25 November 1998

Dr Philip P Mortimer
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Dear Philip

Thank you for sending me the MMWR report which had the section on the US Public Health Service's recommendation for dealing with recipients of blood prior to 1992.

I was actually aware that the US Public Health Service had made this recommendation and I was involved in the meeting in Washington re the introduction of HCV Lookback in the US when they were originally discussing whether or not to and how to do it, if they did. I feel fairly confident that this will not cause us a problem as the reason they have had to do it this way is because most of their hospitals do not keep records for longer than 7 years, and therefore they do not have the capability to do the Lookback in the manner that we did. Their situation is even more complicated as they started with the first generation HCV test in 1991, and didn't change the second generation until 1992. Attempting to start a Lookback now in 1998 makes life very difficult for them when hospitals do not have records any longer than 7 years. This explains why they have had to make the recommendation that all recipients of blood prior to 1992 should be tested for HCV.

Although our Lookback is far from perfect, and we have not been able to trace maybe up to as many as 30% of the issued components, our instruction was to look back as far as records would allow and this I believe we have done as far as possible.

Anyway, thanks for the tip-off. If there is any comeback, I'll be armed and prepared.

Best wishes
Yours sincerely

GRO-C

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NOT RELEVANT

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responded to on hyge file

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ac/nov/robins

11th November, 1998

Dear Angela,

Buried in the document herewith (I have just copied the title page and pages 22/23) is the US Public Health Service's recommendation for dealing with recipients of blood prior to 1992. 'general approaches' (b) amounts to a recommendation that all these recipients should be tested for HCV. I think you ought to know.

Yours sincerely,

GRO-C

PHILIP P MORTIMER

Enc.

Region IV

CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION

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MMWR™

Recommendations and Reports

MORBIDITY AND MORTALITY WEEKLY REPORT

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

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 (*61*). However, issues surrounding prevention of HCV and other bloodborne pathogen transmission in long-term hemodialysis settings are currently 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>.)

Blood-collection establishments and transfusion services should work with local and state health agencies to coordinate this notification effort. Health-care professionals should have information regarding the notification process and HCV infection so that they are prepared to discuss with their patients why they were notified and to provide appropriate counseling, testing, and medical evaluation. Health-education material sent to recipients should be easy to understand and include information concerning where they can be tested, what hepatitis C means in terms of their day-to-day living, and where they can obtain more information.

- **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 (see text box on next page) (*141*). 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 (*158*). 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