** May be most helpful initially

Immunization Action Coalition (IAC)
Hepatitis B Coalition
1573 Selby Avenue, Suite 234
St. Paul, MN 55104
651-647-9009
<http://www.immunize.org/>

National Digestive Diseases Information
Clearinghouse (NDDIC)
2 Information Way
Bethesda, MD 20892-3570
800-891-5389
<http://www.digestive.niddk.nih.gov>

National Foundation for Infectious Diseases
4733 Bethesda Avenue, Suite 750
Bethesda, MD 20814-5278
301-656-0003
<http://www.nfid.org/>

OTHER IMPORTANT WEB SITES

California Department of Health Services
<http://www.dhs.ca.gov/>

Department of Veterans Affairs
<http://www.hepatitis.va.gov/>

Hepatitis C Support Project
<http://www.hcvadvocate.org/>

HIV and Hepatitis
<http://www.hivandhepatitis.com>

United Network for Organ Sharing
<http://www.unos.org>