

## A Targeted Lookback for Recipients of Blood or Blood Components From Donors Who Subsequently Tested Positive for Antibody to the Hepatitis C Virus (HCV)

Screening of blood donors for hepatitis C virus (HCV) antibody began in 1990 with the first generation enzyme immunoassay test. Improved HCV antibody testing became available in July 1992. Testing with this second generation assay reduced false-positive and false-negative results. Since HCV infection is chronic, often with no symptoms, it is possible that many donors who tested positive after 1992 were infected at much earlier points in time and may have been sources of potentially contaminated blood prior to effective donor screening. Based on these concerns, the Food and Drug Administration (FDA) recently recommended that blood establishments and hospitals identify recipients of blood or blood components received between 1987 and 1992 from donors who tested positive for HCV antibody after second generation testing became available. The date of 1987 was chosen because many hospitals don't have records available of care provided before 1987 and locating patients from records more than 10 years old can be very labor-intensive with a minimal public health benefit.

Blood establishments are in the process of identifying donations from donors who later tested positive for HCV antibody. This information is then

being transmitted to hospital transfusion services who will then identify the recipients. The transfusion services will either notify recipients directly or request physicians to notify the recipients. Recipients will be encouraged to be tested for HCV antibody and receive further medical evaluation as needed.

The notification process for this "targeted lookback" has begun in Minnesota. Recipients will receive letters indicating that they may have been exposed to HCV through a transfusion received between 1987 and 1992. In many instances, hospitals in Minnesota will offer free testing to these recipients; however, recipients will also be informed that they may wish to see their current primary care provider.

The Centers for Disease Control and Prevention (CDC) has recently published a document entitled, "Recommendations for Prevention and Control of Hepatitis C Virus (HCV) Infection and HCV-Related Chronic Disease" (MMWR 1998; 47 [No. RR-19]:1-39). This document outlines primary and secondary prevention measures for hepatitis C and provides current background about the disease. The prevention and control recommendations from this document are included

in this issue of the *Disease Control Newsletter*.

In March 1997, the National Institutes of Health (NIH) prepared a document entitled, "Consensus Statement: Management of Hepatitis C." (This document was published in the *Disease Control Newsletter* in September 1997. To receive a copy, please contact the Minnesota Department of Health Acute Disease Epidemiology Section at 612/676-5414.) The NIH Consensus Statement provides information on diagnosis, monitoring, and treatment of HCV infection. In general, if an infected patient is being considered for antiviral therapy, liver biopsy is commonly performed to assess disease severity. Therefore, it is reasonable to refer HCV antibody positive persons to physicians who specialize in caring for such patients.

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# Recommendations for Prevention and Control of Hepatitis C Virus (HCV)--Infection and HCV-Related Chronic Disease\*

## RATIONALE

Reducing the burden of HCV infection and HCV-related disease in the United States requires implementation of *primary* prevention activities that reduce risks for contracting HCV infection and *secondary* prevention activities that reduce risks for liver and other chronic diseases in HCV-infected persons.

Primary prevention activities can reduce or eliminate potential risk for HCV transmission from a) blood, blood components, and plasma derivatives; b) such high-risk activities as injecting-drug use and sex with multiple partners; and c) percutaneous exposures to blood in health care and other (i.e., tattooing and body piercing) settings. Immunization against HCV is not available; therefore, identifying persons at risk but not infected with HCV provides opportunity for counseling on how to reduce their risk for becoming infected.

Secondary prevention activities can reduce risks for chronic disease by identifying HCV-infected persons through diagnostic testing and by providing appropriate medical management and antiviral therapy. Because of the number of persons with chronic HCV infection, identification of these persons must be a major focus of current prevention programs. Identification of persons at risk for HCV infection provides opportunity for testing to determine their infection status, medical evaluation to determine their disease status if infected, and antiviral therapy, if appropriate. Identification also provides infected persons opportunity to obtain information concerning how they can prevent further harm to their liver and prevent transmitting HCV to others.

Hepatitis C is a disease of major public health importance, and suitable and accurate diagnostic tests as well as behavioral and therapeutic interventions are available. Counseling and

testing can prevent disease transmission and progression through reducing high-risk practices (e.g., injecting-drug use and alcohol intake). However, the degree to which persons will change their high-risk practices based on knowing their test results is not known, and possible adverse consequences of testing exist, including disclosure of test results to others that might result in disrupted personal relationships and possible discriminatory action (e.g., loss of employment, insurance, and educational opportunities). Antiviral treatment is also available, and treatment guidelines have been developed. Such treatment is beneficial for many patients, although sustained response rates and mode of delivery are currently less than ideal.

Persons at risk for HCV infection who receive health-care services in the public and private sectors should have access to counseling and testing. Facilities that provide counseling and testing should include services or referrals for medical evaluation and management of persons identified as infected with HCV. Priorities for implementing new counseling and testing programs should be based on providing access to persons who are most likely to be infected or who practice high-risk behaviors.

## PRIMARY PREVENTION RECOMMENDATIONS

### Blood, Plasma Derivatives, Organs, Tissues, and Semen

Current practices that exclude blood, plasma, organ, tissue, or semen donors determined to be at increased risk for HCV by history or who have serologic markers for HCV infection must be maintained to prevent HCV transmission from transfusions and transplants. Viral inactivation of clotting factor concentrates and other products derived from human plasma, including IG products, also must be continued, and all plasma-derived products that do not undergo viral inactivation should be

HCV RNA negative by RT-PCR before release.

### High-Risk Drug and Sexual Practices

Health-care professionals in all patient care settings routinely should obtain a history that inquires about use of illegal drugs (injecting and noninjecting) and evidence of high-risk sexual practices (e.g., multiple sex partners or a history of STDs). Primary prevention of illegal drug injecting will eliminate the greatest risk factor for HCV infection in the United States. Although consistent data are lacking regarding the extent to which sexual activity contributes to HCV transmission, persons having multiple sex partners are at risk for STDs (e.g., HIV, HBV, syphilis, gonorrhea, and chlamydia). Counseling and education to prevent initiation of drug-injecting or high-risk sexual practices is important, especially for adolescents. Persons who inject drugs or who are at risk for STDs should be counseled regarding what they can do to minimize their risk for becoming infected or of transmitting infectious agents to others, including need for vaccination against hepatitis B. Injecting and noninjecting illegal drug users and sexually active men who have sex with men also should be vaccinated against hepatitis A.

Counseling of persons with potential or existing illegal drug use or high-risk sexual practices should be conducted in the setting in which the patient is identified. If counseling services cannot be provided on-site, patients should be referred to a convenient community resource, or at a minimum, provided easy-to-understand health-education material. STD and drug-treatment clinics, correctional institutions, and HIV counseling and testing sites should routinely provide information concerning prevention of HCV and HBV infection in their counseling messages.

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\*Adapted from MMWR 1998; 47 (No. RR-19)

## **Percutaneous Exposures to Blood in Health Care and Other Settings**

### Health-Care Settings

Health-care, emergency medical, and public safety workers should be educated regarding risk for and prevention of bloodborne infections, including the need to be vaccinated against hepatitis B. Standard barrier precautions and engineering controls should be implemented to prevent exposure to blood. Protocols should be in place for reporting and follow-up of percutaneous or permucosal exposures to blood or body fluids that contain blood.

Health-care professionals responsible for overseeing patients receiving home infusion therapy should ensure that patients and their families (or caregivers) are informed of potential risk for infection with bloodborne pathogens, and should assess their ability to use adequate infection-control practices consistently. Patients and families should receive training with a standardized curriculum that includes appropriate infection-control procedures, and these procedures should be evaluated regularly through home visits.

Currently, no recommendations exist to restrict professional activities of health-care workers with HCV infection. As recommended for all health-care workers, those who are HCV-positive should follow strict aseptic technique and standard precautions, including appropriate use of hand washing, protective barriers, and care in the use and disposal of needles and other sharp instruments.

In chronic hemodialysis settings, intensive efforts must be made to educate new staff and reeducate existing staff regarding hemodialysis-specific infection-control practices that prevent transmission of HCV and other bloodborne pathogens. Hemodialysis-center precautions are more stringent than standard precautions. Standard precautions require use of gloves only when touching blood, body fluids, secretions, excretions, or contaminated items. In contrast, hemodialysis-center precautions require glove use whenever patients or hemodialysis equipment is touched. Standard precautions do not restrict use of supplies, instruments, and medications to a single

patient; hemodialysis-center precautions specify that none of these items be shared among any patients. Thus, appropriate use of hemodialysis-center precautions should prevent transmission of HCV among chronic hemodialysis patients, and isolation of HCV-positive patients is not necessary or recommended.

### Other Settings

Persons who are considering tattooing or body piercing should be informed of potential risks of acquiring infection with bloodborne and other pathogens through these procedures. These procedures might be a source of infection if equipment is not sterile or if the artist or piercer does not follow other proper infection-control procedures (e.g., washing hands, using latex gloves, and cleaning and disinfecting surfaces).

## **SECONDARY PREVENTION RECOMMENDATIONS**

### **Persons for Whom Routine HCV Testing is Recommended**

Testing should be offered routinely to persons most likely to be infected with HCV who might require medical management, and testing should be accompanied by appropriate counseling and medical follow-up. In addition, anyone who wishes to know or is concerned regarding their HCV-infection status should be provided the opportunity for counseling, testing, and appropriate follow-up. The determination of which persons at risk to recommend for routine testing is based on various considerations, including a known epidemiologic relationship between a risk factor and acquiring HCV infection, prevalence of risk behavior or characteristic in the population, prevalence of infection among those with a risk behavior or characteristic, and the need for persons with a recognized exposure to be evaluated for infection.

### Persons Who Have Ever Injected Illegal Drugs

Health-care professionals in primary-care and other appropriate settings routinely should question patients regarding their history of injecting-drug use, and should counsel, test, and evaluate for HCV infection, persons with such histories. Current injecting-

drug users frequently are not seen in the primary health-care setting and might not be reached by traditional media; therefore, community-based organizations serving these populations should determine the most effective means of integrating appropriate HCV information and services into their programs.

Testing persons in settings with potentially high proportions of injecting-drug users (e.g., correctional institutions, HIV counseling and testing sites, or drug and STD treatment programs) might be particularly efficient for identifying HCV-positive persons. HCV testing programs in these settings should include counseling and referral or arrangements for medical management. However, limited experience exists in combining HCV programs with existing HIV, STD, or other established services for populations at high risk for infection with bloodborne pathogens. Persons at risk for HCV infection through limited or occasional drug use, particularly in the remote past, might not be receptive to receiving services in such settings as HIV counseling and testing sites and drug and STD treatment programs. In addition, whether a substantial proportion of this group at risk can be identified in these settings is unknown. Studies are needed to determine the best approaches for reaching persons who might not identify themselves as being at risk for HCV infection.

### Persons with Selected Medical Conditions

Persons with hemophilia who received clotting factor concentrates produced before 1987 and long-term hemodialysis patients should be tested for HCV infection. Educational efforts directed to health-care professionals, patient organizations, and agencies who care for these patients should emphasize the need for these patients to know whether they are infected with HCV and encourage testing for those who have not been tested previously. Periodic testing of long-term hemodialysis patients for purposes of infection control is currently not recommended. However, issues surrounding prevention of HCV and other bloodborne pathogen transmission in long-term hemodialysis settings are currently

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undergoing discussion, and updating recommendations for this setting is under development.

Persons with persistently abnormal ALT levels are often identified in medical settings. As part of their medical work-up, health-care professionals should test routinely for HCV infection persons with ALT levels above the upper limit of normal on at least two occasions. Persons with other evidence of liver disease identified by abnormal serum aspartate aminotransferase (AST) levels, which is common among persons with alcohol-related liver disease, should be tested also.

#### Prior Recipients of Blood Transfusions or Organ Transplants

Persons who might have become infected with HCV through transfusion of blood and blood components should be notified. Two types of approaches should be used: a) a targeted, or directed, approach to identify prior transfusion recipients from donors who tested anti-HCV positive after multiantigen screening tests were widely implemented (July 1992 and later); and b) a general approach to identify all persons who received transfusions before July 1992. A targeted notification approach focuses on a specific group known to be at risk and will reach persons who might be unaware they were transfused. However, because blood and blood-component donor testing for anti-HCV before July 1992 did not include confirmatory testing, most of these notifications would be based on donors who were not infected with HCV because their test results were falsely positive. A general education campaign to identify persons transfused before July 1992 has the advantage of not being dependent on donor testing status or availability of records, and potentially reaches persons who received HCV-infected blood from donors who tested falsely negative on the less sensitive serologic test, as well as from donors before testing was available.

- *Persons who received blood from a donor who tested positive for HCV infection after multiantigen screening tests were widely implemented.* Persons who received blood or blood components from donors who subsequently tested positive for anti-

HCV using a licensed multiantigen assay should be notified as provided for in guidance issued by FDA. For specific details regarding this notification, readers should refer to the FDA document, *Guidance for Industry. Current Good Manufacturing Practice for Blood and Blood Components: (1) Quarantine and Disposition of Units from Prior Collections from Donors with Repeatedly Reactive Screening Tests for Antibody to Hepatitis C Virus (Anti-HCV); (2) Supplemental Testing, and the Notification of Consignees and Blood Recipients of Donor Test Results for Anti-HCV.* (This document is available on the Internet at <<http://www.fda.gov/cber/gdlns/gmphcv.txt>>.)

- *Persons who received a transfusion of blood or blood components (including platelets, red cells, washed cells, and fresh frozen plasma) or a solid-organ transplant (e.g., heart, lung, kidney, or liver) before July 1992.* Patients with a history of blood transfusion or solid-organ transplantation before July 1992 should be counseled, tested, and evaluated for HCV infection. Health-care professionals in primary-care and other appropriate settings routinely should ascertain their patients' transfusion and transplant histories either through questioning their patients, including such risk factors for transfusion as hematologic disorders, major surgery, trauma, or premature birth, or through review of their medical records. In addition, transfusion services, public health agencies, and professional organizations should provide to the public, information concerning the need for HCV testing in this population. Health-care professionals should be prepared to discuss these issues with their patients and provide appropriate counseling, testing, and medical evaluation.

#### Health-Care, Emergency Medical, and Public Safety Workers After Needle Sticks, Sharps, or Mucosal Exposures to HCV-Positive Blood

Individual institutions should establish policies and procedures for HCV testing of persons after percutaneous or permucosal exposures to blood and ensure that all personnel are familiar

with these policies and procedures. Health-care professionals who provide care to persons exposed to HCV in the occupational setting should be knowledgeable regarding the risk for HCV infection and appropriate counseling, testing, and medical follow-up.

IG and antiviral agents are not recommended for postexposure prophylaxis of hepatitis C. Limited data indicate that antiviral therapy might be beneficial when started early in the course of HCV infection, but no guidelines exist for administration of therapy during the acute phase of infection. When HCV infection is identified early, the individual should be referred for medical management to a specialist knowledgeable in this area.

#### Children Born to HCV-Positive Women

Because of their recognized exposure, children born to HCV-positive women should be tested for HCV infection. IG and antiviral agents are not recommended for postexposure prophylaxis of infants born to HCV-positive women. Testing of infants for anti-HCV should be performed no sooner than age 12 months, when passively transferred maternal anti-HCV declines below detectable levels. If earlier diagnosis of HCV infection is desired, RT-PCR for HCV RNA may be performed at or after the infant's first well-child visit at age 1-2 months. Umbilical cord blood should not be used for diagnosis of perinatal HCV infection because cord blood can be contaminated by maternal blood. If positive for either anti-HCV or HCV RNA, children should be evaluated for the presence or development of liver disease, and those children with persistently elevated ALT levels should be referred to a specialist for medical management.

#### **Persons for Whom Routine HCV Testing is Not Recommended**

For the following persons, routine testing for HCV infection is not recommended unless they have risk factors for infection.

#### Health-Care, Emergency Medical, and Public Safety Workers

Routine testing is recommended only for follow-up for a specific exposure.

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### Pregnant Women

Health-care professionals in settings where pregnant women are evaluated or receive routine care should take risk histories from their patients designed to determine the need for testing and other prevention measures, and those health-care professionals should be knowledgeable regarding HCV counseling, testing, and medical follow-up.

### Household (Nonsexual) Contacts of HCV-Positive Persons

Routine testing for nonsexual household contacts of HCV-positive persons is not recommended unless a history exists of a direct (percutaneous or mucosal) exposure to blood.

### **Persons for Whom Routine HCV Testing Is of Uncertain Need**

For persons at potential (or unknown) risk for HCV infection, the need for, or effectiveness of, routine testing has not been determined.

### Recipients of Transplanted Tissue

On the basis of currently available data, risk for HCV transmission from transplanted tissue (e.g., corneal, musculoskeletal, skin, ova, or sperm) appears to be rare.

### Intranasal Cocaine and Other Noninjecting Illegal Drug Users

Currently, the strength of the association between intranasal cocaine use and HCV infection does not support routine testing based solely on this risk factor.

### Persons with a History of Tattooing or Body Piercing

Because no data exist in the United States documenting that persons with a history of such exposures as tattooing and body piercing are at increased risk for HCV infection, routine testing is not recommended based on these exposures alone. In settings having a high proportion of HCV-infected persons and where tattooing and body piercing might be performed in an unregulated manner (e.g., correctional institutions), these types of exposures might be a risk factor for HCV infection. Data are needed to determine the risk for HCV infection among persons who have been exposed under these conditions.

### Persons with a History of Multiple Sex Partners or STDs

Although persons with a history of

multiple sex partners or treatment for STDs and who deny injecting-drug use appear to have an increased risk for HCV infection, insufficient data exist to recommend routine testing based on these histories alone. Health-care professionals who provide services to persons with STDs should use that opportunity to take complete risk histories from their patients to ascertain the need for HCV testing, provide risk-reduction counseling, offer hepatitis B vaccination, and, if appropriate, hepatitis A vaccination.

### Long-Term Steady Sex Partners of HCV-Positive Persons

HCV-positive persons with long-term steady partners do not need to change their sexual practices. Persons with HCV infection should discuss with their partner the need for counseling and testing. If the partner chooses to be tested and tests negative, the couple should be informed of available data regarding risk for HCV transmission by sexual activity to assist them in making decisions about precautions (see section regarding counseling messages for HCV-positive persons). If the partner tests positive, appropriate counseling and evaluation for the presence or development of liver disease should be provided.

### **Testing for HCV Infection**

Consent for testing should be obtained in a manner consistent with that for other medical care and services provided in the same setting, and should include measures to prevent unwanted disclosure of test results to others. Persons should be provided with information regarding:

- exposures associated with the transmission of HCV, including behaviors or exposures that might have occurred infrequently or many years ago;
- the test procedures and the meaning of test results;
- the nature of hepatitis C and chronic liver disease;
- the benefits of detecting infection early;
- available medical treatment; and
- potential adverse consequences of testing positive, including disrupted personal relationships and possible discriminatory action (e.g., loss of employment, insurance, and educational opportunities).

Comprehensive information regarding hepatitis C should be provided before testing; however, this might not be practical when HCV testing is performed as part of a clinical work-up or when testing for anti-HCV is required. In these cases, persons should be informed that: a) testing for HCV infection will be performed, b) individual results will be kept confidential, and c) appropriate counseling and referral will be offered if results are positive.

Testing for HCV infection can be performed in various settings, including physicians' offices, other health-care facilities, health department clinics, and HIV or other freestanding counseling and testing sites. Such settings should be prepared to provide appropriate information regarding hepatitis C and provide or offer referral for additional medical care or other needed services (e.g., drug treatment), as warranted. Facilities providing HCV testing should have access to information regarding referral resources, including availability, accessibility, and eligibility criteria of local medical care and mental health professionals, support groups, and drug-treatment centers. The diagnosis of HCV infection can be made by detecting either anti-HCV or HCV RNA. Anti-HCV is recommended for routine testing of asymptomatic persons, and should include use of both EIA to test for anti-HCV and supplemental or confirmatory testing with an additional, more specific assay. Use of supplemental antibody testing (i.e., RIBA™) for all positive anti-HCV results by EIA is preferred, particularly in settings where clinical services are not provided directly. A summary of currently available tests is provided in Table 1.

Supplemental anti-HCV testing confirms the presence of anti-HCV (i.e., eliminates false-positive antibody results), which indicates past or current infection, and can be performed on the same serum sample collected for the EIA (i.e., routine serology). Confirmation or exclusion of HCV infection in a person with indeterminate anti-HCV supplemental test results should be made on the basis of further laboratory testing, which might include repeating the anti-HCV in two or more months or testing for HCV RNA and ALT level. In clinical settings, use of RT-PCR to

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**TABLE 1. Tests for hepatitis C virus (HCV) infection**

Test/Type	Application	Comments
<b>Hepatitis C virus antibody (anti-HCV)</b> <ul style="list-style-type: none"> <li>EIA (enzyme immunoassay)</li> <li>Supplemental assay (i.e., recombinant immunoblot assay [RIBA™])</li> </ul>	<ul style="list-style-type: none"> <li>Indicates past or present infection, but does not differentiate between acute, chronic, or resolved infection</li> <li>All positive EIA results should be verified with a supplemental assay</li> </ul>	<ul style="list-style-type: none"> <li>Sensitivity ≥97%</li> <li>EIA alone has low-positive predictive value in low-prevalence populations</li> </ul>
<b>HCV RNA (hepatitis C virus ribonucleic acid)</b> <p><b>Qualitative tests**</b></p> <ul style="list-style-type: none"> <li>Reverse transcriptase polymerase chain reaction (RT-PCR) amplification of HCV RNA by in-house or commercial assays (e.g., Amplicor HCV™)</li> </ul>	<ul style="list-style-type: none"> <li>Detect presence of circulating HCV RNA</li> <li>Monitor patients on antiviral therapy</li> </ul>	<ul style="list-style-type: none"> <li>Detect virus as early as 1-2 weeks after exposure</li> <li>Detection of HCV RNA during course of infection might be intermittent; a single negative RT-PCR is not conclusive</li> <li>False-positive and false-negative results might occur</li> </ul>
<p><b>Quantitative tests**</b></p> <ul style="list-style-type: none"> <li>RT-PCR amplification of HCV RNA by in-house or commercial assays (e.g., Amplicor HCV Monitor™)</li> <li>Branched chain DNA<sup>§</sup> (bDNA) assays (e.g., Quantiplex™ HCV RNA Assay)</li> </ul>	<ul style="list-style-type: none"> <li>Determine concentration of HCV RNA</li> <li>Might be useful for assessing the likelihood of response to antiviral therapy</li> </ul>	<ul style="list-style-type: none"> <li>Less sensitive than qualitative RT-PCR</li> <li>Should not be used to exclude the diagnosis of HCV infection or to determine treatment endpoint</li> </ul>
<p><b>Genotype**</b></p> <ul style="list-style-type: none"> <li>Several methodologies available (e.g., hybridization, sequencing)</li> </ul>	<ul style="list-style-type: none"> <li>Group isolates of HCV based on genetic differences, into 6 genotypes and &gt;90 subtypes</li> <li>With new therapies, length of treatment might vary based on genotype</li> </ul>	<ul style="list-style-type: none"> <li>Genotype 1 (subtypes 1a and 1b) most common in United States and associated with lower response to antiviral therapy</li> </ul>
<p><b>Serotype*</b></p> <ul style="list-style-type: none"> <li>EIA based on immunoreactivity to synthetic peptides (e.g., Murex HCV Serotyping 1-6 Assay)</li> </ul>	<ul style="list-style-type: none"> <li>No clinical utility</li> </ul>	<ul style="list-style-type: none"> <li>Cannot distinguish between subtypes</li> <li>Dual infections often observed</li> </ul>

\* Currently not U.S. Food and Drug Administration approved; lack standardization.

† Samples require special handling (e.g., serum must be separated within 2-4 hours of collection and stored frozen [-20 C or -70 C]; frozen samples should be shipped on dry ice).

§ Deoxyribonucleic acid.

detect HCV RNA might be appropriate to confirm the diagnosis of HCV infection (e.g., in patients with abnormal ALT levels or with indeterminate supplemental anti-HCV test results) although RT-PCR assays are not currently FDA-approved. Detection of HCV RNA by RT-PCR in a person with an anti-HCV-positive result indicates current infection. However, absence of HCV RNA in a person with an anti-HCV-positive result based on EIA testing alone (i.e., without supplemental anti-HCV testing) cannot differentiate between resolved infection and a false-positive anti-HCV test result. In addition, because some persons with HCV infection might experience intermittent viremia, the meaning of a single negative HCV RNA result is difficult to interpret, particularly in the absence of additional clinical information. If HCV RNA is used to confirm anti-HCV results, a separate serum sample will need to be collected and handled in a manner suitable for RT-PCR. If the HCV RNA result is negative, supplemental anti-HCV testing should be performed so that the anti-HCV EIA result can be interpreted

before the result is reported to the patient.

Laboratories that perform HCV testing should follow the recommended anti-HCV testing algorithm, which includes use of supplemental testing. Having assurances that the HCV testing is performed in accredited laboratories whose services adhere to recognized standards of good laboratory practice is also necessary. Laboratories that perform HCV RNA testing should review routinely their data regarding internal and external proficiency testing because of great variability in accuracy of HCV RNA testing.

**Prevention Messages and Medical Evaluation**

HCV-specific information and prevention messages should be provided to infected persons and individuals at risk by trained personnel in public and private health-care settings. Health-education materials should include: a) general information about HCV infection; b) risk factors for infection, transmission, disease progression, and

treatment; and c) detailed prevention messages appropriate for the population being tested. Written materials might also include information about community resources available for HCV-positive patients for medical evaluation and social support, as appropriate.

Persons with High-Risk Drug and Sexual Practices

Regardless of test results, persons who use illegal drugs or have high-risk sexual practices or occupations should be provided with information regarding how to reduce their risk for acquiring bloodborne and sexually transmitted infections or of potentially transmitting infectious agents to others (see section regarding primary prevention).

Negative Test Results

If their exposure was in the past, persons who test negative for HCV should be reassured.

Indeterminate Test Results

Persons whose HCV test results are

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indeterminate should be advised that the result is inconclusive, and they should receive appropriate follow-up testing or referral for further testing (see section regarding testing for HCV infection).

#### Positive Test Results

Persons who test positive should be provided with information regarding the need for: a) preventing further harm to their liver; b) reducing risks for transmitting HCV to others; and c) medical evaluation for chronic liver disease and possible treatment.

- To protect their liver from further harm, HCV-positive persons should be advised to:
  - not drink alcohol;
  - not start any new medicines, including over-the-counter and herbal medicines, without checking with their doctor; and
  - get vaccinated against hepatitis A if liver disease is found to be present.
- To reduce the risk for transmission to others, HCV-positive persons should be advised to :
  - not donate blood, body organs, other tissue, or semen;
  - not share toothbrushes, dental appliances, razors, or other personal-care articles that might have blood on them; and
  - cover cuts and sores on the skin to keep from spreading infectious blood or secretions.
- HCV-positive persons with one long-term steady sex partner do not need to change their sexual practices. They should:
  - discuss the risk, which is low but not absent, with their partner (If they want to lower the limited chance of spreading HCV to their partner, they might decide to use barrier precautions [e.g., latex condoms]); and
  - discuss with their partner the need for counseling and testing.
- HCV-positive women do not need to avoid pregnancy or breastfeeding. Potential, expectant, and new parents should be advised that:
  - approximately 5 out of every 100 infants born to HCV-infected women become infected (this occurs at the time of birth, and no

treatment exists that can prevent this from happening);

- infants infected with HCV at the time of birth seem to do very well in the first years of life (more studies are needed to determine if these infants will be affected by the infection as they grow older);
  - no evidence exists that mode of delivery is related to transmission; therefore, determining the need for cesarean delivery versus vaginal delivery should not be made on the basis of HCV infection status;
  - limited data regarding breastfeeding indicate that it does not transmit HCV, although HCV-positive mothers should consider abstaining from breastfeeding if their nipples are cracked or bleeding;
  - infants born to HCV-positive women should be tested for HCV infection and if positive, evaluated for the presence or development of chronic liver disease (see section regarding routine testing of children born to HCV-positive women); and
  - if an HCV-positive woman has given birth to any children after the woman became infected with HCV, she should consider having the children tested.
- Other counseling messages:
    - HCV is not spread by sneezing, hugging, coughing, food or water, sharing eating utensils or drinking glasses, or casual contact.
    - Persons should not be excluded from work, school, play, child-care or other settings on the basis of their HCV infection status.
    - Involvement with a support group might help patients cope with hepatitis C.
  - HCV-positive persons should be evaluated (by referral or consultation, if appropriate) for presence or development of chronic liver disease including:
    - assessment for biochemical evidence of chronic liver disease;
    - assessment for severity of disease and possible treatment according to current practice guidelines in consultation with, or by referral to, a specialist

knowledgeable in this area (see excerpts from NIH Consensus Statement in the following section); and

- determination of need for hepatitis A vaccination.

#### **NIH Consensus Statement Regarding Management of Hepatitis C (Excerpted)**

The NIH "Consensus Statement on Management of Hepatitis C" was based on data available in March 1997. Because of advances in the field of antiviral therapy for chronic hepatitis C, standards of practice might change, and readers should consult with specialists knowledgeable in this area.

#### Persons Recommended for Treatment

Treatment is recommended for patients with chronic hepatitis C who are at greatest risk for progression to cirrhosis, as characterized by:

- persistently elevated ALT levels;
- detectable HCV RNA; and
- a liver biopsy indicating either portal or bridging fibrosis or at least moderate degrees of inflammation and necrosis.

#### Persons for Whom Treatment Is Unclear

Included are:

- patients with compensated cirrhosis (without jaundice, ascites, variceal hemorrhage, or encephalopathy);
- patients with persistent ALT elevations, but with less severe histologic changes (i.e., no fibrosis and minimal necroinflammatory changes) (In these patients, progression to cirrhosis is likely to be slow, if at all; therefore, observation and serial measurements of ALT and liver biopsy every 3-5 years is an acceptable alternative to treatment with interferon); and
- patients aged less than 18 years or greater than 60 years (note that interferon is not approved for patients aged less than 18 years).

#### Persons for Whom Treatment Is Not Recommended

Included are:

- patients with persistently normal ALT values;
- patients with advanced cirrhosis who

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might be at risk for decompensation with therapy;

- patients who are currently drinking excessive amounts of alcohol or who are injecting illegal drugs (treatment

should be delayed until these behaviors have been discontinued for greater than or equal to 6 months); and

- persons with major depressive

illness, cytopenias, hyperthyroidism, renal transplantation, evidence of autoimmune disease, or who are pregnant.

**Anne M. Barry, J.D., M.P.H.**  
**Commissioner of Health**

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717 Delaware Street SE  
Minneapolis, MN 55414**

**The *Disease Control Newsletter* is available on the MDH Acute Disease Epidemiology Section web site at [www.health.state.mn.us/divs/dpc/ades/pub.htm](http://www.health.state.mn.us/divs/dpc/ades/pub.htm)**